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Executive Director

Annual activity report 2023

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Management Board's assessment report

The Management Board,

- having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,
- having regard to the Financial Regulation applicable to the budget of the European Medicines Agency ('the Agency') and in particular Article 48 thereof,
- having regard to the 2023 work programme of the Agency, adopted by the Management Board at its meeting in December 2022,
- having regard to the annual report 2023 of the Agency adopted by the Management Board on 21 March 2024,
- having regard to the annual activity report 2023 of the Agency presented to the Management Board at its meeting of 12 June 2024,

1. Praises the Agency and the European Medicines Regulatory Network (EMRN) for the achievements reached in the implementation of the European Medicines Agencies Network Strategy (EMANS) to 2025 and the Regulatory Science Strategy to 2025. Welcomes the progress detailed in the mid-term implementation reports and looks forward to the updated revised EMAN Strategy beyond 2025.
2. Welcomes the Agency and the EMRN decision to lift their respective COVID-19 business continuity measures, in alignment with the World Health Organisation (WHO) declaration of the end of COVID-19 as a public health emergency of international concern. Encourages the Agency and the EMRN to continue to build on the recommendations published in the EMA/HMA joint report on COVID-19 lessons learned.
3. Thanks again the scientific committees' members, experts, and patient representatives, as well as all EMRN staff for their exceptional commitment and dedication during the whole COVID-19 pandemic and appreciates the good collaboration in the network.
4. Acknowledges the results presented in the Annual Activity Report 2023 and the successful effort of the Agency to fulfil its mission while continuously improving the regulatory system by complying in a timely manner with the implementation of new laws and regulations.
5. Is pleased with the Agency's contribution toward the European Union's policy agenda, in the areas of promoting the functioning of the single market for the protection of public and animal health, the new European Health Union legal framework, the EU Chemical Strategy for Sustainability, the European One Health Action Plan against antimicrobial resistance, the EU Beating Cancer Plan and in the area of EU Strategic Approach on pharmaceuticals in the environment.
6. Recognises the Agency and the EMRN participation in expert group meetings and in the EC targeted consultations with regards to the preparation of the revision of the basic pharmaceutical legislation and of variations framework for medicines for human use.
7. Looks forward to receiving the outcome of the formal WHO (World Health Organisation) Listing Authorities (WLA) benchmarking assessment. The assessment serves the purpose of identifying the reference authorities that meet the relevant indicators and requirements of high performing regulatory authorities.

ACTIVITIES

8. Notes the work on marketing authorisations via the centralised procedure, both in human and veterinary medicines, which resulted in 2023 in EMA recommending for marketing authorisation 77 new human medicines, including 39 new active substances, and 14 new veterinary medicines, including 9 new active substances.

9. Is pleased that 3 PRIME-designated medicines were recommended for approval, helping patients to benefit as early as possible from promising medicines that target unmet medical needs.

10. Appreciates the Agency's confirmation of 17 orphan status designations under the EU framework for orphan medicines, the purpose of which is to encourage the development and marketing of medicines for patients with rare diseases. Overall, 142 applications received a positive opinion and 137 were approved by the European Commission.

11. Praises the Agency's efforts to implement the objective of the EU Beating Cancer Plan ensuring high-quality treatment to cancer patients and underlines the 25 cancer medicine authorised.

12. Commends the Agency for the cooperation with the WHO in the context of the EU Medicines for all (EU-M4All) procedure, which led to 2 medicines recommended for use outside of the European Union.

13. Is pleased with the publication, following a joint effort from EMA, HMA and EC, of the ACT EU 2023-2026 workplan and the establishment of the ACT-EU multi-stakeholders' platform to advance discussions on priority topics by efficiently incorporating the views, needs and concerns of all parties.

14. Commends the Agency for the continuous engagement and recognises the significant effort of the network, in taking up and implementing the use of Clinical Trials Information System as the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. Although recognises that further development of CTIS is necessary for improve functioning of the system and user-friendliness.

15. Congratulates the Agency for the finalisation of the implementation of the Regulation (EU) 2022/123 on the EMA extended mandate. EMA has established the Medical Devices Shortages Steering Group (MDSSG) and the medical devices SPOC Working Party.

16. Commends EMA for the continuous extraordinary effort on its communication, media monitoring and social listening activities for replying promptly to requests for information and for stepping up its communication campaigns on key public and animal health topics.

17. Commends EMA support to the European Commission in preparing for the implementation of Regulation (EU) 2021/2282 on health technology assessment and by progressing parallel joint scientific consultation involving the Scientific Advice Working Party (SAWP) and EUnetHTA under transitional arrangements until the date of application of the new HTA Regulation. in addition, the Agency provided regular contributions to meetings of MEDEV/ESIP, granting feedback on completed product evaluations.

18. Commends EMA commitment to ensure HCP and patients experts' involvement in the Agency's activities and to enforce Stakeholder engagement. In particular, in October 2023, the Board endorsed the principles to establish a framework to renumerate external experts as per Article 93 of EMA Financial Regulation. In addition, the Agency published the new version of the Stakeholder engagement annual report.

19. Congratulates the Agency for the great improvements made in the functionalities of the union product database (UPD) and advise to go on with further possible developments linked with the reduction of administrative burden.
20. Congratulates the Agency for the continuous enhancement of the EU Network Training Centre (EUNTC) and for its contribution to the development of Network capacity and capabilities. In particular, praises the roll out of the Learning Design and Development Toolkit, the implementation of the EUNTC Engagement portal and the implementation of the remuneration process of NCAs for the development and delivery of the training.

ADDRESSING MEDICINES SHORTAGES

21. Praises the Agency and the Executive Steering Group on Shortages and Safety of Medicinal Products for the publication of the first *Union list of critical medicines*, for developing the proposal for the *MSSG Solidarity Mechanism* and for providing guidance to facilitate the identification of recommendations on critical shortages of medicinal products, through the *Toolkit on recommendations on tackling shortages of medicinal products*.

22. Welcomes the signature of the working arrangements with the Health Emergency Preparedness and Response Authority (HERA) which sets out the areas of collaboration between them and how to coordinate their work and in particular in relation to coordination of Member States in preventing and managing critical shortages of medicines in the EU and encourages the Agency to capitalize on the lessons learnt toward this working arrangement in order to reinvest them also in the veterinary sector.

ANTIMICROBIAL RESISTANCE

23. Applauds the Agency for the publication of the final European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report and for the establishment of the European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG) subgroup on Analysis and reporting to guide the drafting of the outline of the future Agency's reports for both sales and use data.

24. Is pleased with the continuous effort to support the implementation of the One Health approach. In 2023, EMA continued to support the implementation of European One Health Action Plan against Antimicrobial Resistance with a wide range of activities. In addition, the Agency provided support to the European Commission and the EU network to ensure that a "One Health" approach is applied to ERA.

25. Praises the Agency continuous progress on the Antimicrobial Sales and Use data (ASU) project, in particular for the enhanced effort on the trainings and guidance offered to ASU users through 2023.

DATA ANALYTICS AND METHODS

26. Congratulates the Agency for the delivery of the DARWIN EU® 2023 work plan. In particular, for the onboarding of ten additional data partners and for the significant increase in the number of studies performed and ongoing.

27. Looks forward to the further development of DARWIN EU® for enabling and establishing the value of the use of real-world evidence across the spectrum of regulatory cases.

28. Welcomes the ambition of connecting the DARWIN EU network with the wider European Health Data Space services (EHDS), to enable the use of the EHDS in medicines regulation in Europe.

INTERNATIONAL COLLABORATIONS

29. Commends the Agency effort to leverage its position as Chair of the ICMRA to progress work on the harmonisation of international regulatory systems.

30. Applauds the Agency's contributions to the work of the International Coalition of Medicines Regulatory Authorities (ICMRA) which received the "Global Award for Outstanding Contribution to Health" awarded by the Drug Information Associations at its Global Annual Meeting of 2023.

31. Welcomes the entry into force of the EU-US Mutual Recognition Agreement (MRA) for veterinary medicines, with the recognition by the US Food and Drug Administration (US FDA) of the capabilities of 18 EU Member States Competent Authorities to carry out good manufacturing practice (GMP) inspections for certain veterinary products.

32. Acknowledges the continuous support offered by EMA to developers and the promotion of parallel work on EU Medicines for all (formerly referred to as 'Art. 58') and centralised submissions.

33. Welcomes the signature of the Contribution Agreement between EMA and the Directorate-General for International Partnership (DG INTPA) to continue the Agency support to the establishment of the African Medicines Agency.

DEVELOPMENTS IN ICT AND PORTFOLIO MANAGEMENT

34. Congratulates the Agency for accelerating the implementation of its "Technology Capability Investment Plan and Cloud Strategy" with the delivery of the software-defined data centre (SDDC) and the migration of workloads to the Cloud.

35. Applauds the Agency innovative approach to contracts, with the introduction of the Agile Capability Delivery Contract (ACDC), which aligns contracting practices with the Scaled Agile Framework (SAFe).

36. Commends the Agency continuous engagement with partners and stakeholders through the discussions with IT Directors community and the Network ICT Advisory Committee (NICTAC) to ensure the development of joint approaches to common challenges as well as the provision of adequate support to National Competent Authorities (NCAs).

FINANCES AND HUMAN RESOURCES

37. Notes that the Agency's final budget for 2023 amounted to EUR 448,603,000; 88,21% derived from the evaluation of medicines and other business-related activities, 11.43% from the European Union budget to fund various public health and harmonisation activities, and 0.36% from various sources. The financial outturn registered a surplus of approx. EUR 20,938.59, representing 0.005% (2.40% in 2022) of total revenue collected, i.e. EUR 461.5 million.

38. Is pleased that the agency met the key budget implementation indicators both for budget 2023 (99% implementation) and for funds carried over from the previous financial year (95.21 % implementation).

39. Notes the 2023 provisional accounts and looks forward to giving an opinion on the EMA 2023 final accounts, following the receipt of the European Court of Auditors' observations on the provisional accounts.

40. Welcomes the roll-out of the Agency's HR Strategy, which includes the long-term strategic resources planning and initiatives supporting talent acquisition, onboarding performance and development.

41. Acknowledges that the Agency managed to reach 97% occupancy rate for temporary agents, and notes that during 2023 the total number of statutory staff joining EMA amounted to 93, while the total number of statutory staff leaving the Agency during the same year amounted to 36.

42. Welcomes the positive outcome of the 2023 Staff Engagement Survey (SES), which reported a 3-percentage point increased engagement levels compared to the previous survey. It encourages the Agency management to work on the four key areas for improvement identified in order to champion improvement actions.

AUDITS AND INTERNAL CONTROLS

43. Welcomes the results of the audit of the European Court of Auditors (ECA), confirming the reliability of the 2022 accounts and the legality and regularity of the transaction underlying the accounts of the Agency.

44. Notes that the report of the ECA draws attention to the uncertainty with the lease agreement for the Agency´s previous premises in London which underlines the standing position of the management board that the matter of the post-Brexit building needs to be resolved at the EU level, and includes two observations on management and control systems and one observation on budgetary management. Is satisfied with the progress on the implementation of the recommendations.

45. Notes that the report includes a follow up of five previous years' observations and welcomes that corrective actions have been put in place by the Agency, leading to the closure of all observations.

46. Notes that the Internal Audit Service of the Commission carried out an audit on 'Information security management at EMA", and that improvements are needed in the areas of the information security management framework, of the protection of information systems during their development lifecycle and of vulnerability management, therefore encourages the Agency to address promptly these needs of improvements.

47. Notes the result of the activities carried out by the Agency's internal audit capability, with 13 critical and 16 very important recommendations were issued in 2023. Invites the Agency to address the 15 open critical recommendations where only one is overdue.

48. Welcomes the positive result of the Benchmarking European Medicines Agencies exercise, confirming that the Agency maintains a high level of maturity.

49. Is pleased that the Internal Control system functions reasonably well; notes that some of its principles could be adjusted or improved to enhance its overall efficiency and effectiveness.

50. Notes that weaknesses highlighted by the ex-post controls are being addressed by specific improvement action plans and the re-assessment of the effectiveness of the actions has been recommended in the next ex-post controls cycle.

DECLARATION OF ASSURANCE

51. Takes note of the declaration of assurance of the Executive Director and acknowledges that no reservations were made.

52. Remains deeply concerned that EMA, being a health agency, has been placed in a position after Brexit where it is required to act as a landlord in a third country by virtue of having to manage the former premises thus diverting resources to perform an activity which is outside of its legal mandate, at the time when the agency had to protect public health during COVID-19

pandemic, had to implement Clinical Trials, veterinary, extended mandate legislation and to respond to numerous challenges in the public health domain.

53. Commends the Executive Director for effectively addressing the challenges caused by the situation with the parent company of the subtenant and the subtenant itself, following the significantly deteriorated situation in the office real estate market as a result of macroeconomic changes during and after the pandemic period, and for effective collaboration with the EU institutions and the Budgetary Authority in the process. Considers it essential and is satisfied that the required EU funding will be made available, and that the Agency's and National Competent Authorities' public health responsibilities will thus be safeguarded.

54. Calls on EU institutions to act at a political level to resolve the unsustainable situation with the post-Brexit premises in London, and to continue providing the required EU funding to ensure that EMA and NCAs' public and animal health mission and activities are not negatively impacted.

ACKNOLWEDGMEMENTS

55. Welcomes Mr La Via as a new Representative of the European Parliament to the EMA Management Board.

56. Welcomes the establishment of a 'Management Board Audits and Risks Group' ('MBARG'). The MBARG plays a critical role in ensuring that the organisation operates ethically, effectively, and in accordance with established standards and regulations while managing risks appropriately.

57. Welcomes the effort of EMA's and national authorities' staff for their collaborative and effective work in protecting and promoting public and animal health in the European Union.

Amsterdam, 14 June 2024

Lorraine Nolan

Management Board Chair

[signature on file]

Introduction

The consolidated Annual activity report provides an overview of the activities and achievements of the European Medicines Agency (hereinafter EMA or the Agency) in 2023. The EMA Annual activity report 2023 is a report of the EMA Executive Director. It is a key component of the strategic planning and programming cycle and the basis upon which the EMA Executive Director takes their responsibility for the management of resources, and the achievement of objectives. It also allows the EMA Executive Director to decide on the necessary measures in addressing any potential management and control weaknesses identified.

The Annual activity report 2023 comprises five main parts and annexes, as follows:

Part I: Key achievements in 2023. This section provides information on achievements of objectives and performance indicators set in the EMA annual work programme. This section mirrors the structure of the annual work programme of EMA for the year 2023 and provides information on achievements of objectives set in the annual work programme. This section also includes references to key performance indicators (KPIs) and targets.

Part II: Management. This section provides an overview of the Agency's major achievements and includes information on EMA governance; information on budgetary, financial and human resources management; assessment of audit results during 2023; as well as the follow-up on recommendations and action plans resulting from audits. It also includes components of the follow-up on observations from the Discharge Authority.

Part III: Assessment of the effectiveness of the internal control systems. This section includes the assessment of the effectiveness of the internal control systems and their components.

Part IV: Management assurance. This section describes the building blocks of assurance and the materiality criteria on the basis of which the Authorising Officer by Delegation determines whether significant weaknesses should be subject to a formal reservation. Any reservations are also detailed in this section.

Part V: Declaration of assurance. The report concludes with a declaration of assurance in which the EMA Executive Director, in her role as the authorising officer, takes responsibility for the legality and regularity of all financial transactions.

In the *annexes*, the report provides information on the EMA establishment plan, human and financial resources used by activity, the organisational chart, project implementation, and further specific annexes related to Part II and Part III of the report.

The EMA Annual activity report is a public document and is available on the EMA corporate website.

Executive summary

European Medicines Agency in brief

The European Medicines Agency is a decentralised agency of the European Union (EU), created in 1995. The mission of EMA is to protect human and animal health in the EU, and to ensure access to medicines that are safe, effective and of good quality. It is the sole EU body responsible for the scientific assessment of medicines for human use, with respect to the authorisation, maintenance and supervision, for treatment of cancer, diabetes, neuro-degenerative dysfunctions, viral diseases, acquired immune deficiency syndrome, and auto-immune diseases and other immune dysfunctions and rare human diseases ('orphan' medicines). Medicines derived from biotechnology processes (such as genetic engineering), as well as advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) must also be submitted for assessment to EMA on behalf of the EU. For veterinary medicines, innovative and technologically advanced products, in particular those derived from biotechnology, must also be assessed by the Agency. To achieve this, EMA provides a single route for the evaluation of innovative medicines in the EU, thus avoiding the duplication of the evaluation in each of the Member States. This allows making highly needed medicines available to all EU citizens and within the shortest possible timeframe, whilst guaranteeing a robust scientific assessment process.

In addition, EMA monitors the safety of all medicines authorised in the EU throughout their lifecycle and provides for regulatory action (such as restricting a medicine's use or withdrawing a medicine from the EU market) within the shortest possible timeframe, where public or animal health is endangered. Information to patients and healthcare professionals is simultaneously made available in all EU languages, ensuring that consistent information on medicines is provided to all EU citizens. To achieve its tasks, EMA brings together the best scientific expertise on medicines from across the EU. This translates into 7 scientific committees[1] which evaluate medicines along their lifecycle, from early stages of development, through marketing authorisation, to safety monitoring once they are on the market. These scientific committees are supported by working parties and scientific advisory groups and can draw from a network of over 4000 scientific experts, made available by the Member States to the Agency.

EMA is also involved in other public health activities, such as in stimulating research and innovation in the pharmaceutical sector. It facilitates medicines development by giving scientific advice and guidance to developers of medicines, including on the development of medicines for children or medicines to treat rare diseases. On behalf of the EU, EMA coordinates inspections to verify compliance with the principles of good manufacturing, clinical, pharmacovigilance and laboratory practices.

EMA is responsible for the provision of data and information technology (IT) services to implement European pharmaceutical policy and legislation. These services are provided to the EU regulatory network, comprising national competent authorities (medicines regulatory authorities in Member States), the European Commission and EMA. In this context, EMA delivers, maintains and provides data services, IT systems and infrastructure to Member States.

On behalf of the EU, EMA hosts a number of databases important for public health, such as EudraVigilance — one of the largest databases in the world of adverse reactions reported for all

[1] CHMP: Committee for Medicinal Products for Human Use
CVMP: Committee for Medicinal Products for Veterinary Use
PDCO: Paediatric Committee
COMP: Committee for Orphan Medicinal Products
CAT: Committee for Advanced Therapies
PRAC: Pharmacovigilance Risk Assessment Committee
HMPC: Committee on Herbal Medicinal Products.

medicines authorised in the EU. In addition, EMA plays a key role in tackling public health threats, such as antimicrobial resistance, and public health emergencies. Over the past years, EMA has also become a recognised pioneer in terms of transparency and openness of operation, and in terms of interaction with patients.

Since its creation in 1995, the environment in which EMA operates has undergone major changes. As a result of the Agency's achievements over the years – EMA's responsibilities have continuously increased, resulting not only in a well-established and mature agency, but also an agency that covers a wide range of activities in the regulation of human and veterinary medicines.

The Agency has a formal role in preparing for and managing crisis situations affecting the European Union (EU) single market for medicines and medical devices, based on legislation that took effect on 1 March 2022 (Regulation (EU) 2022/123), except for the provisions for the management of shortages of critical medical devices, which apply from 2 February 2023.

The legislation formalises some of the structures and processes set up by EMA during the COVID-19 pandemic and assigns new tasks to the Agency in the following areas:

- Monitoring and mitigating potential or actual shortages of critical medicinal products and medical devices;
- Providing scientific support to the timely development of high quality, safe and effective medicines during public health emergencies;
- Ensuring the smooth functioning of expert panels to assess high-risk medical devices and advise on crisis preparation and management.

The success of EMA is based on the EU regulatory system for medicines. At the heart of it is a network of around 50 medicines regulatory authorities from the European Economic Area (EEA) Member States, the European Commission, and EMA. National competent authorities (NCA) work closely with EMA, providing scientific expertise to EMA committees, working parties and expert groups for: assessing centralised products; supporting innovation, including centralised scientific advice; working on orphan and paediatric medicines; and EU-wide safety procedures. This network is what makes the EU regulatory system unique. The diversity of the experts from across Europe, involved in the regulation of medicines in the EU, encourages the exchange of knowledge, ideas, and best practices between scientists striving for the highest standards for medicines regulation.

2023 in brief

During 2023, the Agency started to shift its focus away from crisis management towards upcoming challenges and opportunities. During 2023, members of the EU Medicines Regulatory Network, including the European Medicines Agency took the decision to lift their respective COVID-19 business continuity measures. This had been anticipated in the 2023-25 Single Programming Document (SPD) and coincided with the announcement from the World Health Organization (WHO), declaring the end of COVID-19 as a public health emergency of international concern. During the month of January CTIS became the single-entry point for the submission and assessment of clinical trials data. The network initiated the onboarding of ten additional data partners to DARWIN EU® and performed increased number of studies (18 completed or on-going studies in 2023 versus 4 in 2022). EMA reflected on the use of real-world evidence in regulatory decision making by publishing a report on the experience gained with regulator-led studies from September 2021 to February 2023.

In February, the last piece of Regulation 123/2022 on the Agency's extended mandate, namely EMA additional responsibilities for monitoring and mitigating shortages of critical medical devices during public health emergencies, became applicable. In the area of medical devices, the Agency implemented the MDR/IVDR and launched the medical device implementation group. April marked an important milestone with the EC publishing the legal proposal for the revision of the general EU pharmaceutical legislation for human medicines, which will significantly impact the Agency and the Network's way of working. With the WHO declaration ending the public health emergencies for COVID-19 and mpox the Agency lifted its business continuity status which had been in place for almost five years. This allowed the relaunch of previously reduced activities, like the publication of clinical data for all products. 2023 also marked the 10th year of the International Coalition of Medicines Regulatory Authorities. In the context of international cooperation activities, the EC approved the EMA support plan for the establishment of the African Medicines Agency. Lastly, the 2023 has brought to the fore the concerns the Agency has been raising for a number of years with regards to the management of its former premises in London. In fact, this issue remained unresolved, after EMA was relocated to the Netherlands. Until a long-term solution is reached, human and financial resources will need to be dedicated to this activity, which falls outside of the Agency's legal mandate. Unless an agreement is reached on a long-term solution, the matter will remain a significant risk factor for the Agency and its objectives.

Key achievements are detailed in section 1 here below, whereas major developments are reported in section 2.2. The full set of key quantitative data of the reporting year can be found in section 1 and section 2.

Key conclusions

Following more than two years profoundly affected by the COVID-19 pandemic, 2023 has been a transition year for the European Medicines Agency. With the end of the public health emergency the Agency has been able to start shifting its focus to address opportunities and ambitions. The finalisation of the implementation the EMA's extended mandate obligations, of the MDR/IVDR, the first reflections on the EC proposal for the revision of the general EU pharmaceutical legislation for human medicines and the relaunch of previously reduced activities have characterised 2023. The year has also once again highlighted the need to find a long-term solution for the Agency's former premises in London, to mitigate a significant risk factor for the Agency and its objectives.

All the achievements of 2023 have been reached also through a full implementation of the 2023 budget, which was closed with a small surplus of about €20 thousands.

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the Court of Auditors on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Agency can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

1. Achievements of the year

2023 at a glance

Human medicines

In 2023, EMA recommended 77 medicines for marketing authorisation, 39 of which had a new active substance. The Agency also recommended 90 extensions of indication of medicines already authorised for marketing in the EU, offering new treatment opportunities for patients.

During 2023, three medicines received a recommendation for marketing authorisation following an accelerated assessment (this mechanism is reserved for medicines that are able to address unmet medical needs, allowing for faster assessment of eligible medicines by EMA's scientific committees); eight medicines received a recommendation for a conditional marketing authorisation, one of the possibilities in the EU to give patients early access to new medicines; one medicine was authorised under exceptional circumstances, a route that allows patients' access to medicines that cannot be approved under a standard authorisation, as comprehensive data cannot be obtained. In the context of the PRIME scheme, which aims to help patients benefit as early as possible from promising medicines that target an unmet medical need, three PRIME-designated medicines were recommended for approval. In addition, the Agency confirmed seventeen orphan-status designations under the EU framework for orphan medicines, the purpose of which is to encourage the development and marketing of medicines for patients with rare diseases. With regards to COVID-19 vaccines, the Agency has recommended one new vaccine, which was evaluated in the context of the OPEN initiative, an initiative launched in 2020 to increase international collaboration in the EU review of COVID-19 medicines. Lastly, in the context of medicines recommended for use outside the European Union, EMA assessed two medicines under a regulatory procedure known as EU-Medicines for all (EU-M4All) that enables EMA, in cooperation with the World Health Organization, to support global regulatory capacity building and contribute to the protection and promotion of public health beyond the EU.

Veterinary medicines

In 2023, EMA recommended fourteen medicines for marketing authorisation, nine out of these have new active substances not previously authorised in the EU. Moreover, the Agency gave positive opinion on eight already known products to be used in new species or with a new indication. This offers new treatments opportunity. Lastly, as part of its post-authorisation activities, three positive opinions were adopted recommending the extension of maximum residual limits (RMLs), i.e. where a medicine is marketed for use in food-producing animals, any human safety concerns that might result from exposure to residues of the medicine remaining in animal-derived food need to be addressed. The maximum residue limits (MRLs) recommended by EMA reflect how much residue of the veterinary medicine in food derived from a treated animal is safe for consumption. The MRL is established before the medicine for food-producing animals is authorised in the EU and entered in the annex to Commission Regulation (EU) No 37/2010.

Contributing to EU priorities

In 2023, EMA continued to promote a functioning single market for human and veterinary medicines by acting as the hub of the European network of regulatory medicines authorities operating the applicable EU legislative framework for such products. A functioning single market for medicines is important both to protect public and animal health and to allow the European biomedical industry to innovate and create jobs and growth. By authorising several new cancer medicines (25 cancer medicines were

authorised in 2023), EMA continued to contribute to the implementation of the objective of the EU Beating Cancer Plan to ensure high-quality treatment to cancer patients.

In the first part of 2023, EMA continued to provide support to the implementation of the EU response to the COVID-19 pandemic by authorising one new vaccine, Bimervax, and the adaptation of three approved vaccines (Comirnaty, Spikevax and Nuvaxovid) to the Omicron XBB.1.5 variant.

As one of the EU decentralised agencies at the forefront of the EU's response to COVID-19 pandemic, EMA's activities in 2023 have contributed to the implementation of the new European Health Union legal framework (see more details in the section above on the implementation of the EMA's extended mandate). In addition, EMA significantly increased its interactions with the Health Emergency Preparedness and Response Authority (HERA) in relation to coordination of Member States in preventing and managing critical shortages of medicines in the EU. In March 2023, the Agency signed working arrangements between EMA and HERA, which set out the areas of collaboration between them and how they coordinate their work.

In 2023, EMA continued the implementation of actions within its remit under the EU Strategic Approach on pharmaceuticals in the environment, which aims to address the environmental implications of all phases of the lifecycle of human and veterinary medicinal products. In 2023, EMA continued to support the European Commission, as requested, with the preparation of proposals to revise the human pharmaceutical legislation in the areas of environmental risk assessment and continued to engage in relevant research projects of the Innovative Medicines Initiative exploring the prioritisation of human medicinal products without an (adequate) environmental risk assessment and identified as potentially harmful to the environment.

As part of the implementation of the EU Chemical Strategy for Sustainability, the Agency supported the European Commission in the preparation of the 'one substance, one assessment' chemicals assessment reform, which was proposed in December 2023 and, once adopted, will assign new tasks to EMA as regards the sharing and re-use of hazard/risk assessment of chemicals data across other EU agencies (ECHA, EFSA, EEA) and the Commission.

In 2023, EMA continued to support the implementation of European One Health Action Plan against Antimicrobial Resistance with a wide range of activities. The key activities in 2023 in this area relate to: the preparation for the collection of sales and use data for antimicrobials used in animals, as mandated in the new veterinary medicines legislation; the restart of referrals to harmonise and modernise the summaries of product characteristics (SmPC) of old antibiotics for human and veterinary use; and the support to international efforts for the harmonisation of regulatory requirements for the development of novel antimicrobials via quarterly dedicated cluster meetings with the US FDA, Health Canada and the Japanese MHLW/PMDA, as well as in the Transatlantic Taskforce on AMR (TATFAR).

In 2023, by participating in expert group meetings and responding to targeted consultations of the Commission, EMA continued to provide significant scientific support to the European Commission with regards to the preparation of the revision of the basic pharmaceutical legislation, which was published in April 2023, and of variations framework for medicines for human use, which is expected to conclude in early 2024.

In 2023, EMA contributed to the EU objective to foster wider patient access to innovative medicines. It did so mainly by supporting the European Commission in preparing for the implementation of Regulation (EU) 2021/2282 on health technology assessment and by progressing parallel joint scientific consultation involving the Scientific Advice Working Party (SAWP) and EUnetHTA under transitional arrangements until the date of application of the new HTA Regulation.

Implementation of the Network and Regulatory Strategies

2023 marked the mid-term implementation of both the European Medicines Agencies Network Strategy as well as of the EMA Regulatory Science Strategy to 2025. The Agency has published two reports highlighting mid-term achievements and progress status. With regard to the EMAN Strategy the report finds the pandemic strengthened the network and supported transformative change in the European system across key strategic areas. On the same note, the mid-term report of the Regulatory Science Strategy highlights achievements for the top five human and top three veterinary recommendations thought to deliver the most significant change over the course of the five-year strategy, according to an extensive stakeholder consultation process that took place with EMA's scientific committees, stakeholders and EU regulatory partners.

COVID-19 lessons learned

In December 2023, EMA and the Heads of Medicines Agencies (HMA) issued a joint report highlighting the main learnings from the COVID-19 pandemic, to be applied for future health crises. The review highlights some of the unprecedented challenges related to COVID-19 that had to be addressed, the activities and areas that enabled the effective response to the COVID-19 emergency and provides recommendations on which improvements are needed.

Regulation (EU) 2022/123 on the EMA extended mandate

During 2023, EMA has finalised the implementation of the Regulation (EU) 2022/123 on the EMA extended mandate, by establishing the Medical Devices Shortages Steering Group (MDSSG) and the medical devices SPOC Working Party. Moreover, the Agency has finalised the minimum viable product of EMA's Critical Medical Devices Shortages (CMDS) system. The Agency's preparedness activities continue in light of the Single Point of Contact Working party (SPOC WP) and Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) established mandates.

Addressing medicines shortages

In the context of the responsibilities set out in Regulation (EU) 2022/123, the Agency established the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to ensure a robust response to medicine supply issues caused by major events or public-health emergencies. The Group coordinates urgent actions within the European Union (EU) to manage medicine supply issues and issues related to the quality, safety and efficacy of medicines. During 2023, the group held ten meetings and published:

- the *Toolkit on recommendations on tackling shortages of medicinal products*: a guidance document to facilitate identification of recommendations on critical shortages of medicinal products;
- the *MSSG Solidarity Mechanism:* the MSSG discussed the proposal of developing an EU Solidarity mechanism for MSs experiencing critical shortages of important medicines where all other available options have been exhausted. The proposal was agreed, and a Working Group was set up to further develop it. The mechanism allows a MS to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages;
- the first *Union list of critical medicines*: a medicine is listed as critical when it is essential to ensure the provision and the continuity of quality healthcare, and to guarantee a high level of public health protection in Europe. This first Union critical medicines list contains more than 200 active substances used in human medicines, which are considered essential in the EU/EEA. The inclusion on this list is not an indication that a medicine is likely to experience a shortage

in the near future. Rather, it signifies the critical importance of averting shortages for these specific medicines, as its unavailability could cause significant harm to patients and pose substantial challenges to health systems.

Development of Network capacity and capabilities

As part of its effort to continuously develop Network's capacity and capabilities, the Agency has delivered during 2023, 89 courses, including 71 online courses. In this context EMA has:

- implemented and rolled out the EU Network Training Centre (EUNTC) Learning Design and Development Toolkit to support Course organisers and Curriculum developers (both in the context of annual planning with Curriculum Leads as well as in response to advance announcements of upcoming courses);
- implemented the EU NTC Engagement Portal (which will provide a single point of access to the EU NTC LMS). The technology for the Portal was selected, the Portal has been built and is now planned for release in January 2024. The Portal was demonstrated at the Quarterly Demo in December 2023;
- implemented the process for remuneration of NCAs for the development and delivery of training.

Real-world evidence

Real-world evidence (RWE) from studies led by regulators can complement evidence from other sources including clinical trials. RWE can support both pre-authorisation and post-approval assessments of EMA's scientific committees, working parties and national competent authorities. During 2023, EMA reflected on the use of real-world evidence in regulatory decision-making by publishing a report on the experience gained with regulator-led studies from September 2021 to February 2023. During this period, 61 real-world data (RWD) research opportunities were identified, 30 studies initiated and 27 completed. The report provides a set of recommendations to address identified opportunities and challenges. Overseen by the EMA-HMA Big Data Steering Group, EMA and EMRN are working towards setting up a sustainable framework that enables the use and establishes the value of RWE in decision-making across the entire product lifecycle.

DARWIN EU®

DARWIN EU® is a platform to generate RWE to support the decision-making of EMA scientific committees and national competent authorities in EU Member States throughout regulatory processes. DARWIN EU® had an ambitious 2023 plan and it was delivered. The network initiated the onboarding of ten additional data partners and performed increased number of studies (18 completed or on-going studies in 2023 versus 4 in 2022). Results from the completed studies have been provided to the relevant EMA committees to support their future work. By 2025, DARWIN EU® will be fully operational, delivering around 150 RWE studies per year. The EU's vision is that by then the use of RWE will have been enabled and value established across the spectrum of regulatory use cases. The network will ultimately connect to the European Health Data Space (EHDS) services, enabling the use of the EHDS in medicines regulation in Europe.

Artificial intelligence workplan to guide use of AI in medicines regulation

During 2023, EMA and the Heads of Medicines Agencies (HMAs) have published an artificial intelligence (AI) workplan to 2028, setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks. The workplan will help the European medicines regulatory

network (EMRN) to embrace the opportunities of AI for personal productivity, automating processes and systems, increasing insights into data and supporting more robust decision-making to benefit public and animal health. The AI workplan, prepared under the joint HMA-EMA Big Data Steering Group (BDSG), ensures the EMRN remains at the forefront in benefiting from AI in medicines regulation. Recognising the importance of Artificial Intelligence, the Agency conducted also risk assessments and integrated emerging AI-powered productivity tools to boost workplace efficiency.

Use of artificial intelligence in the lifecycle of medicines

As part of the Workplan 2022-2025: HMA-EMA joint Big Data Steering Group, EMA published a draft reflection paper outlining the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines. This paper reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting. With this paper, a dialogue with all interested stakeholders has been opened to discuss ways forward and ensuring that the full potential of these innovations can be realised for the benefit of patients. The public consultation closed on 31 December 2023. The feedback from stakeholders is analysed and considered for the finalisation of the reflection paper and future development of guidance as relevant.

EU Data Quality Framework

Building a European data quality framework for the regulatory use of data sources with associated quality metrics is one of the key 'Data Quality and Representativeness' deliverables set out in the joint HMA-EMA Big Data Steering Group workplan (2023-2025).

The data quality framework was co-produced by EMA, the Heads of Medicines Agencies (HMA) and the Joint Action Towards the European Health Data Space (TEHDAS) and the final version has been published following a public consultation.

The document provides general considerations that can be applied to a wide range of data sources for the purpose of characterising and assessing data quality for decision making. It also outlines what data quality actions and metrics can be put in place in different regulatory decision-making scenarios and introduces maturity models for the characterisation of data quality for regulatory purposes. The Agency collaborated with international organisations and regulatory authorities, to progress on data standardization, contributing to the global implementation of medicinal product standards.

Clinical Trial Regulation (CTR)

The application of the CTR strengthens Europe as an attractive location for clinical research. The new regulation streamlines the processes for the application and supervision of clinical trials, and their public registration: all clinical trial sponsors now use the same system and follow the same procedures to apply for the authorisation of a clinical trial. From 31 January 2023, all initial clinical trial applications in the EU must be submitted via the Clinical Trials Information System (CTIS). CTIS is the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. Over 1800 clinical trials have been authorised so far under the CTR and its business tool, CTIS. The system performance and usability have been improved through 16 IT releases.

CTIS became a registered WHO data provider. Data from authorised trials published on the CTIS website - excluding those with category 1 deferrals of the main characteristics - is now included in the search portal of WHO's International Clinical Trials Registry Platform (ICTRP).

Following a public consultation, in 2023 EMA has adopted Revised CTIS Transparency Rules for the publication of information on clinical trials submitted through CTIS. The simplifications introduced will give access to clinical trial information to stakeholders including patients and healthcare professionals in a faster and more efficient way.

ACT EU

Accelerating clinical trials in the EU (ACT EU) is a collaboration between EMA, HMA and EC that seeks to transform how clinical trials are initiated, designed, and run. This initiative aims to place stakeholders at the centre of its activities by giving them the opportunity to steer the direction of the programme. ACT EU has launched its dedicated website and published its workplan for 2023-2026. This plan outlines the initiative's updated priorities as endorsed by the ACT EU Steering Group.

The ACT EU multi-stakeholder platform on clinical trials is being established to advance discussions on priority topics by efficiently incorporating the views, needs and concerns of all parties involved in the process. To understand different stakeholder perspectives and agree on the format of the platform going forward, the kick-off workshop for the multi-stakeholder platform was held in June 2023. The ACT EU multi-stakeholder platform Advisory Group, composed of 21 representatives from key stakeholder groups, will provide strategic advice on ACT EU activities and on stakeholder engagement. Two other public workshops (ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation and ACT EU PA08 multi-stakeholder methodology workshop) were held in 2023.

Support to the establishment of the African Medicines Agency

During 2023, EMA set up a project team tasked with the preparation of the EMA proposal for DG INTPA contribution agreement to support the establishment of the African Medicines Agency (AMA) and regulatory system strengthening at continental, regional and national levels. In this context the Agency also established an EMRN alignment platform to discuss AMA support. The group has worked to identify priority areas and activities for 2024. EMA signed the contribution agreement with DG INTPA in December 2023.

Using its unique expertise and regulatory model, the EMRN will share experience with AMA and African regulators in pooling resources and coordinating work to regulate medicines efficiently and effectively, ensuring high-quality standards and use of the best available expertise, reducing administrative burden to allow medicines to reach patients faster.

Support For EU candidate countries and potential candidates

Under the DG NEAR funded Instrument for Pre-Accession Assistance (IPA II) programme a 2-day webinar (April) and two face-to-face training events at EMA (June and November) were organized – reaching over 500 colleagues from national regulatory authorities in EU candidate countries and potential candidates. Shared expertise from colleagues from the National Competent Authorities in the EMRN as well as EMA enabled EU candidate countries and potential candidates to further align rules, regulations and guidelines in medicines regulation to the EU *Acquis Communautaire*. The exchanges also contributed to further regulatory capacity building in these target countries.

In December 2023, EMA signed a renewed contract with DG NEAR, securing continued engagement and support from EMA to EU candidate countries and potential candidates through the IPA III programme until 2026.

Legal overview

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law or procedural irregularities remains high. During 2023, the Legal Department worked on 16 court cases, without the assistance of any outside counsel. Significant guidance from the Court of Justice of the European Union was obtained in two landmark rulings favourable to EMA ("*Tecfidera*" and "*Aplidin*").

- Legal scrutiny of 84 Committees' opinions and nearly 60 paediatric decisions was completed within the assigned deadlines.
- In the framework of the Agency's transparency activities, 449 initial decisions and 56 confirmatory decisions on requests to access to documents were scrutinised and co-executed by the Legal Department in 2023.
- In the Inter-Agency Legal Network EMA continues to lead the working group on Transparency and Ethics and the anti-fraud workstream, building up on a solid experience and cooperation with OLAF.

BEMA (Benchmarking of Medicines Agencies)

BEMA is a benchmarking program organised by the Heads of Medicines Agencies (HMA) to compare human and veterinary medicine agencies. It evaluates agencies' systems and processes in four main areas: Management, Marketing Authorisation Assessment, Drug Safety (Pharmacovigilance), and Inspection Services. In 2023, the Agency went through their fifth benchmarking assessment cycle exercise. Following their visit, the external team of BEMA assessors issued their report confirming the Agency maintains a high level of maturity. The report outlines some of the Agency's strengths and good practices, and also provides opportunities for improvement to further enhance operational effectiveness, which are now under management's review.

Staff Engagement Survey (SES)

The last EMA Staff engagement survey (SES) was conducted in April 2023. It is a benchmarked organisational health indicator that highlights trends and changes over extended periods of time and provides the necessary insights to prioritise and implement impactful improvements. The aim is to create the right conditions at EMA so that all colleagues can thrive and achieve their highest potential. It uses a methodology developed with and shared by a group of 30 other decentralised EU Agencies and joint undertakings. This helps ensure best practices to common challenges are shared across other agencies, and that results can be benchmarked against all agencies results. In 2023, the response rate was 73%. The overall total favourable score (i.e. percentage of respondents agreeing or strongly agreeing with the statements) was 65%, which represents a 3-percentage point (pp) improvement from the last survey. Four key areas for improvement were identified, and co-sponsors from among the Leadership team and the Staff Committee were assigned to each one, in order to champion and report on improvement actions.

Scaled Agile Framework (SAFe)

Digital transformation

As part of its digital transformation, the Agency accelerated the implementation of its' Technology Capability Investment Plan and Cloud Strategy, delivering a software-defined data centre (SDDC) and migrating workloads to the Cloud. The new SDDC offers reliable performance, with a 99.99% uptime and efficient disaster recovery capabilities.

In order to support digital capacity and capability building with EMA and the Network, new modules within the Digital Skills Framework of the Digital Academy were developed and implemented, including modules on Lean, Artificial Intelligence (AI), Robotic Process Automation (RPA), Cloud Computing, and Agile. These modules complement already existing ones on the Digital Mindset and Digital Wellbeing (which have also been updated), as well as Design Thinking (to be updated in January 2024).

Additionally, a Digital Academy collection of learning resources on UX/UI/Usability was developed and will be further expanded in 2024. The Digital Academy was opened up to the Network in September

2023, with the publication of modules in the EU NTC LMS on AI, Digital Mindset, RPA, and Cloud Computing.

Moreover, to align with the Agency's Scaled Agile Framework (SAFe), the Agency introduced the Agile Capability Delivery Contract (ACDC), representing an innovative approach to EMA contracts.

Involvement of partners and stakeholders

In this context the Agency actively worked to strengthen partnerships with key stakeholders, engaging in discussions with the IT Directors community and the Network ICT Advisory Committee (NICTAC). Initiatives included meetings with the EU Presidency and NICTAC, where common challenges and collaboration opportunities were explored. EMA received positive feedback for its supportive role during periods of change for National Competent Authorities (NCAs). Working with sister Agencies, such as EFSA, has also been a priority for 2023. This allowed the Agency to explore collaboration opportunities and share digital initiatives.

Future direction of technology implementation

The Agency kept a forward-looking gaze with regards to future technology implementation and has worked on developing strategic roadmaps for the future. These roadmaps cover areas such as legacy modernization, CTIS modernisation, the gradual implementation of ServiceNow across key service management processes and will help the Agency to meet legislative requirements, enhance cybersecurity, and improve administrative and regulatory workflows.

Work programme implementation

This section includes reference to progress against all key performance and workload indicators set in the Single Programming Document and the Annual Work Programme. The forecasts of the workload indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

Each of the chapters outlines the achievement of the workload and performance indicators included in each chapter of the work programme, as well as covers a set of objectives, with the relevant activities and results outlined.

The work programme consists of four parts: evaluation activities for human medicines; evaluation activities for veterinary medicines; horizontal activities and other areas, and support and governance activities. Each of these is further broken down into chapters covering the Agency's activities in specific areas or stages in the medicines' lifecycle.

Explanation of symbols used

A traffic light system is used to describe performance against objectives and targets.

	Results more than 10% above the 2023 forecast/target
	Results within +/- 10% (included) of the 2023 forecast/target
	Results 10%-25% below the 2023 forecast/target
	Results more than 25% below 2023 forecast/target
	No activity/result to report

In general, the traffic light system reflects the direction and magnitude of changes, as described above.

However, for some performance indicators, where the optimal results should be lower than the targets, such as average assessment or clock-stop days, the traffic light system is reversed to better reflect the essence of these indicators: results below the target are marked green or blue, while results above the target will appear amber or red.

	Results more than 10% below the 2023 forecast/target
	Results within +/- 10% (included) of the 2023 forecast/target
	Results 10%-25% above the 2023 forecast/target
	Results more than 25% above 2023 forecast/target
	No activity/result to report

For indicators that have been included in the work programme for the first time, data on the previous year's results are not provided.

Human Medicines Division

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

Workload indicators

Procedure		2020 result	2021 result	2022 result	2023 forecast	2023 result
	Total scientific-advice and protocol-assistance requests	784	853	833	710	692
	Parallel scientific advice with international regulators requests	6	3	5	4	13
	Joint scientific advice with HTA bodies requests	2	2	4	3	4
	Scientific advice for PRIME products	37	59	37	11	38
	Protocol assistance	143	163	129	125	119
	Novel technologies qualification advice/opinions	15	25	21	21	18
	PRIME eligibility requests received	69	52	45	55	52
	Applications for orphan medicinal product designation	235	251	269	255	195
	Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	735	778	755	801	713
	Requests for classification of ATMPs	74	66	51	50	43

1.2 Initial evaluation activities

Workload indicators

Procedure		2020 result	2021 result	2022 result	2023 forecast	2023 result
	New non-orphan medicinal products	43	43	35	43	35
	New orphan medicinal products	28	29	32	27	23
	Similar biological products	12	10	11	17	21
	Generic products, hybrid and abridged products	24	28	18	22	20
	Scientific opinions for non-EU markets (Art. 58)	0	3	1	0	0
	Paediatric-use marketing authorisations	0	0	2	1	1
	Number of granted requests for accelerated assessment	12	12	4	12	7
	ATMPs marketing application authorisation requests received[2]	-	3	1	8	4
	COVID-19 related product applications received[3]	-	14[4]	2	4	2
	Companion diagnostics opinions[5]	n/a	n/a	n/a	20	9
	Reviews on the maintenance of the orphan designation criteria at MAA stage	n/a	31	38	n/a	32

[2] New indicator introduced in 2021 Work Programme.
[3] New indicator introduced in 2021 Work Programme.
[4] 2 applications were withdrawn during evaluation.
[5] Finalised.

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Average assessment time for new active substances and biosimilars (days) (reversal of traffic lights)	192	183	189.8	205	200.56
Average clock-stop for new active substances and biosimilars (days) (reversal of traffic lights)	166	149	182.1	180	178.29
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	50%	27%	31.30%	60%	75.00%
% of initial marketing authorisation applications that had received centralised scientific advice[6]	70%	78%	62.20%	80%	75.00%

1.3 Post-authorisation activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Type IA variations	3,989	3,809	3,586	3,840	3,864
Type IB variations	2,675	3,102	3,354	3,495	3,332
Type II variations	1,274	1,390	1,388	1,202	1,201
Line extensions of marketing authorisations	35	27	31	29	43
Renewal applications	99	123	132	81	101
Annual reassessment applications	24	27	27	31	33
Transfer of marketing authorisation applications	36	95	74	61	41
Article 61(3) applications	211	396	236	200	270
Post-authorisation measure data submissions	990	1,272	1,278	925	1,146
Plasma master file annual update and variation applications	28	20	17	25	18

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Average assessment time for variations that include an extension of indication (reversal of traffic lights)	167	177	175.19	180	175.5

1.4 Referrals

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Pharmacovigilance referrals started	2	3	4	5	2
Non-pharmacovigilance referrals started	6	10	5	8	8

[6] Scientific advice is not mandatory for applicants, therefore it is not a KPI for the Agency per se. Rather, it could be seen as an indicator of applicants' willingness to engage with the European regulatory system.

1.5 Pharmacovigilance

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Number of signals peer-reviewed by EMA	1,888	2,477	1,605	1,600	1,364
Number of ICSRs for CAPs (reports received)[7]	-	2,989,903	2,273,735	1,500,000	1,389,710
Number of signals assessed by PRAC (validated by EMA)	39	55	39	40	39
PSUSAs (CAPs only) started[8]	n/a	568	n/a	586	584
PSUSAs (mix CAP/NAP) started[9]	n/a	49	n/a	42	38
PSUSAs (NAPs only) started[10]	n/a	287	n/a	255	237
Number of imposed PASS protocol procedures started	4	7	5	4	2
Number of imposed PASS result procedures started	4	11	2	4	7

1.6 Inspections and compliance

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
GMP inspections	130	247	96	310	209
GLP inspections	0	0	1	2	2
GCP inspections	59	36	75	89	75
Pharmacovigilance inspections	16	15	12	15	14
PMF inspections	40	122	84	127	146
Notifications of suspected quality defects	170	178	206	250	257
Medicinal products included in the sampling and testing programme	81	75	85	81	88
Standard certificate requests received	3,115	3,753	3,849	4,520	4,817
Urgent certificate requests received	1,647	1,659	1,147	1,186	1,117
Parallel distribution initial notifications received	3,172	2,555	1,816	2,100	2,092
Parallel distribution annual updates received	11,624[11]	4,816	5,509	5,550	5,477

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Standard certificates issued within established timelines (30 working days)	80%	99%	100%	90%	100.00%
Average days to issue standard certificate (reversal of traffic lights)	23.59	12.81	3.90	15	4.4
Urgent certificates issued within established timelines (2 working days)	98%	99%	100%	98%	99.00%
Parallel distribution initial notifications checked for compliance within the established timeline	90%	99%	99%	98%	99.00%

[7] New indicator introduced in 2021 Work Programme.
[8] New indicator introduced in 2022.
[9] New indicator introduced in 2022.
[10] New indicator introduced in 2022.
[11] The figure includes a backlog of annual updates received in 2018 and 2019.

1.7 Committees and working parties

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Number of reimbursed meetings	52	2	106	420	264
Committee meetings[12]	75	78	76	75[13]	76
Trainings[14]	4	0	2	22	n/a
Workshops	2	0	9	13	n/a
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	112	1	66	310	n/a
Number of virtual meetings/connections (audio-, video- and web-conferences)	5,409	13,227	5,700	6,500	4,600
Number of reimbursed delegates	1,003	30	1,980	8,500	3,476
Number of non-reimbursed delegates	60	0	178	1,500	1,008
Herbal monographs, new	3	3[15]	3	2	1
Herbal monographs, reviewed[16]	14	18	28	20	19
Herbal monographs, revised	8	2	2	5	3
EU herbal List entries	1	0	0	1	0
Working parties	n/a	n/a	n/a	n/a	78
Workshops, Forum, Seminars, Info day	n/a	n/a	n/a	n/a	87
Other meetings	n/a	n/a	n/a	n/a	142

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%	100%	100.00%

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Support the STAMP scientific advice pilot for repurposing established medicines	1.1 (ECP 1, ECP4)	Several prioritised established medicines are enlisted in the pilot	**Delayed**	Completion of all preparatory steps / interactions for enabling start of the SA process for all selected champions with a tailored process introducing further steps to support the champions to shape their briefing documents to kick-off the SA procedure (conduct of academia preparatory meetings, then few rounds of review of draft briefing

[12] Including Management Board meetings.
[13] In 2023 committee meetings will be held physically and remotely.
[14] Includes EU Network training centre meetings.
[15] Not included: two new public statements finalising the assessment of two substances that did not lead to the establishment of a monograph.
[16] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				documents, SA pre-submission meetings) and completion of 4 SA (out of 6 selected candidates) including a debriefing meeting with Rapporteurs
Provide parallel/joint EMA/HTA scientific advice, also in anticipation of and with the new HTA Regulation Progress with the HTA consortium the objectives of and tools for post-licensing evidence generation Launch a pilot for prospective evidence planning with payer's representative, to explore potential scope and feasibility Strengthening guidance through scientific advice, also aiming at reinforcing the coordination with guidance on clinical trial conduct	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	**On track**	Completion of scheduled requests for parallel Joint Scientific Consultation together with the EUnetHTA 21 consortium, under the framework of their service contract. Establishment of transitional arrangements for parallel consultation between September 2023 and December 2024, including publication / communication (see Guidance on Parallel EMA/HTA body (HTAb) Scientific Advice for the Interim Period) Review of experience with providing parallel EMA/HTA scientific advice at the concluding EMA/EUnetHTA bilateral in September 2023, also with identification of learnings for future operations (see meeting report) Delivery of the EMA/EUnetHTA 21 work plan, which also covered developing study methods and guidelines of real-world evidence (including for registries), and publication of a technical report in September 2023 (see Report on the implementation of the EMA-EUnetHTA 21 work plan 2021 – 2023)
Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers Conduct product-specific reviews with HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes	1.2 (ECP 1)	Stakeholder communication about regulatory assessment is enhanced	**On track**	EMA/EUnetHTA 21 bilateral with focus on ATMP assessment held Q1 2023 (see EMA – EUnetHTA 21 Bilateral) Completion of a review of 3-year experience with webinars between EMA, CHMP Rapporteurs and HTA bodies providing recommendations for the optimisation of CHMP assessment report (AR) template and guidance to address the findings and gaps identified (see technical report on the work plan delivery). Regular contributions to meetings of MEDEV/ESIP, providing feedback on completed product evaluations.
Set up and operate a Quality Innovation Group to serve as platform for interactions with developers and	3.1 & 5.5 (ECP 1)	The implementation of novel manufacturing technologies and capacity	**On track**	**QIG:** QIG group operationalised, 2 listen-learn-focus group meetings held in March and October 2023, meeting reports published in May 2023 and in

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
academia aiming at identifying bottlenecks and facilitating innovative manufacturing technologies and methods Deliver on international activities relating to Pharmaceutical Quality Knowledge Management System (PQKMS) Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12		enablers is facilitated		finalisation stage (to be published end of January 2024) Workplan 2024-2026 finalised and priority topics defined Guidance preparation finalised and ongoing (e.g. x-ray sterilisation, modelling, Q&A on decentralised manufacturing) Product support pathways set-up Collaboration with FDA set-up **ICMRA:** ICMRA pilot initiated, 5 pilot procedures supported (PACMP assessment), lessons-learnt review conducted **ICH Q12:** ICH Q12 principles considered in Pharma strategy variations proposal, variation classification guideline revision initiated Implementation pending Pharma strategies outcome
Deliver tailored engagement with academics and the community of ATMP developers Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant guidance, e.g. on the safety and efficacy follow-up of ATMPs	3.1 (ECP 1)	Increased support to the integration of scientific and technological progress in the development of ATMPs	**On track**	Update to the Draft EU Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials well underway to achieve finalisation in 2024 after a second public consultation. EMA ATMP support pilot ongoing, with selection process and application form published following launch in October 2022. 2 additional candidate projects were successfully selected in Q4-23 with onboarding planned in Q1-24.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2)	**On track**	For principles and Annex 1 (substantive part of the document), document put out to public consultation, comments reviewed for Europe and send to the EWG for discussion. Currently at step 3. Annex 2 drafted, to be sent for Caucus review in Feb 2024.
Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2)	**On track**	For principles and Annex 1 (substantive part of the document), document put out to public consultation, comments reviewed for Europe and send to the EWG for discussion. Currently at step 3. Annex 2 drafted, to be sent for Caucus review in Feb 2024.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Promote the inclusion of neglected populations such as pregnant and lactating women, the elderly and those of diverse ethnicity in clinical trials	3.2 (ECP 1)	Use the revision of ICH E8 and E6 to remove barriers and to encourage the inclusion of neglected populations in clinical trials	**On track**	For principles and Annex 1 (substantive part of the document), document put out to public consultation, comments reviewed for Europe and send to the EWG for discussion. Currently at step 3. Annex 2 drafted, to be sent for Caucus review in February 2024.
Promote more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer	5.2	Review Annex 15 of the GMP guideline on Qualification and Validation to investigate potential extension of scope to APIs Support PIC/s in the revision of the PICs aide memoire "Evaluating management of quality risks at GMP facilities" for reference to development of APIs and identification of impurities	**On track**	The API Programme on exchange of information on inspections of API manufacturers is ongoing. In addition, the partners are discussing the revision and enhancement of the collaboration scheme for exchange of information on supervision of API manufacturing sites. The ICMRA Collaborative Pilot on hybrid inspections has also progressed with 2 agreed and published documents concerning the protocol for the hybrid inspection and the expectations for a hybrid inspection. Furthermore, 1 hybrid inspection has been conducted under this framework in 4Q23 and another is planned for 1Q24. A revision of the Annex 15 of the GMP guideline on Qualification and Validation for the potential extension of scope to APIs, as recommended in the Sartans with nitrosamines Lessons Learnt Report, has been agreed with PIC/s and is included in the 2024-2027 GMDP IWG work plan. As a result of the Sartans Lessons Learnt, as well as taking into consideration the revision of ICH Q9 R1, PIC/s has been working on a revision of the aide memoire "Evaluating management of quality risks at GMP facilities" for reference to development of APIs and identification of impurities, which is expected to be finalised in 2024.
Increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between MS and strategic international partners.	5.2	Improve the exchange of information among MRA and PIC/s partners through international programmes, such as the API International Programme and PICs and ICMRA initiatives on hybrid	**On track**	See above.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		inspections, in order to increase collaboration on reliance and hybrid inspections as needed		
Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/ convergence of practices and training with the Pharmaceutical Inspection Co-operation Scheme, extend EU-US mutual recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA	5.3	Reinforced responsibility for product quality by harmonising and reinforcing guidance	**On track**	The EMA and the GMDP Inspectors Working Group have been working with PIC/s, ICH and its international partner on several GMP guidance and currently under revision or under implementation (such as Annex 11 on computerised systems, Chapter 4 on Documentation, Annex 1). Following the adoption of revised Annex 1 training and implementation activities have been prepared in collaboration with PIC/s. The US MRA extension to veterinary products has been finalised and applies as of 30 May 2023. There has been operational progress on the areas of the MRA expansion: on vaccines and plasma derived products the extension (however this has been delayed due to the Covid-19 pandemic) and on the recognition of third country inspections where an equivalency report has been finalised by the GMDP IWG and is undergoing further discussion.
Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	6.2	Improved benefit/risk communication	**On track**	Group of assessors to conduct pilot has been selected. Methodology for pilot agreed.
Draw lessons from COVID-19 evaluations by applying regulatory agility while maintaining high standards for quality, safety, and efficacy with an aim to reduce assessment time Develop simplifications/reductions of post-	6.2 (ECP 2)	Regulatory innovations and flexibilities to accelerate the availability of medicines are identified, and where feasible, are progressed for implementation	**Completed**	Analysis completed and proposal forwarded to the EC through concept papers in the context of the pharma strategy.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
authorisation procedures Increase sustainability and availability of expertise in the European Network by matching expertise with the existing product pipeline and ensuring adequately trained experts to perform the assessment Invest in accelerated approval pathways to target unmet medical needs and where the Agency provides enhanced support for development under the Priority Medicines (PRIME) scheme				
Management of Medical Devices Expert Panels: Conduct a pilot for providing scientific advice to medical device manufacturers and have lessons learnt to establish an effective scientific advice service Develop a training curriculum on medical devices for scientific staff with experience on medicinal products to increase medical device expertise at the Agency		Experience gained to establish scientific advice for medical devices Reinforced competencies on medical devices	**On track**	Launch of the pilot for advice to manufacturers of high risk medical devices: - webinar in January 2023 - 1st phase of the pilot open for application 27th February 2023 - selection of first 6 applications - 2nd phase of the pilot for applications currently ongoing. In total, 39 letters of interest were submitted, with the greater numbers coming from the Circulatory System (15 requests), Orthopaedics (11 requests) and Neurology and Dentistry (4 requests each). 82% of all the devices in the applications were considered by the developer to be novel, with 54% also claiming to be targeting an unmet medical need and 33% claiming to be an orphan device (categories not mutually exclusive). 70% of all the submissions were from SMEs. Delivery of training to experts: 3 trainings were delivered to the experts

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Innovation Task Force briefing requests (Vet)	5	6	0	5	10
Scientific advice requests received[17]	31	23	39	20	17
Requests for classification as limited market under article 4(29) and eligibility under article 23	n/a	3	21	20	17

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100.00%

2.2 Initial evaluation activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Initial evaluation applications	15	9	22	30	25
New MRL applications	1	0	0	1	0
MRL extension and modification applications[18]	1	3	1	1	2
MRL extrapolations	0	0	0	1	1
Art. 10, Biocides	0	0	0	0	0
Review of draft Codex MRLs[19]	3	0	16	0	0

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Initial procedures completed within legal timeframes	100%	100%	100%	100%	100.00%

[17] Validated requests.
[18] Includes reviews requested in line with Article 11 of Regulation 470/2009.
[19] From 2022 also includes Codex extrapolations.

2.3 Post-authorisation activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Variations requiring assessment, of which[20]	n/a	n/a	252	278	337
Variation requiring assessment level 1	n/a	n/a	2	2	2
Variation requiring assessment level 2	n/a	n/a	75	97	104
Variation requiring assessment level 3	n/a	n/a	70	59	76
Variation requiring assessment level 4	n/a	n/a	105	120	155
Transfers of marketing authorisations	9	8	0	2	1

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Post-authorisation applications evaluated within the legal timeframes	100%	100%	100%	100%	100.00%

2.4 Arbitrations and referrals

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Arbitrations and Community referral procedures initiated	3	0	5	3	1

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Referral procedures managed within the legal timelines	100%	100%	100%	100%	75.00%

2.5 Pharmacovigilance activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Total adverse-event reports, of which:	66,901	80,709	167,546	75,000	149,059
Adverse-event reports (AERs) for CAPs	30,297	43,334	95,959	37,500	81,845
Adverse-event reports (AERs) for NAPs	36,604	37,365	71,587	37,500	67,214

[20] Variations requiring assessment: New indicators introduced following Regulation (EU) 2019/6. For an explanation of the different Variation Levels, please refer to the Explanatory note on general fees payable to the European Medicines Agency.

Performance indicators

Performance indicators related to core business		2020 result	2021 result	2022 result	2023 target	2023 result
	AERs for CAPs monitored within the established timelines[21]	97%	96%	n/a	95%	n/a

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals	3.1 (ECP 1)	Guidance for novel therapies and biologicals developed	**Completed**	The "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy" was revised following the comments received during the consultation period and adopted by CVMP in October 2023 and published on the EMA website.
Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs, and initiate the necessary preparatory and follow-up work	3.1 (ECP 1)	Analysis of impact and plan for future work on guidance and processes	**Completed**	The impact analysis prepared by SWP-V was presented to CVMP in April 2023. The launch of the next phase of the consumer exposure project has been outlined with EC and EFSA. In view of the development of the future common calculation tool, comments on the PRIMo4 EFSA tool have been sent. The impact assessment may be revised during work on the activity listed below.
Implement in the veterinary medicines field the recommendations of the "Report on development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin"	3.1 (ECP 1)	Harmonised methodology in place: legislation, guidelines and templates revised; exposure assessment tool made available to CVMP experts	**On track**	As agreed at trilateral meeting EC/EMA/EFSA in June, EMA and EFSA launched informal discussions on technical matters to provide EC with elements to be included in a follow-up mandate. This mandate would address the development of the common calculation tool. The 1st bilateral EMA/EFSA meeting was held in July 2023, the 2nd was held January 2024. In parallel, the final SWP-V comments on PRIMo4 in view of the development of the

[21] The new systems are not yet 100% up and running and several products have not yet been migrated, therefore, at the moment is not possible to calculate the percentage of AERs monitored by the established timeline.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				calculation tool were forwarded to EFSA in September 2023.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	3.1 (ECP 1)	Guidance for surveillance and signal detection developed Enhanced communication with the network	**Delayed**	Development of guidance for surveillance and signal detection has been developed in the "P-SMEG Handbook", for internal use. The guidance has been linked to the P-SMEG interim report 2022-2023, which will be presented to CVMP in January 2024. In addition, the Union PhV Database Best Practice Guide is currently being updated by P-SMEG to provide additional practical guidance and examples to facilitate the interpretation and implementation of the VGVP guidelines to MAHs. A final report with in-depth review and recommendation will be provided by the end of the pilot.
Using data on the sales of veterinary products, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use	3.1 (ECP 1)	Methodology established and guidance developed	**On track**	The form to collect the sales data has been established by the UPD product owners together with the EVVET product owners. The methodology for deriving the dose factor has been drafted and the final guideline published in December 2023. The development work on the data warehouse to allow publishing the available reporting incidences by end January 2024, is on track as planned.
Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label	3.1 (ECP 1)	Expert group established with mandate and objectives	**Completed**	Two Focus Groups on pharmacovigilance reporting have been held in October and November 2023, respectively with veterinary experts working in the field of poultry and in the field of aquaculture. See related events pages: Focus group on veterinary pharmacovigilance reporting in poultry Focus group on veterinary pharmacovigilance reporting in aquaculture
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances,	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	**Delayed**	A pilot study is being performed at the request of the EC.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
including legacy active substances for which there is limited environmental information, providing input as required				
Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish cooperation with international institutions, academic organisations and relevant initiatives	3 (additional RSS recommendation)	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	**On track**	Ad-hoc cooperation with other Agencies and academia has started. In 2022, the ERAWP/EMA started an ongoing cooperation with EFSA concerning the elaboration of an approach for the environmental risk assessment of veterinary medicinal products/feed additives intended for use in aquaculture.
Provide scientific support to the European Commission and the EU network to ensure that a "One Health" approach is applied to ERA	3 (additional RSS recommendation)	Support to EC provided "One Health" approach for ERA implemented	**On track**	EMA provides input to EC/other Agencies when requested on ERA "One Health" topics. No specific request was received in 2023.
Expand current data-collection system to include other antimicrobials	4.1 (ECP 1)	Collection of data expanded to include all antimicrobials	**Completed**	Development of the ASU IT System is ongoing and the following milestones have been achieved: final improvements to the ASU Platform web interface to enhance usability, development and improvement of the ASU Power BI data validation reports, creation of the ASU PROD environment and final technical preparations for the go live of the system planned for Q1 2024, among others. Furthermore, the ASU PROD environment was opened to testers from all Member States in September 2023 in order to provide access to real product data in ASU templates and start improving product data quality in collaboration with UPD colleagues.
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1 (ECP 1)	Establish governance for JIACRA report under EMA and CVMP	**On track**	The mandate, objectives and rules of procedure for the European Sales and Use of Veterinary Antimicrobials Working Group (ESUAvet Working Group) have been adopted by CVMP in November 2022. A call for nomination of experts was circulated in Q1 2023, the group started its operations in June 2023, and had so far two plenary meetings, and at least one

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				meeting of sub-group delivering the work. The workplan for 2023/2024 was agreed by CVMP.
Implement use data collection by animal species	4.1	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578	**On track**	The development of the ASU IT system to collect and analyse antimicrobial sales and use data is ongoing and is on track to be ready to support the first data call and report development under Reg. (EU) 2019/6 in 2024.
Communicate effectively on consumption data	4.1	The outline of the ESVAC report reviewed to improve communication Group of experts to define the outline of the volumes of sales and use of antimicrobials (Article 17 of the Commission Delegated Regulation (EU) 2021/578)	**On track**	The final ESVAC report was published in November 2023. Within the ESUAvet WG, a subgroup was created (analysis & reporting) to draft the outline of the future Agency's reports for both sales and use data. The first meeting took place on 1 December 2023 at EMA, during which tasks were split between the members. On 29 January 2024 the subgroup will convene to discuss the proposals and progress made by the members. This activity is a priority for the ESUAvet WG and EMA. The WG workplan foresees CVMP adoption of the draft layout by Q4 2024.
Adjust the methodology for analysis of antimicrobial data, by considering approaches developed internationally	4.1 (ECP 1)	Analyse international approaches and integrate where possible in methodology	**Completed**	A survey was sent in Q4 2022 to contacts of the ESVAC network (as representatives of MSs) regarding national animal population statistics. The results of the survey were analysed in Q1-Q2 of 2023 and a draft guideline on denominators and indicators was adopted by CVMP in June 2023 and published for 1 month consultation. The guideline was adopted by CVMP in October 2023 and published on the EMA website.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals	4.1 (ECP 1)	Define new requirements and develop guidance on new requirements based on Commission Delegated Regulation (EU) 2021/578 and Commission Implementing Regulation (EU) 2022/209	**Completed**	An update of the ASU protocol (combining the previous 2 protocols and including new information) was completed during the second half of 2023 and is planned to be published on the corporate website in January 2024, in addition to updated versions of the three ASU reporting templates. Furthermore, specific user guides on how to use the ASU Platform and how to use the ASU Power BI application were also developed and shared with ASU users. Much emphasis was placed on training with the ASU team providing a total of five webinars in the second half of 2023 (four focused on ASU/UPD data quality and one on how to report animal population data via the ASU platform). Furthermore, eight 30-min Q&A sessions were held with Member State ASU Data Managers to help them prepare for the go live of the ASU Platform and to address data quality issues in the ASU templates. Other materials such as infographics and check lists have also been developed with the change management team to further support ASU Member State users. Finally, a collaborative training on how the ASU Platform can be used by Member States to report data for WOAH took place in November at the WOAH workshop held in Serbia.
Inform policy decisions via enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food	4.1 (ECP 1)	Policy decisions based on the outputs from JIACRA reports	**On track**	The 4th JIACRA report is under drafting and is planned to be finalised by Q1 2024. The report will be published on all the three Agencies' websites in Q1 2024. A simplified summary document will also be published for policymakers to assist with implementation.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Participate in international initiatives to reduce the risk of AMR.	4.1 (ECP 1)	Actively participating in international fora	**On track**	In Q3-Q4 2023, EMA veterinary colleagues actively participated in the following events: AMR One Health Network of the EU , 21 September 2023, virtual meeting WOAH AMR WG meeting 10 - 12 October 2023, virtual meeting EU Pre-Accession visit, Surveillance of sales and use data for antimicrobials in veterinary medicine, Kosovo, 10 October 2023, virtual meeting EU High-level meeting on AMR under the Spanish Presidency, 18-19 October 2023, Pamplona, Spain Scientific Network for Zoonoses Monitoring Data (EFSA), 13th specific meeting on AMR, 8-9 November 2023, virtual meeting WOAH Veterinary Focal Point Training on ANIMUSE, 6-10 November 2023, Belgrade, Serbia EC One Health meeting, 13 November 2023, Luxembourg, Luxembourg TATFAR in person meeting, 14-15 November 2023, Luxemburg, Luxembourg 3rd RAGNA meeting, 15 November 2023, virtual meeting 4 meetings of dedicated TATFAR action groups 1.1, 4.3, and 2.3
Foster development of POC diagnostics for veterinary use	4.2	Review availability and characteristics of diagnostic tests	**On track**	The concept paper on the development of the reflection paper on Diagnostic Tests was adopted by CVMP at its meeting in July 2023 and released for public consultation until 31 October 2023. After analysis of comments received the work on the reflection paper will start in 2024.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Prioritise and trigger referral procedures and/ or support MS in activities to review available data on emerging AMR risks, clinical effect, PK/PD, dose regimens	4.2	Support CVMP on VMP referrals and act on the recommendations from the Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation	**On track**	The Antimicrobials Dose Review and Adjustment group (ADRA working group) was established with members from CVMP, AWP and CMDv. A questionnaire is under development to gain information from stakeholders in respect of Recommendation #3 from the CVMP 'PPHOVA' reflection paper. The questionnaire will be sent to CVMP for its agreement in October. Legal and regulatory aspects for the implementation of the dose review and adjustment were discussed in Q3-Q4 2023.
Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	4.3	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	**On track**	A scientific article on "The use of aminopenicillins in animals within the EU, emergence of resistance in bacteria of animal and human origin and its possible impact on animal and human health" was published in the Journal of Antimicrobial Chemotherapy in May. This article is based on the CVMP's reflection paper. The authors are AWP members and EMA staff members.
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 3)	Develop and revise relevant guidance	**On track**	The Efficacy working party started the revision of the "Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances" and the "Guideline on the conduct of efficacy studies for intramammary products for use in cattle". Both guidelines were reviewed by the Antimicrobial working party, additional comments were also received from EC in Q1 2024. CVMP will review the comments received and the guidelines are expected to be finalised in Q3 2024.
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received Invite CHMP to derive conclusions for human	4.3 (ECP 3)	Reflection paper finalised and published Review of novel risk assessment methodologies for AMR in the environment	**Delayed**	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
medicines based on CVMP reflection paper				
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms	4.3 (ECP 3)	Reflection paper developed Communication with stakeholders	**On track**	This activity has been further discussed at the CVMP Veterinary Domain and an internal plan has been established. The topic was also discussed at the Informal CVMP meeting held in Spain in Q3 2023. In 2024 a horizon scanning will be performed by the NTWP including alternatives to antimicrobials. Based on the outcome, it will be re-assessed how this activity will progress.
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	4.3 (ECP 3)	Guidance development Communication with stakeholders	**On track**	A Q&A document on the inclusion of clinical breakpoints in the SPC for generic antimicrobial VMPs was finalised and published in June 2023. A concept paper for the development of a reflection paper on Diagnostic Tests was adopted by CVMP at its meeting in July 2023 and released for public consultation until 31 October 2023. AWP started developing the reflection paper in Q4 2023 and expect to finalise it in 2025.
Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health	4.3 (ECP 3)	Guidance development on ATAm	**On track**	A workshop on bacteriophages took place on 11 May 2023. Information on the workshop, including links to presentations, is available from https://www.ema.europa.eu/en/events/focus-group-meeting-bacteriophages-veterinary-medicines. The "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy" was revised following the comments received during the consultation period and adopted by CVMP in October

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				2023 and published on the EMA website.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives	4.3 (ECP 3)	Cooperation at EU and International level for events Common approach agreed	**On track**	Under TATFAR Action 1.1, a paper on reporting of sales and use of antimicrobials per animal species was published in November 2023 on the TATFAR website. EMA is collaborating with EFSA, ECHA, ECDC and EEA on a scientific opinion on the impact of the use of azole fungicides on resistance in Aspergillus. The 5 EU agencies asked an extension of deadline on the azoles opinion until the end of 2024. Good progress is being made on term of reference 1, 2 and 3 and the work has been started on term of reference 7 as well, where EMA takes the lead.
Include AMR as a regular topic at meetings with HMA and veterinary stakeholders	4.5	Actively propose AMR topics for HMA and stakeholders' meetings	**On track**	A joint HMA/EMA workshop at which EMANS actions on AMR were discussed was held on 18-19 October 2023 in Pamplona. The EMANS mid-term report agreed with HMA was published in December 2023.
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)	4 (additional RSS recommendation)	Identify different benefit-risk approaches per type of vaccines Guidance on benefit-risk	**On track**	Following comments from the EC, the work on these guidelines has restarted in 2023. The "Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets" and the "Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6" were adopted for release for public consultation at the CVMP September 2023 meeting. Consultation will end on 31 January 2024. The expected completion date is Q2 2024.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best practices on the use of veterinary antiparasitic medicines	4 (additional RSS recommendation)	Improve interaction with International organisations Best practices embedded in guidance	**On track**	The final meeting of the WOAH Electronic Expert Group on Antiparasitic Resistance was held on 17 April 2023. The WOAH will reflect on the new topics to be addressed and new groups to be constituted, depending on the expertise needed. A collaboration with FAO was established on the topic of acaricide resistance in cattle, including filling a specific FAO questionnaire. Further contacts followed, including participation in webinars on acaricide resistance organised by FAO. An EMA project relating to various antiparasitic resistance aspects involving an external collaborating expert (under EMA policy 80) took place during 2023.
Promote responsible use of antiparasitic VMPs in the EU.	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	Revised VICH guidelines on efficacy of anthelmintics: the EWP/CVMP have provided two sets of responses to the comments received from stakeholders during public consultation. Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (which also addresses reduction in the antiparasitic resistance): comments from stakeholders on the antiparasitic resistance section have been addressed and the section has been revised accordingly. Guideline for the demonstration of efficacy of ectoparasiticides: a concept paper for the revision of the guideline was adopted by the CVMP at its July 2023 meeting and published for a 3-months period of public consultation. The comments received following the concept paper public consultation support the revision of the guideline, which will be performed in 2024.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Prepare for and implement Veterinary Medicines Regulation	6.1	Prioritised guidance, processes and IT systems in place in time for implementation; monitor implementation from 2022	**Completed**	The Veterinary Medicines Regulation is applicable since 28 January 2022. Procedures were aligned with the changed requirements. The development of required IT system is either completed (UPD, EVV, MWD) or on track to be completed in 2023 (ASU - see related activities); all projects were transferred to the Agency value stream model in 2022 (see pillar III). Recommendation to EC: - The "List of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))" was adopted by CVMP in June 2023.
Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision-making	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance	**On track**	A drafting group of the CVMP is working on a revision of the "CVMP recommendation on the evaluation of the benefit-risk balance", to improve the current benefit-risk methodology and align with the Regulation (EU) 2019/6 provisions. A concept paper for consultation was published in Q4 2021 and comments received have been reviewed by the drafting group. A draft guideline was adopted for release for a 6 months consultation at CVMP December 2023 meeting and will be finalised in 2024. The guideline will need to be also aligned with the EC Guidance to Applicants.
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	**On track**	In addition to the work of the NTWP, the list of EMA/CVMP stakeholders has been revised and interaction between CVMP (and its working parties) and stakeholders were discussed. The EMA Veterinary Medicines Info Day was held in February 2023, a Focus group meeting on bacteriophages was held in May 2023, the CVMP

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Interested Parties Meeting was held in June 2023. In the second half of 2023, the Veterinary Awareness day meeting was held in September 2023 and the 3rd Veterinary Big data stakeholder Forum in November 2023.
Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 2)	Compilation of a Veterinary data sources catalogue and metadata analysis Define and implement the Big Data Strategy workplan Hold events, workshops, and training to engage and communicate with stakeholders	**On track**	A research study to develop a data sources catalogue was initiated in Q1 2023 and is expected to complete in 2024.
Contribution to Chemical Strategy for Sustainability, particularly on the 'One substance one assessment' (1S1A) initiative, including the establishment of the EU Common Data Platform for Chemicals (EU-CDPC) Consequently, implement the initiative as/if required	ECP 3	EMA data and legal requirements to be provided in the frame of the EU policy-making process Implementation of the initiative as/if required	**On track**	EMA is requested by the EC (DG ENV and DG SANTE) to provide input to the relevant legislative drafts and other types of documents, as well as to make a resource estimation for the activities envisaged. The draft legislation was published in December 2023.

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
New scientific, regulatory and telematics curricula developed	2	1	1	1	0
Number of training events advertised to the EU Network	46	77	76	60	79
Number of reimbursed training events to the EU Network	1	0	4	5	3
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	7	15	11	6	13
Number of Epics[22]	n/a	n/a	n/a	34	39

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop a digital skills framework for EMA and lead on digital capability building		Validated Digital Skills framework for EMA Creation of introductory training on topics in the digital skills framework with links to further learning on each topic to enable deeper skill development Creation of a platform to act as entry point to the introductory training content Deliver agency-wide awareness campaign to engage staff and create engagement through gamification and events	**On track**	As part of supporting digital capacity and capability building with EMA and the Network, new modules within the Digital Skills Framework of the Digital Academy were developed and implemented, including modules on Lean, Artificial Intelligence (AI), Robotic Process Automation (RPA), Cloud Computing, and Agile. These modules complement already existing ones on the Digital Mindset and Digital Wellbeing (which have also been updated), as well as Design Thinking (to be updated in January 2024). Additionally, a Digital Academy collection of learning resources on UX/UI/Usability was developed and will be further expanded in 2024. The Digital Academy was opened up to the Network in September 2023, with the publication of modules in the EU NTC LMS on AI, Digital Mindset, RPA, and Cloud Computing.
Modernise the delivery of scientific advice at central and national level by developing Network skills and processes: support		Develop a future state learning delivery model and landscape that serves new and	**On track**	See above.

[22] New indicator introduced in the context of EMA Agile transformation. Number of Epics completed.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
futureproofing of EMA and the Network by developing regulatory capacity through the EU NTC Develop a future state learning delivery model and landscape that serves new and existing audiences, in co-creation with the EU-NTC		existing audiences, in co creation with the EU-NTC		
Establish a digital innovation lab to explore, pilot and develop solutions and processes, across the drug regulation spectrum, that leverage novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making	2.2 (ECP 2)	Build pragmatic and innovative solutions for new and existing EMA business needs using data analytics and experimentation with new emerging technologies	**On track**	The Agency continued to deliver on experimentation and automation though its Digital Innovation Lab (DigiLab) and the Analytics Centre of Excellence (ACE) including the following projects, several of which directly result in efficiency gains for EMA and its stakeholders: Launch of the new Certificates Process System: streamlining manual processes for the generation of certificates for human and veterinary medicines. With this new application, EMA is only issuing certificates for human and veterinary medicines that are signed and authenticated electronically, as of March 2020. It is not issuing paper certificates. Launch of the new EURD List Database: streamlining manual processes for the publication of the list of European Union reference dates and frequency of submission of periodic safety update reports Collection of more than 80 ideas for automation across the Agency with a focus on delivering efficiency gains Launch of more than 9 projects under EXB request on automation: - NRG Checklist: Automatic generation of Name Review Group checklist - ESPDITE: Early screening of product documentation for input on techniques and evidence - INN Web Search: Scraping the web for INN information

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- New module in AVS (Art 61.3): Automating validation of Art 61.3 submissions - BURT - Batch update review tool: Application to modify template in batch - QRD Template validation: Application to validate documents submitted against the QRD Template - Generation of SAS Report: Develop a solution that could automatically trigger the SAS code every week - Automatic recording of VRA procedures: Automate the process to automatically register VRA procedures - PDF Vendor invoicing: Automate the process of invoice parking, in order to eliminate the manual, repetitive and time consuming task. ChatGPT@EMA pilot to experiment with OpenAI capabilities at EMA: preparing EMA for strategic adoption of AI capabilities exploring the technology to understand EMA use cases and the technology limitations Launch of QR Code Business Card : A modern and paperless exchange of contact information New Early Notification System pilot finished: Preparing for a more digital and secure means of communication for ENS notification
Establish an EU collaboration on AI to support regulatory decision making with other Agencies in the EU Network		Develop and promote the AI community Increase synergies, re-use, and efficiency Share knowledge and increase maturity Collaborate for the implementation of common AI initiatives and projects"	**On track**	This year the community started its work in Q2 2023. Since the beginning, the community organised different session for the rest of the year. The main achievement of the community for this year is the Workshop hosted in Parma in November where all the agencies met to identify common use cases and build a roadmap of possible common projects among the members of the community. In addition, the community hosted two EU AI Virtual talks and one Community meeting.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop capacity and expertise across the regulatory network through curriculum development and knowledge-sharing initiatives on data science, digital technologies and artificial intelligence- related solutions, products and endpoints, and their applications in the regulatory system	2.3	Develop a future state learning delivery model and landscape that serves new and existing audiences, in co creation with the EU-NTC	**On track**	Availability of courses to the Network: Delivery of 89 courses, including 71 online courses. Several meetings held with course organisers, and with members of Paediatric Curriculum Steering group to progress future development of training. Implementation and roll out of the EU NTC Learning Design and Development Toolkit to support Course organisers and Curriculum developers (both in the context of annual planning with Curriculum Leads as well as in response to advance announcements of upcoming courses). Development of the EU NTC Engagement Portal (which will provide a single point of access to the EU NTC LMS). The technology for the Portal was selected, the Portal was built and is now planned for release in January 2024. The Portal was demonstrated at the Quarterly Demo in December 2023. Implementation of the Process for remuneration of NCAs for the development and delivery of training which was adopted by the Management Board in June 2023. Agreement for remuneration of NCA experts was agreed for 5 individual courses to end of 2023. Further to a tender for services to develop a Big Data curriculum, two training modules in Pharmacoepidemiology were developed by the selected training providers and published on the EU NTC LMS. Five training modules were developed as part of a Data Science curriculum and will be published in the coming months. Improvement Action Plan developed to address recommendations identified in an Internal Audit on EU NTC Governance and Capacity Building.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Improvements to the EU NTC Learning Management System (LMS) / Automation of user management processes: Self-service password reset implemented. On track to eventually integrate LMS with EMA account – allowing users to have same login details for LMS as for other EMA systems. EU NTC webpage published on EMA's corporate website. EU NTC Engagement Event involving EU NTC Training Champions, Local Administrators, Curriculum Steering Group Leads and Training Steering Group members held on December 5th2023 Discussion is continuing on the extension of EU NTC training to new audiences including Medical Device Authorities, HTAs, International Regulators.
Develop the integrated evaluation pathways in cooperation with medical device authorities and notified bodies Strengthen the coordination between relevant actors for the assessment of combinations of medicinal products with medical devices and of companion diagnostics	3.4	Design and implement an integrated regulatory pathway for the assessment of medical devices and IVDs intended to be used with medicinal products or support their development Ensure an overall more efficient and consolidated input in the development and management of such products	**On track**	A first draft of the integrated pathways roadmap document was developed. Useful comments were received for implementation in the update of the roadmap document that will be then circulated as second draft. Planning of workshops and drafting of relevant guidance documents have been considered in the roadmap document.
Identify and enable access to the best expertise across Europe and internationally	3.4	Map all current working groups (i.e. at EMA, HMA/CAMD, NCA, EC) working on medical devices and in vitro diagnostic where there is a connection to medicinal products and identifying common tasks/topics Establish a more formal link between the current groups and the experts at the NCA's facilitating systematic interaction	**Completed**	See integrated pathways. The planning of a mapping exercise of the currently available medical device expertise (including NCAs) was described in the first draft of the integrated pathways roadmap document. Furthermore, in March 2023 the Medical Devices Implementation Group (MDIG) was established in EMA. MDIG is a cross-organisational group of EMA experts formed for the coordination of EMA's implementation activities according to MDR/IVDR

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				provisions as well as for discussion of and information / knowledge sharing across the Agency on EMA's MDR/IVDR implementation activities including also expert panel related activities.

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Workload indicators

Procedure		2020 result	2021 result	2022 result	2023 forecast	2023 result
	Number of MLM ICSRs created	n/a	9,193	n/a	9,000	9,698
	Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments	n/a	3	n/a	6	6

Performance indicators

Performance indicators related to core business		2020 result	2021 result	2022 result	2023 target	2023 result
	Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	97%	91%	n/a	95%	98%

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network -DARWIN EU) Build a business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines, by informing those decisions with robust evidence from healthcare	2.1 (ECP 2)	DARWIN EU Coordination Centre established EU regulatory network routine access to RWE established DARWIN EU pilot with EHDS initiated Processes for EMA oversight of DARWIN EU activities in place, including review of all deliverables and DARWIN EU outputs	**On track**	During 2023, DARWIN EU® has continued to deliver as per plan. Number of studies performed has increased in comparison to 2022 (18 on-going or completed studies in 2023 vs. 4 in 2022); the onboarding of 10 additional European data partners has been initiated which will result in 20 active or being onboarded data partners at the end of 2023. The studies have covered a range of use cases and have responded to the requests from most of EMA's committees and from other stakeholders (ECDC via the Vaccine Monitoring Platform, HTA & payers).
EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	2.4 (ECP 2)	Process established to identify the committees' needs and feed RWE in their decision-making processes for prioritising analytical requests established	**Completed**	The value of RWE is being established, use case by use case. Solid demand for RWD studies continued to be seen in 2023. Learning not only from DARWIN EU® studies but also from other RWE pilots, EMA

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		Processes for the drafting and review of study protocols and study reports Processes for choice of analytical strategy depending on research question and committees' needs (in-house analysis, use of framework contracts, feeding into DARWIN EU) Users' training on utilisation of IHD and analytical templates		published in 2023 a report on its experience in using real-world evidence to support regulatory decision-making between September 2021 and February 2023. During this period, 61 RWD research opportunities were identified focusing on medicine safety, medicine use, disease epidemiology, design and feasibility of clinical trials and clinical management, 30 pilot studies were initiated and 27 completed. In 2023 more specifically, 58 studies have been requested/offered, of which 29 studies have been considered feasible to be conducted via the Agency's in-house databases (8), framework contracts (3) or DARWIN EU® (18). Of these, 27 studies were initiated in 2023, including: 1 study following a request from COMP, 4 studies from PDCO, 3 studies from CHMP, 8 studies from PRAC and 1 study from the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG). Of the remaining 10 studies, most have been conducted in collaboration with the extended network of decision makers including HTA/payer organisations (2), the European Centre for Disease Prevention and Control (ECDC) and the Vaccine Monitoring Platform (VMP) (6), and the European Commission (1, EHDS pilot). Several studies launched in 2023 have been linked to broader research projects that will continue in 2024: - five studies were commissioned in accordance with the vaccine monitoring platform (VMP) research agenda, looking at the effectiveness of COVID-19 vaccines, background incidence of selected chronic diseases of interest linked to vaccines, age-specific incidence rates of RSV-related disease and

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				effectiveness of Human Papillomavirus Vaccines; - two studies were requested and are explored in line with the CHMP 2023/2024 workplan item on geriatrics (frailty/polypharmacy and inappropriate prescribing); - a pilot study was conducted to develop a framework for RWE to support regulatory decisions for paediatric extrapolation (natural history of dermatomyositis and polymyositis); - two studies were requested within the mandate of MSSG to support the monitoring of prescription of medicines for public health emergencies at risk of shortages and inform on medicines used in mechanically ventilated patients. In addition, two HMPC pilot studies were explored for their feasibility via DARWIN EU® (use of medicinal cannabis and use and safety of Pelargonium radix in children) and may lead to specific studies in 2024.
Support EMA operations and Committees with advice and epidemiological expertise on: - methods for RWE collection, analysis, and reporting in the fields of health care and medicinal products evaluation - portfolio of real-world data sources existing in Europe and elsewhere to answer research questions - identification of research questions appropriate for further investigation and their translation into study protocols - evidentiary standards and formats and		Guideline on evidentiary standards, methodological aspects, formats, and contents of RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of RWE data sources used in regulatory decision-making (e.g., registries and electronic health care records) Participation and contribution to SAWP, pre-submission, PRIME, and other relevant meetings where RWE is addressed	**On track**	EMA subject matter experts have participated and contributed to SAWP, pre-submission, PRIME, and other relevant meetings where RWE is addressed. Tracking table of SAWP, pre-submission and PRIME meetings is up to date. Screening of the ESPEDITE report received once a month to identify new initial applications that include keywords related to RWD, review and feedback to CHMP members with epidemiology expertise for preparation of the CHMP plenaries. ESPEDITE is a listing of all new marketing authorisation and extension of indication applications received by EMA and including RWD keywords. Collaboration with eSubmission team to include tick boxes

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
contents of RWE submitted by MAAs/MAHs - lessons learnt from review of RWE submitted by MAAs/MAHs - literature review of published articles with RWE on utilisation, safety, and effectiveness of medicinal products				related to RWD in the eSubmission form so applications including such data are automatically flagged to us for further screening.
To pilot the use of AI to increase efficiency to extract information from EMA documents and real-world data, including development of good practices and training		Report on lessons learnt from the test Paper on methods developed and published Application to extract and communicate data extracted from SmPCs, other documents, and RWD Reflection paper on gaps in guidance on use of AI and on how to validate AI-based algorithms in healthcare and medicine AI glossary	**On track**	In 2023, the first EU AI reflection paper (including a glossary) to support the safe and effective development, use and regulation of human and veterinary medicines was published as draft for public consultation. In December 2023, the AI workplan to 2028 (linked to BDSG activities) was published, setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks. The AI Workplan to 2028 covers activities across four domains (guidance, policy and product support; tools and technology; collaboration and change management; experimentation). The second joint HMA/EMA AI workshop took place in November 2023 to discuss with stakeholders the latest developments in AI technology, policy, and its potential applications in medicines regulation. The Health Data Lab activities have been initiated in June 2023 and are on-going. And application to extract ADRs from SmPCs were tested in 2023 on 1000+ documents.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Establishment of a monitoring system in the post-authorisation safety and effectiveness monitoring of vaccines		Core infrastructure for prioritisation, launch and supervision of vaccine studies Establish and operate working arrangements with ECDC Identification of EU networks with capacity to perform representative and reliable studies Identification of the need of studies Management of public calls and monitoring of funded studies Results of studies that are publicly available and made available to EU decision-makers	**Completed**	Vaccines Monitoring Platform Steering Group and Joint Secretariat fully operational: Steering Group meets monthly and drives strategic aspects and needs for studies; Secretariat oversees operational aspects of the platform, with support of the Steering Group. Meeting of the IVMAB (Immunisation and Vaccine Monitoring Advisory Board) was held in Q2 (virtual) and a further meeting was held in Stockholm in Q3 (hybrid). The EMA work plan to address key topics of the VMP research agenda was developed and made publicly available on EMA and ECDC dedicated VMP webpages. VMP studies as per VMP research agenda were fully integrated in EMA's RWE generation strategy (framework contracts and DARWIN EU). EMA-funded studies (for all of 2023): 2 effectiveness studies and 2 safety studies completed; extra component/analyses to mpox study; new tender (Framework for the post-authorisation safety evaluation of vaccines in the EU).
Enable data discoverability; the final output will be to interlinked public catalogues - one of EU RW data sources, the other of EU observational studies. This will be built on the RW metadata list and replace the ENCePP resources database and EU PAS register Identify key meta-data for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote	2.1 (ECP 2)	MINERVA final study report (EMA/2017/09/PE/16) Design and delivery of a Catalogue of Observational Studies Design and delivery of a Catalogue of Real-World Data sources	**On track**	Delivered several features of the new catalogues, following an Agile methodology for delivery. On track for delivery of the new catalogues by end of Q1 2024. Data Quality Framework (DQF) - final DQF adopted by CHMP and published on EMA website. Drafting of the DQF for RWD (Real-World Data) version for Network and public consultation completed. Started drafting the DQF for ADR (Adverse Drug Reaction Data). Collected metadata for more than 100 real world data sources. Process ongoing to maintain and capture additional Data sources.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable)				
Resolve the current difficulties that PhV Office and HCD teams are experiencing with the tools used for Signal Detection and ICSR data analysis, and future-proof EV based on data security SPOR and cloud technology		Replacement of the current EV analytics system and integration with EMA systems (SPOR) to increase performance, security, usability and reduce maintenance costs	**On track**	The Signal and Safety analytics project will provide modern and user friendly analytics platform for the EudraVigilance system. Financial terms agreed with software vendor in March. Preliminary Data Protection Impact Assessment (DPIA) prepared through 1st half 2023. Updated project plan approved by Portfolio Board in July. Participation in PI Planning in December.
Implement the Clinical Trials Safety Monitoring Implementing regulation		Deliver IT tools and processes described in Art. 11 of the IR of the Clinical Trials Regulation	**On track**	As per ACT EU work plan and an action for EMA, based on Article 11 of the Implementing Regulation, safety assessment and IT functionalities for safety must be reviewed at least annually. EMA completed this review in 2023 and planned accordingly a 2024 review.
Strengthen the EU Network on methodology and RWE in committee advice and assessment Develop Big Data learning initiative with a view to developing guidelines and processes that learn from applications Work with international partners to develop roadmap and guidance		Embed identification of submissions with complex methodological and RWE aspects into EMA forecast and tracking processes Establish a systematic lessons-learnt process for challenging methodological regulatory procedures Fully integrate RWE and AI as key expertise in the methodology domain Start a European Specialised Expert Community (ESEC) Prioritise RWE topics that need guidance development	**On track**	All methodological guidance development prioritised in MWP work plan launched. Of note, consultation with the EMA Committees and WPs on the draft Reflection Paper on RWE completed. RWE guidance development roadmap: review of existing regulatory guidance completed. CHMP endorsement of Data Quality Framework (included in the MWP workplan) and publication on the website. Methodology ESEC set up and populated, including identifying specific expertise and interest in RWE and AI; kick off meeting of the RWD Special Interest Area.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Collaborate with international initiatives on Big Data Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners		Standardise clinical study protocols and reports and enable data exchange	**On track**	Progressed on development of ICH M11 logical model for clinical trial protocols with the update of the draft planned for March 2024. Support provided to the HL7 Vulcan Accelerator/CDISC logical model for clinical trial protocols. Contribution to the ICH M11 standardisation of regulatory submissions and preparation of a core clinical trial template: Public consultation completed on 27 February 2023 Adjudication of 2000+ comments completed in October 2023 with the protocol update to be finalised in March 2024. Since March 2023, the EC, EU representatives (topic lead, deputy topic lead, regulatory chair) have attended the EWG, subgroup meetings or the ICH M2/M11 meeting on a weekly basis. Workplan revised in November 2023 to take into account the planned update of the Technical Specification and its data elements. EC, EU representatives contributed to finding a solution for the maintenance of the ICH M11 data elements and for drafting the process between CDISC and ICH. Initiated the consultation in EU on the endorsement of the proposal for maintenance of the ICH M11 data elements. Launched successful call for external Subject Matter Experts to support the work of ICH M11. EMA co-led the ICH Reflection Paper on "Harmonisation of Real-World Evidence Terminology and Convergence of General Principles Regarding Planning and Reporting of Studies Using Real-World Data, with a Focus on Effectiveness of Medicines" adopted by ICH Assembly in June and launch of

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				a 3-month public consultation. ICH M14 (General Principles on Planning and Designing Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of a Medicine): first draft available and reviewed by internal organisations of the working group, including CHMP/PRAC/MWP representatives. In December 2023, decision taken to move to public consultation in early 2024.
Build capacity and capability to receive, store, manage and analyse raw data	2.1 (ECP 2)	Determine the regulatory and public health benefit of access to raw data	**Delayed**	Reached halfway point in the raw data pilot with 5 out of 10 procedures by Q4 2023. 14 sub-studies included in the raw data pilot, with raw data analysis conducted for clinical efficacy, PK/PD and GCP site selection. Raw data analysis under the raw data pilot conducted with all three different operating scenarios, including EMA, EMA contractor and Rapporteur/Co-Rapporteur teams. Network community on 'Raw Data' established in Q1 2023. Communication activities with this community took place every quarter in 2023. Feedback surveys for interim pilot report have been disseminated in December 2023 to all stakeholders involved.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Support an initiative with the EC and HMA to transform CT in Europe, including modernisation of CT design and good clinical practice Strengthen EU-level governance of CT; leverage data on CT to support regulatory decision-making		Establish EMA support to ACT EU Engage external stakeholders and lay foundations for a multi-stakeholder platform Develop business case for CT data analytics Establish a roadmap for methodologies guidance Adopt a plan for GCP modernisation implementation Deliver CT training curriculum with links to universities and SMEs Develop RACI matrix for network governance groups Launch a scheme to support large multinational CTs One stop-shop for academic sponsors	**On track**	Creation of a multi-stakeholder platform advisory group (MSP AG) agreed in June 2023. Completed stakeholder call for expression of interest in October 2023. Composition of the MSP AG adopted by the ACT EU Steering Group in December 2023. Preparations made for workshop on Clinical Trials Analytics scheduled for 25-26 January 2024 where use cases for use of data about clinical trials will be collected and prioritised, and feed into a clinical trials analytics research agenda. Roadmap for CT methodologies under development following multi-stakeholder event on 23 November 2023. Scheme to support academic sponsors conduct more multi-national clinical trials, with the creation of a regulatory helpdesk presented to EXB in December 2023 in collaboration with TRS. Plan for GCP modernisation adopted with ACT EU multi-annual workplan focusing on change management and EU guidance revision. Completion of regulator gap analysis and training needs assessment in November 2023 as part of the CT curriculum. Continued monitoring of CTR implementation through monthly publication of KPIs reports. 2023 yearly CTR survey launched and analysed. Adoption of the revised transparency rules for CTIS in October 2023 to facilitate sharing of information on clinical trials data in CTIS public website.
Data standardisation in medicines regulation across the lifecycle of a medicine: Develop a data	2.1 (ECP 2)	Enable effective interrogation of scientific information across the lifecycle of medicines and for multiple types of users within and across	**On track**	Clinical Trial Navigator: Successful completion of the Proof of Concept of ingestion of FHIR data sources, accessing the technical feasibility of using

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
standardisation strategy, drive standardisation of regulatory submissions across the lifecycle of a medicine, search the unstructured data stored at the Agency, collaborate with worldwide standards data organisations		regulatory procedures. Drive up the quality of data submitted to EMA through the use of standards		FHIR data standards, and developing a User Interface to search and display content of clinical trial protocols, in that it created a search tool addressing various user needs and will allow to search within and display specific fields to obtain fast access to summarised information. Onboarded external FHIR expert to support the extension versions (amendments). Onboarded external consultants. Developed change management plan and aligned communication with projects that have interdependencies. Finalised stakeholder analysis. Engagement with EMA Data Board. Initiated work on the alignment of ICH M11 Data models to CTIS. Scientific explorer: Scientific explorer will be the first AI driven knowledge mining tool for the EMRN. Delivery as per plan. Completed ingestion mechanism for Scientific Advice Letters and briefing documents. Completed frontend development of basic search, grid view results, facets, and display options features. Ongoing frontend development of advanced search fields. Started frontend development of saved search feature. Validated quality for AI extractions for 12 Yes/No questions and 10 terms. Authentication user login completed. Query builder for advanced search Proof of Concept completed. Developed change management plan and aligned communication with other Knowledge Mining products. Engagement with external stakeholders (National Competent Authorities). Data Governance: Updated BDSG & NDB mandates updated June 2023 and implemented September 2023.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				EMA Data Governance concept model & priorities agreed by EXB September 2023. EMA Data strategy agreed October 2023 and implementation plan developed, preparations for implementation initiated, roll out planned. Draft data catalogue template developed. Stakeholder input on roles & responsibilities received, data asset definition and prioritisation principles presented to EMA Data Board December 2023. Change management plan version 1 agreed December 2023. Engagement for drafting an EMRN network data strategy in 2024 initiated with BDSG and NDB.
CTIS and CTR: Training and operations and IT project		Deliver CTIS to support the Clinical trial regulation, continue to provide training of users, change management and deliver IT project by providing new functionality	**On track**	Over 1800 clinical trials authorised under the Clinical Trials Regulation (CTR) and its business tool, the Clinical Trials Information System (CTIS). The performance and usability of CTIS improved through 16 IT releases (including multi-factor authentication, dual MS API versions). CTIS became a registered WHO data provider. The guidance on company confidential data and personal data published. Sponsor handbook updated. Business intelligence for Member States launched. Training on building and running queries using CTIS data delivered. CTIS performance for large trials improved. CTIS migrated to a high availability data centre. Following a public consultation, the revised CTIS transparency rules adopted by the EMA Management Board. The simplifications introduced will give access to clinical trial information to stakeholders

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				including patients and healthcare professionals in a faster and more efficient way. Stakeholder meetings organised: 4 CTIS forum, 12 CTIS MS POEG, 40 CTIS Assessors Roundtable, 5 CTIS Bitesize Talk, 10 CTIS Walk-in Clinic, 3 CTIS Info events (plus 1 workshop on transitional trials associated to the Info event in July 2023), 5 CTIS Sponsor end-user training events (organised by DIA).
Full Implementation of the EU-DPR and monitoring of compliance for exchange with international partners	6.2 (ECP2)	In the initial implementation phase, assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, privacy statements, DPIA reports, joint controllership agreements; adopt instruments for international data transfers; conclude appropriate contracts with data processors) Following the first implementation phase, as necessary, update and adopt further annexes to 0055-2020 Internal Guidance of Personal Data Protection. Update, develop and deliver data protection trainings on request or upon own initiative	**On track**	DPO and Data Protection Coordinators continue to drive Data Protection activities and ensures compliance with the European Union Data Protection Regulation by providing advice on all data protection related matters at the Agency and additional support through training for the Network. More specifically, the DPO continues to provide assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, data protection notices, DPIA reports, joint controllership agreements; adopting instruments for international data transfers; advise on data protection provisions with data processors). The update to the 0055-2020 Internal Guidance of Personal Data Protection Annexes and the development and delivery of targeted data protection trainings to EMA staff, contractors and the Network based of topics of specific interest, was core of the 2023 data protection deliverables.

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Innovation Task Force briefing meetings	27	36	34	35	29
Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[23]	0	0	1	4	0
Business Pipeline briefing meetings[24]	-	15	21	18	21
Regulatory assistance, including SME briefing meetings[25]	-	180	207	183	230[26]
Requests for SME qualification	518	504	412	516	428
Requests for SME status renewal	1,205	1,293	1,432	1,260	1,432

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Satisfaction level of SMEs[27]	89%	98%	n/a[28]	80%	85.00%

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Improve further the collaboration with international partners on shortages at the level of ICMRA and the Global Regulators Working Group, including in the area of supply disruptions due to manufacturing quality issues	1.1 (ECP 1, ECP 4)	Established framework for collaboration with international regulators	**On track**	Collaboration with international partners continues - for shortage case management and strategic topics - on quarterly basis through the Global Regulatory Shortage Working Group and ICMRA. Bilateral exchanges with FDA continue on set cadence (i.e. every quarter) as well as other Regulatory Authorities (TGA, Health Canada).

[23] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[24] New indicator introduced in Work Programme 2021.
[25] New indicator introduced in Work Programme 2021.
[26] 220 Requests received for administrative assistance and 10 SME briefing meetings on regulatory strategy.
[27] New indicator introduced in Work Programme 2021.
[28] No info day was held in 2022.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	EMA workshop on RNA technologies additional expert recruitment for ITF briefing meetings and inclusion into EMA expert database
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1 (ECP 1)	New technologies identified and integrated within EU-NTC	**On track**	Discussion with EU-IN members and agreement as focus area in 2024. Integration of task to EU-IN 2024 work plan deliverables.
Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients	3.3	Topics for network training identified and communicated to EU-NTC	**On track**	1. Collaboration on EU4Health work programme 2. Regulatory and scientific virtual conference on RNA-based medicines workshop Feb 2023 3. EMA & EITHealth expert workshop on genome editing Mar 2023 4. EMA bilateral annual meetings with C-Path and TransCelerate
Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	3.4	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	**On track**	1. TRIP Digital workplace for Horizon scanning and Regulatory science delivered (technical go-live Dec 2023) 2. TRIP presented to EU-IN and INNO in Q4 2023 3. EU-IN Horizon scanning drafting group monthly meetings co-chaired, driving forward systematic, collaborative analysis of evolving trends in innovation 4. Completed drafts of AMR veterinary, Digital Health 2050, nanomedicine and Alzheimer Horizon scanning reports 5. EU-IN Plenary monthly meetings inform on EMA ITF topics 6. Monthly presentation of EMA ITF topics and trend analyses to EMA Committee and Working parties

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	**On track**	1. RSS Midpoint report, published Mar 2023 2. Conducted survey at EMA, EU-IN and SciCoBo to prioritise identified Horizon scanning topics 3. Completed draft deep dive reports on Alzheimer, Digital Health 2025, Future of vaccines 4. Progressed implementation of recommendations from Genome editing, AMR and RNA medicines Horizon scanning report (Regulatory and scientific virtual conference on RNA-based medicines workshop February 2023, EMA EITHealth expert workshop on genome editing challenges March 2023)
Improve monitoring of shortages and enhance communication of supply problems to EU citizens, their representatives and HCPs	1.1 (ECP 1, ECP4)	Enhanced communication of supply problems to stakeholders to facilitate mediating action	**Completed**	The HMA/EMA multi-stakeholder workshop on shortages took place on 1-2 March. This event brought together (300+) representatives of national competent authorities, industry, patient and healthcare professionals as well as veterinary medicine representatives from across the EU/EEA to learn about the Task Force activities and share perspectives and initiatives to address availability issues and discuss how these can contribute to the future deliverables of the Task Force. A pilot with HCPs on shortage detection and reporting to EMA is currently ongoing. EMA presentations on shortages to multiple Pts/HCPs platforms (inc. PCWP & HCPWP) have taken place aligned with EMA stakeholder engagement plans.
Develop guidance for MAH's to undertake a risk assessment of supply chain and have a 'resilience plan' including shortage prevention and management Start a pilot for key medicines including training	5.4	Promoted supply chain resilience and reliability of supply of APIs and medicinal products	**Completed**	Good practice guide for industry on the prevention of shortages published on 17 May 2023. Shortage prevention and mitigation plan (SPMP) template developed and agreed by the Steering Committee of the HMA/EMA TF AAM.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Review of the mandate of EMA to include the activities of the EU Executive steering group, the iSPOC, and the EU SPOC Network	1.1 (ECP 1, ECP4)	Fulfilment of the requirements established by EMA's extended mandate for availability of medicines	**Completed**	Implementation of Medical Devices Steering Group (MDSSG) and the medical devices SPOC Working Party in May and June 2023, respectively. Development and finalisation of the IT system for the management of shortages of critical medical devices, the Critical Medical Devices system (CMDS) in July 2023.

Advisory functions (International affairs, Institutional and Policy, Health Threats and Vaccines Strategy, Chief Medical Officer, Internal audit, Legal department)

Pillar 2 – Public health activities and Business Services

Workload indicators[29]

Procedure		2020 result	2021 result	2022 result	2023 forecast	2023 result
	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	n/a	n/a	n/a	130	279
	Number of participations in external forums	n/a	n/a	n/a	60	34
	Number of external participants in training organised by International Affairs	n/a	n/a	n/a	150	630
	Number of visits to EMA / fellowships organised by International Affairs	n/a	n/a	n/a	10	15

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
ICMRA secretariat, including COVID-19 response	1.1 (ECP 1, ECP 4)	Continue demonstrating leadership of and secretariat to ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication Provide strategic directions for enhanced collaboration, improved communication and approaches to jointly address common challenges	**On track**	Support to EMA Executive Director as chair and management of the ICMRA secretariat continued in 2023. During the first semester of 2023 the following meetings/workshops were organised virtually: Executive Committee meetings in February, April and July Plenary meeting in May Regulatory Forums deep dive discussions in April (on: Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) and June (on regulatory control of excipient supply-chain - Lessons from recent events) Workshop on COVID-19 variant in May 2023 The following documents were published on the ICMRA website: ICMRA COVID-19 variant workshop report (May 2023) ICMRA statement on safety of COVID-19 vaccines (June 2023) In June 2023, ICMRA received the 'Global Award for Outstanding Contribution to Health' at DIA 2023 in Boston.

[29] New indicators introduced in 2023 work programme.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				In November 2023, a series of meetings were held in Melbourne, including the ICMRA summit and a plenary face-to-face ICMRA meeting. Important strategic directions were discussed by the ICMRA Heads of Agency at the summit, related in particular to Artificial Intelligence, ATMPs and evolution of Clinical Trials. Important decisions on the future of the ICMRA work were made at the plenary, including the organisation in 2024 of workshops on Point of Care manufacturing and innovation applied to ultra-rare diseases. TFDA, Chinese Taipei was accepted as a new associate ICMRA member.
ICMRA workstream leadership and contribution	1.1 (ECP 1, ECP4)	1- Track and Trace (T&T) (currently on hold pending Executive Committee decision) 2- Pregnancy and Lactation (P&L) 3- Pharmaceutical Quality Knowledge Management System (PQKMS) 4- (Public Health Emergency Clinical Trials Working Group)	**On track**	Currently there are 5 ICMRA workstreams active and meeting regularly: Pharmaceutical Quality Knowledge Management System (PQKMS), Public Health Emergency Clinical Trials (PHECT), Innovation Network, Vaccine Pharmacovigilance Network, RWE and observational studies. EMA is actively participating to all this groups, leading on the PHECT and co-leading on innovation and RWE.
Nitrosamines	1.1 5.5 (ECP 1, ECP 4)	Participation in Nitrosamines International Steering Group (NISG)	**Completed**	Continuous collaboration with international regulators in identifying new medicines containing Nitrosamine impurities, new Nitrosamines acceptable intakes, CAPAs and supporting safety information through participation in the Nitrosamines International Steering Group (NISG).
Extension of US MRA	1.1 5.5 (ECP 1, ECP 4)	Extension to vaccines and veterinary medicines	**On track**	Extension to veterinary medicines The EU-US MRA for veterinary medicines entered into force on 30 May with the recognition by US FDA of the capability 16 EU Member States Competent Authorities to carry out good

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				manufacturing practice (GMP) inspections for certain veterinary products at a level equivalent to the US. The EU also recognised the FDA as an equivalent authority for GMP inspections of sites manufacturing veterinary medicines. Sweden was added to the list of recognised Authorities on 3 October and Latvia on 28 November. The remaining Authorities will be assessed by FDA in accordance with an agreed schedule.
Fostering reliance on EMA scientific outputs: EU-M4all	1.2 (ECP 1)	Provide scientific opinions on high-priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	8 pre-submission interactions with developers to clarify questions around the following topics: eligibility, collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, active participation by WHO and non-EU experts during scientific advice or during the evaluation (in particular supporting the use of the product in the target population and local knowledge), reliance on the EU MA to streamline WHO prequalification or speed up national authorisations, parallel EU-M4all and Centralised applications, independence in national decision making. Interactions with WHO to optimise the information WHO needs for experts' appointment and update guidance for experts to increase their input. Support WHO/NRA expert involvement for 3 scientific advices on possible EUM4all opinions. Support to the product team during the evaluation of the initial evaluation for Arpraziquantel (arpraziquantel), a new treatment option for young children with schistosomiasis, a neglected tropical disease caused by parasitic blood flukes (trematode worms) that can in the long term cause damage to organs such as the bladder, the kidneys, and the liver; and the extension of the indication for Fexinidazole Winthrop (fexinidazole), a medicine used to treat human African trypanosomiasis, also

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				known as sleeping sickness. to also include treatment of the more acute and lethal form of the disease caused by trypanosoma rhodesiense. Workshop WHO-EMA-Swissmedic on EU-M4all and MAGHP with industry representatives and other interested stakeholders to identify and analyse the strengths, challenges, communalities, opportunities and areas of improvement for the two procedures, and share best practices and recommendations. Workshop WHO-EMA-Swissmedic with experts from 9 National Regulators on the EUM4all and MAGHP to discuss how we work, how EMA and Swissmedic involve experts, what we expect and impact on these procedures.
Fostering reliance on EMA scientific outputs: Collaborative registration and other reliance pathways	1.2 (ECP 1)	Engagement with WHO, NRAs and applicants, to promote and support use of the WHO-SRA collaborative registration procedure, facilitated approvals and other pathways Capacity building in low- and middle-income countries	**On track**	Coordination of 5 Collaborative registration procedures (CRP) that aimed to facilitate registration of 5 products in 13 countries. Facilitation of greater public awareness of this facilitated pathway through publication of a CRP information webpage on EMA's corporate website. Participation in two workshops organised by WHO to promote awareness, engagement and capacity building with CRP: Benin (September 23) and 11th Annual meeting on CRP (December 23).
Provide assistance to candidate countries (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process, in particular via scientific and regulatory training activities	6.1	Facilitate EU integration to EU candidate countries and Potential candidate countries Increased visibility of EMA Training on acquis Communautaire of candidate and accessing countries	**On track**	Delivered advanced virtual EMA training on genotoxic impurities on 3 April (200 participants). Delivered two-day F2F advanced EMA training on quality and inspections from 15-16 June in Amsterdam (60 in-person participants, incl. Moldova, Georgia and Ukraine delegations and up to 180 participants joining remotely) Delivered two-day F2F advanced EMA training on clinical trials, pharmacovigilance and inspections on 16-17 November 2023 (60 in-person participants, incl. Moldova, Georgia and Ukraine delegations and up to

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				200 participants joining remotely) Facilitated in-person and remote participation IPA country delegations in EMA Pharmacovigilance Inspections Training on 7 and 8 December 2023 Organized three meetings of IPA contact point (March, May, December 2023) Signed ad-hoc CA with the 7 IPA beneficiaries Drafted and signed contract IPA III in December 2023 (2024-2026)
OPEN project	6.5	Active collaboration of selected regulatory authorities in CHMP and European Task Force for COVID-19 vaccines and therapeutics; Extension of the OPEN model to other therapeutic areas	**On track**	Inclusion of products under the expanded OPEN scope ongoing. Active engagement with industry stakeholders to increase awareness of pathway. First products under the OPEN Framework under assessment at CHMP.
Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	6.1	Support training and capacity building of non-EU regulators	**On track**	Launch of pilot for non-EU regulators.
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	**Delayed**	No international awareness sessions for non-EU regulators were organised in first half of 2023. Plans for re-launch are being developed for 2024.
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building and regulatory system strengthening at continental, regional and national levels through provision of adequate guidance, and other support as needed, as part of wider EU engagement strategy	**On track**	Project team created to prepare EMA proposal for DG INTPA contribution agreement to support the establishment of the African Medicines Agency and regulatory system strengthening at continental, regional and national levels. Submission of Description of Action to the European Commission Internal and external communication and engagement with stakeholders

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Participation and engagement with AUDA-NEPAD/AMRH technical committees (review of procedures and trainings) Established EMRN alignment platform on AMA support and organized two meetings in 2024 Identification of first geographical focus areas (SADC) Identification of priority activities for 2024 Identification of priority areas and activities Signature of Contribution Agreement with DG INTPA in December 2023
Anti-Tuberculosis Medicines Project		Collaboration with WHO to support child-friendly TB medicines Approve anti-TB medicines for unmet medical needs in the EU	**Completed**	Prior-Information Notice and the information on the Tuberculosis call were published by HaDEA in November 2023.
International Cooperation Platform (IntCoP)		Strengthen exchange of information and coordination, fostering a harmonised EU approach to international cooperation on medicines between national competent authorities, DG SANTE/the European Commission and EMA, through a dedicated communication and discussion channel	**On track**	Virtual meetings held in March and June 2023 First IntCoP face-to-face meeting organized in Madrid on 12 December 2023 Increased sharing of information, moving towards better coordination of 'Team Europe' positions, and greater engagement of NCAs.
Reliance on scientific output of EMA committees	1.2 (ECP 1)	Promote reliance on scientific output of EMA committees by non-EU regulators, in particular through WHO facilitated pathways	**On track**	Establishment of a Focus Group on Regulatory Reliance between EMA and EU industry aiming to promote reliance practices and understand challenges faced by industry in the reliance of scientific outputs of EMA committees. Participation in a number of workshops to promote international collaboration and reliance: DIA Middle East (February 2023), Workshop on Reliance and Registration in Vietnam (November 2023) and SCOMRA (December 2023). Support a pilot promoting simultaneous reliance of Post-

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Approval changes for a variation in 48 countries to demonstrate feasibility and public health benefit of regulatory reliance. Support the ICMRA regulatory collaboration pilots addressing facility inspections and CMC and Post-Approval Change assessments and related regulatory actions.
Develop international collaboration and reliance including through Confidentiality Arrangements	6.5	Update existing and putting in place new confidentiality arrangements	**On track**	One new confidentiality arrangement negotiated together with European Commission, awaiting final decision with international partner. Ongoing discussions with other regulators, including update to one existing confidentiality arrangement.
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	**On track**	Activities with Russia suspended due to international political situation. Visit of delegation from CDSCO, India to EMA in November 2023, in margins of the WHO World Local Production Forum. Discussion led by International Affairs started in 2nd half of 2023, through the international platform.
Increase the number of opportunities for non-EU regulators, in particular those of candidate and potential candidate countries, to participate in scientific and regulatory training activities	6.1	Support training and capacity building of non-EU regulators	**On track**	Pilot opening up EU-NTC to selected non-EU regulators completed Impact of Pilot measured via benchmarking survey Potential follow-up to Pilot formulated
Communication of information, answer to queries, internal coordination Monitoring of the matrix of the tracking of interactions. Organisation of cluster	1.1	Support to the International Affairs Division and its specific activities	**On track**	Organisation of 80+ face to face meetings and teleconferences Management of 279 product-related interactions with international stakeholders – including requests for information and requests for documents Management of 630 in person and remote participants in

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
meetings, teleconferences and preparations of visits, missions' preparation, support to FDA, Health Canada, PMDA and other international partners, fellowships and expert visits Selected redaction of documents				training organised by International Affairs Management of 15 visits organised by International Affairs Managing 20+ ICMRA meetings
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1, ECP4)	Increased awareness to facilitate the uptake of biosimilars	**Completed**	All completed but the last point: Tool kit for information under development by HMA Working Group • Revised and updated statement on interchangeability of biosimilars (April 2023) • Explainer video on interchangeability (March 2023) - What is a Biosimilar? - Video Explainer - YouTube • EMA/HMA Multi-stakeholder meeting on shortages including breakout on biosimilars (March 2023) HMA/EMA multi-stakeholder workshop on shortages. • Tool Kit for information under development by HMA Working Group expected to be finalised in Q4 2023-Q1 2024
Foster development of POC diagnostics for human and veterinary use	4.2 (ECP 1)	Inclusion of diagnostics in the discussion on a new business model on the antibacterial agent	**Suspended**	This initiative is currently pending commencement and is slated to begin once the Antimicrobial Resistance (AMR) strategy has been formally established.
Define approaches for review of data with international regulators	4.2 (ECP 1)	Build on the experience acquired with COVID to establish the approach for future emergencies.	**On track**	Completion of lessons learned occurred throughout the year 2023. Ongoing discussions under the umbrella of ACT EU Priority Action 2 are addressing the topic of Clinical Trials in Public Health Emergencies. Furthermore, proactive discussions have been conducted with ICMRA regarding Covid-19 vaccines update.
Communicate proactively with key stakeholders on	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA	**On track**	Activities in outreach, specifically within the context of the

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
benefit-risk using evidence-based tools to tackle vaccine hesitancy				vaccination strategy, have been restarted.
Engage with public health authorities and NITAGs to better inform vaccine decisions	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute	**On track**	Ongoing collaboration demonstrated through active participation and contributions in meetings and webinars with NITAGs.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval;	4 (additional RSS recommendation)	Set up the platform and conduct first studies	**On track**	The Vaccine Monitoring Platform is established and is currently operational. The research agenda from the Immunisation and Vaccine Monitoring Advisory Board (IVMAB) has been officially published.

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Number of cases of patient/consumer engagement [30] in EMA (medicines-related) activities	594	485	n/a	n/a	n/a[31]
Number of cases of healthcare professionals' engagement[32] in EMA (medicines-related) activities	176	202	n/a	n/a	n/a[33]
Number of professional membership organisation events attended by participating Agency staff[34]	n/a	202	35	30	28
Number of sessions with Agency representatives[35]	n/a	27	157	158	168
Number of messages circulated via 'Early Notification System'	612	1,206	646	500	616
Number of EMA communications pro-actively sent to stakeholders	178	182	206	200	225
Number of EPAR summaries and EPAR summaries updates published	297	239	204	160	173
Number of summaries of orphan designation published	154	167	178	0	0[36]
Access to documents, requests received	597	710	676	750	709
Access to documents, documents released	1,024	1,136	1,128	1,500	1,037
Requests for information received	7,055	12,500	7,342	8,000	6,965
Clinical Data Publication (CDP), Procedures published[37]	n/a	11	n/a	45	41
Clinical Data Publication (CDP), Documents published[38]	n/a	215	n/a	750	714
Number of documents published on EMA website	5,963	6,712	6,403	7,500	6,611
Number of pages published and updated on EMA website	2,511	3,064	2,851	3,500	5,105
Number of press releases and news items published	217	220	164	140	124
Numbers of press briefings conducted	3	19	15	5	4
Numbers of social media posts published	484	975	704	1,300	1,016
Completed requests for interviews and comments by media representatives	1,770	5,000	1,269	1,500	1,242
Number of reports, brochures, leaflets laid out or printed, social media visuals	357	989	811	800	586

[30] These include any interactions that a patient, consumer, carer, or healthcare professional may have with the Agency, such as acting as a committee/working party member, reviewing a package leaflet, being invited to a SAG meeting, or any other activity which entails engagement from both sides.
[31] In 2018, the Public and Stakeholder Engagement department changed its methodology to reporting on the number of medicine-related activities where patients and healthcare professionals were involved (described in Stakeholder report). In 2022, we have moved to measurements that were consistently quantifiable for engagement such as the number of eligible patient, consumer and healthcare professional organisations registered with EMA and the number of patient, consumer and healthcare professionals in the Experts database that are EMA nominated and whose declaration of interest was current during 2022.
[32] These include any interactions that a patient, consumer, carer, or healthcare professional may have with the Agency, such as acting as a committee/working party member, reviewing a package leaflet, being invited to a SAG meeting, or any other activity which entails engagement from both sides. Revised 2020 final figure.
[33] In 2018, the Public and Stakeholder Engagement department changed its methodology to reporting on the number of medicine-related activities where patients and healthcare professionals were involved (described in Stakeholder report). In 2022, we have moved to measurements that were consistently quantifiable for engagement such as the number of eligible patient, consumer and healthcare professional organisations registered with EMA and the number of patient, consumer and healthcare professionals in the Experts database that are EMA nominated and whose declaration of interest was current during 2022.
[34] Indicator introduced in the 2023 Work programme.
[35] Indicator introduced in the 2023 Work programme.
[36] Public summaries for orphan designation are now replaced by a report from IRIS.
[37] Numbers based on publications solely linked to Covid-19 related medicinal products.
[38] Numbers based on publications solely linked to Covid-19 related medicinal products.

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Satisfaction level of patient and consumer organisations[39]	92%	n/a	n/a	90%	100.00%
Satisfaction level of healthcare professional organisations[40]	90%	n/a	n/a	85%	88.00%
Triage of incoming requests received via AskEMA within set timelines[41]	n/a	100%	99.00%	100%	99.30%
Responses to Access to Document (ATD) requests provided within set timelines	90%	92%	88.50%	90%	93.00%
Responses to Request for Information (RFI) within set timelines (for EMA)	82%	85%	87.00%	95%	83.00%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their Request for Information (RFI)	83%	81%	68.00%	75%	76.00%
Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"[42]	78%	n/a	76.00%	n/a	n/a
Average rating of pages on corporate website during the year[43]	3.7	3.2	3.2	3.6	3.8

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Design communication campaigns in collaboration with relevant stakeholders to proactively approach key public-health areas (e.g. vaccines) Improve communication for patients, healthcare professionals and other stakeholders including HTAs and payers Enhance professional outreach through scientific publications & conferences	1 RSS	Delivery of communication campaigns on key topics, with focus on COVID-19	**On track**	ICMRA statement on safety of COVID-19 vaccines COVID-19 lessons learned Input into vaccine campaigns: review of EVIP materials and EIW materials Input into MEP queries on vaccines Continuous update of LTT on COVID-19, including LTT on Long COVID Communication package with vaccines key facts and vaccines safety page updates Coordinated reviews for 87 manuscripts, open access evaluations for 18 manuscripts 80 published manuscripts in 2023, 11 in high-impact journals, 64 available as Full Open Access Other scientific articles drafted: User-testing of COVID-19 vaccine Editorial on CT transparency Co-authored article between representatives of eligible healthcare professionals' organisations and regulators entitled Inclusion of functional measures and frailty in the development and evaluation of

[39] Survey carried out every 2 years.
[40] Survey carried out every 2 years.
[41] New indicator introduced in 2021 Work Programme.
[42] Survey carried out every 2 years.
[43] Based on data up to 5 December 2023 (website relaunch).

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				medicines for older adults in the Lancet Healthy Longevity, in November 2023. Paper on 'Accelerating Clinical Trials in EU (ACT EU): Transforming the EU clinical trials landscape' although not published yet (Nature Reviews Drug Discovery has been approached) European Journal of Hospital Pharmacy. 2023 February 8 (doi: 10.1136/ejhpharm-2022-003554) Paper on Public information on shortages in the EU/EEA: improvement made between 2018 and 2020, Abed I, Garcia Burgos J, Knudsen Y Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU & Update to Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU Communication package on EU list of critical medicines Communication plan on shortages Expansion on the shortage catalogue Survey to patients and healthcare professionals on communications about shortages Communication campaigns delivered: - on the transition period for CTIS - European Immunisation Week, - best practices for industry to avoid shortages, - European Antibiotic Awareness Day (EAAD). Communication plans have been drafted and are being implemented for: -RWE, -revision of the pharmaceutical legislation, -ACT-EU/CTIS, -OPEN initiative. Communication plans are being developed for Cancer and Vaccine Monitoring Platform. Social media strategy was developed and is now being implemented, e.g. with the testing of new functionalities such as LinkedIn live interviews (on mRNA technology, DARWIN-EU and veterinary medicines). A plan for communication about COVID-19 in 2023 and beyond was developed and implemented; additional content on the safety of COVID-19 vaccines was developed

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				and disseminated; two press briefings on COVID-19 were held in 2023. A plan for media relations beyond COVID-19 has been adopted; a press briefing on mRNA technologies was held under this plan. A media survey was conducted to identify opportunities for further improvements of media relations. New communication materials have been created: - Videos: on biosimilars, orphan medicines, EUM4all, the CHMP, safety of medicines, interaction with HCPs, ACT-EU, RWE, COVID-19 vaccine safety, new corporate video, - the corporate brochure was updated and published and translated in all EU/EEA languages, - Human and Veterinary Highlights, - The Annual Report 2022 was published and a revamp was agreed. EMA's crisis communication plan was reviewed in light of the COVID-19 experience and is being updated to take learnings into account. A communication plan in support of the 10 year anniversary of ICMRA was drafted and successfully implemented, including production and dissemination of a video, infographic, press release. A style guide for all digital communication from EMA was developed and published; new templates for reports, agendas and workplans were developed; a SharePoint asset repository has been launched. All of these initiatives aim to enable better design across EMA and its campaigns.

Information Management Division

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Number of information services/IT systems provided by EMA	25	25	28	28	28

Performance indicators

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Satisfaction of EMA internal and external users	92.8%	95.8%	96.00%	80%	94.70%
Availability of IT systems and corporate website	98.2%	99%	98.20%	98%	99.96%

Administration Division

Workload indicators

Procedure	2020 result	2021 result	2022 result	2023 forecast	2023 result
Total TA staff recruited against vacant posts	51	70	45	50	35
Staff turnover rate (staff leaving against total no. of staff TA & CA)	4.81%	5.10%	5.30%	5%	4.10%
Total TA, CA, END at the Agency	n/a	875	n/a	930	928
Onboarding of staff (TAs, CAs, ENDs)	n/a	65	n/a	75	121
Staff entitlements management	n/a	880	n/a	950	937
Procurement procedures implemented	n/a	63	n/a	56	n/a
Contracts under management (excluding expert contracts)	n/a	352	n/a	364	n/a
Financial transactions initiated (in thousands)	n/a	10	n/a	14	n/a
Financial Transactions verified (in thousands)	n/a	18.6	n/a	24.1	n/a
Invoices issued (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)	n/a	40.8	n/a	50	48
-Procurement procedures finalised	n/a	n/a	n/a	n/a	43
-Financial commitments initiated	n/a	n/a	n/a	n/a	1,575
-Payment transactions initiated	n/a	n/a	n/a	n/a	35,403
-Number of sales orders	n/a	n/a	n/a	n/a	34,500
-Number of registration activities	n/a	n/a	n/a	n/a	13,200
-PRE financial queries and disputes	n/a	n/a	n/a	n/a	300

Performance indicators/ Forecast activity

Performance indicators related to core business	2020 result	2021 result	2022 result	2023 target	2023 result
Posts on the Agency establishment plan filled (reversal of traffic lights)	100.00%	98.00%	99.40%	100.00%	97.00%
Average time to run selection procedures from vacancy notice to establishment of reserve list	88% < 3 months	65%	3.1 calendar months	100% average < 3 months	36% <= 3 months, average 3.5 months
Revenue appropriations implemented	104.30%	99.87%	98.35%	97%	97.82%
Expenditure appropriations implemented	98.83%	96.38%	96.80%	95%	99.00%
Payments against appropriations carried over from year N-1	95.49%	92.87%	95.11%	95%	95.16%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1 (reversal of traffic lights)	4.62%	5.75%	4.34%	10%	4.89%
Title 2 (reversal of traffic lights)	20.71%	24.31%	26.38%	20%	24.86%
Title 3 (reversal of traffic lights)	31.47%	37.59%	40.06%	30%	32.59%
Payments made within 30 days' time	96%	96.6%	97.98%	98%	98.03%
Receivable overdue for more than 30 days (including provision for bad debts)	6%	2.89%	2.54%	<10%	4.15%
Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)	n/a	335	n/a	400	341[44]

[44] Provisional figure subject to change after audit opinion has been issued.

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Implement the revised human resource and talent management strategy	6.2	The HR strategy will consolidate practices into a coherent system and practices and will lead to continuously improving approaches in domains of staff wellbeing, leadership and management, talent management and culture Staff engagement survey carried out in Q1 2023	**Completed**	HR Strategy endorsed by the Executive Board on 22 June 2023. HR Strategy endorsed by the Management Board on 5 October 2023. Implementation Plan for 2023-2025 published. Staff Engagement Survey carried out in 2023.
Potential replacement of the human resource management and the financial systems taking into account the discontinuation of the support for the current system by vendors	6.4	Gradual replacement of the financial and HR system in line with the future project plan	**On track**	In the first half of the year, the analysis to have a gradual replacement for SAP HR And SAP FIN took place as planned. More specifically, the draft roadmap for SAP Core HR replacement had been drafted and the first steps in the implementation began in Q4 2023. SAP FIN replacement proceeded with the gathering of business requirements and resources.
New Fee Regulation: optimisation and review of revenue and expenditure process	6.3	Support provided to the EU institutions in the review of the new fee regulation to ensure sustainability of the Agency and the European Medicines Regulatory Network	**On track**	In the first six months, The Enabler Epic and work with the consultant company on the analysis and impact assessment progressed resulted in the following achievements: • review of the New Fee Regulation impact on the current EMA processes • identification of the future state addressing open items and key interdependencies • review of the proposed roadmap to implement the NFR changes Throughout the year, several reviews took place internally and in liaison with the EU Commission to support the legislative process and to optimise EMA's processes and legal provisions for revenue and expenditure linked to the upcoming New Fee Regulation. The text was formally adopted by the European Parliament in December 2023 and

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				endorsed by the Council of the EU in January 2024.
Improve efficiency of certain administrative processes	6.3	The identified improvement in the accounts receivable and customer data management processes implemented	**On track**	The implementation of SAP FIN AR enhancements was completed between in 2022. The Customer Master Data process improvement is to be mastered within OMS (SPOR) and implemented in the context of Customer Relationship Management (CRM) epic. Some elements of the One-Stop-Shop solution for applicants (CRM) will also be implemented in the context of the New Fee Regulation, for example with the adaptation of IRIS to cater for pre-payment of fees at submission.

Network Portfolio implementation 2023

Following the implementation of the SAFe Agile methodology during 2022, the Agency migrated all of its former programmes and projects into the new agile governance model. To reflect this change, the 2023 Single Programming Document no longer included a separate Annex XIV with programmes and projects. Instead, all activities falling under Pillar III were centralised into a new chapter. The table below details the main products and deliverables (epics) that were planned for 2023, and what was achieved during the year (status as of 31 December 2023).

Status:
On Track
Delayed
Suspended
Achieved

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
Product Lifecycle Management Value Stream (PLM VS)						**Budget 2023 (M€) 17.6**
Electronic Application Form (Product Lifecycle Management Portal) *(Formerly DADI)*		2021	2024	– Human Variations Form – Human + Vet Marketing Authorisation Application (MAA) – Vet Variation Form – Renewals – Product User Interface (for viewing, submitting and correcting product data)	Delayed	Knowledge base live on PLM Portal Publication of variations roll-out plan Human Variation electronic Application Form (eAF) available for optional use for Centrally Authorised Products (CAP) Product User Interface (UI) work started
Regulatory Procedure Management for PLM (IRIS)		2022	2024	– Process Core (Variations, Transfers, Art 61.3) – PSURs, post-authorisation measures – MAA + additional functionality	On track	Second User Acceptance Test (UAT) completed for variations, transfers and Art. 61.3 procedures, in preparation for launching the first phase of replacing SIAMED in January 2024 Detailed roll-out plan prepared Preparatory work for PSUR, PAM processes
Electronic Product Information (ePI)		2022	2023	– Authoring Portal – Publishing and Consuming – Pilot planning	On track	Pilot period started for set of CAPs and NAPs to test the business process and develop guidance for inclusion of ePI in regulatory procedures New ePIs published for CAPs and NAPs as outcome of the ePI pilot
Expert Panels for Medical Devices (EXPAMED)	Regulation (EU) 2022/123 on a reinforced role for the European	2022	2023	– Procedure Management	Achieved	Go-live of collaboration platform for expert panels for medical devices in support of

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
	Medicines Agency in crisis preparedness and management for medicinal products and medical devices			– Collaboration Enablement		EMA extended mandate on 3 April 2023
Medicinal Product Management System (PMS)	Regulation 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 Clinical trials reg. 536/2014, art.8193) Pharmacovigilance fees reg. 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2024	– XEVMPD Integration (Data migration/transformation into ISO IDMP format) – IDMP Implementation (Data migration/transformation into ISO IDMP format) – XEVMPD Integration (Feedback Loop – capabilities to ensure XEVMPD and PMS are fully synchronised) – FHIR Ingestor (Capabilities to import IDMP compliant product data to PMS) – IDMP compliance (Capabilities to validate ISO 11615 compliance)	On track	Migration and synchronisation of product data from SIAMED into PMS Continuous implementation of IDMP standards and compliance to enhance data quality for reuse across the product lifecycle XEVMPD Integration started in preparation for NAPs data publication in PMS in Q2 2024
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	– eCTD v4.0 preparation and implementation	On track	Review of Implementation Guide and Specification for eCTD v4.0 in the European region launched and underway EURS Next Proof of Concept ongoing
Veterinary Union Product Database (UPD)		2021	2023	– Union Product Database (UPD)	On track	UPD v 1.6.40 deployed on 8 December 2023 New training materials published Continuous improvements to UPD performance and reliability ASU-UPD integration completed in January 2024
Research and Development Value Stream (R&D VS)						**Budget 2023 (M€) 14.7**
Clinical Trials Information System (CTIS)	Regulation (EC) 536/2014, art.80-82 Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	2023	– After go-live version for January 2023 – Transition to the agile governance model	On track	Mandatory use for submissions of initial clinical trials since 31 January 2023 Continuous improvements to CTIS user experience Transition to SAFe Agile governance started

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
Regulatory Procedure Management for R&D (IRIS)		2023 2023	2023 2024	– Priority Medicines (PRIME) – Maintenance activities (Scientific Advice, Orphan Designation, Innovation Task Force) – Paediatrics procedure	Achieved On track	Main PRIME Eligibility process onboarded onto IRIS platform on 10 July 2023 Additional PRIME Eligibility process onboarded onto IRIS platform on 3 October 2023 Analysis and development of the main Paediatrics processes onto IRIS started
Lifecycle Regulatory Submission Metadata (LRSM)		2020	2024 2023	– Scientific Explorer: regulatory and scientific documents searching interface – Clinical Trial Navigator: Proof of concept for the interrogation of Clinical Trial Study Protocol and development of the logical and conceptual data model	Delayed Achieved	Scientific Explorer: completion of architecture design, ingestion mechanisms and UI/UX design Clinical Trial Navigator: user interface proof of concept for the interrogation of structured clinical trial study protocols delivered in Q3; development of the logical and conceptual data model ongoing
T.R.I.P. (Horizon Scanning)		2023	2023	– Platform to support horizon scanning capability (identify futures innovations and trends earlier to support development)	Achieved	Technical go-live for T.R.I.P in December 2023 with launch in mid-January 2024
Real World Metadata & Studies catalogues		2021	2024	– Catalogues of real-world evidence data sources and studies	Delayed	Two UATs completed successfully (access management and institutions registration) Website's main features delivered, including integration with data sources and studies catalogues
Data Analytics Accelerator (new)		2023	2024	– A dashboard to compare the impact of the CTR v CTD – Enhanced interoperability of onboarded data sources	On track	Platform core set-up completed First iteration of data model and dashboard created Delivery of a dashboard to compare the impact of the CTR v CTD, using EudraCT and CTIS data Development of self-service analytics capabilities ongoing
Monitoring Value Stream (MON VS)						**Budget 2023 (M€) 13.2**

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2025	– Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) – Monitoring of Critical Medicines during PHE/ME – Support the work of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	On track	ESMP roadmap adopted by MSSG Data Analytics Platform for crisis reporting developed Conclusion of most features for MAH reporting Face to face workshops on interoperability held with network and industry subject matter experts, ESMP-MSSG-WG, and DG HERA
Critical Medical Devices Shortages (CMDS)	Regulation (EU) 2022/123	2022	2023	– IT implementation medical devices shortages	Achieved	CMDS go-live in July 2023
Inspections and Parallel Distribution				– Inspections – Parallel Distribution	On track	Inspections: Redesign of good manufacturing practices case management in IRIS Parallel Distribution: Efficiency improvements
Veterinary Union Pharmacovigilance Database (UPhV, formerly EVVet3)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2024	– UPhV MVP completion and improvements	On track	UPhV vision and roadmap approved and communicated Save & resume draft Adverse Events Reports (AER) for case management Predefined search functionalities available for AERs Precalculations and product grouping in signal detection dashboard
Antimicrobial Sales & Use (ASU)		2021	2024	– Transfer reporting functionalities for sales data from existing ESVAC	On track	ASU and Union Product Database user interfaces successfully merged Development and finalisation of the IT system for go-live (29 January 2024)
Signal and Safety Analytics (SSA)		2023	2024	– Conclude implementation of the new solutions – Implement change management plan	On track	Project started in Q4/2023
Managing the Agency Value Stream (MTA VS)						**Budget 2023 (M€) 8.8**
Expert Database replacement		2022	2023	– Expert Database replacement	Achieved	Experts Management Tool go-live on 29 March 2023 as a single system to manage declarations of interests (DoIs) for medicines

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
						experts, medical device experts and Management Board (MB) members, and to manage experts-related legal and financial commitments User support to accompany the tool release
Admin Data Quality		2022	2023	– Admin data quality management	Achieved	Corporate Data governance model and process approved Review of Power BI reports in four corporate business areas
SAP Finance replacement		2023	2025	– Start implementation of selected solution	On track	Analysis of SUMMA project (EC) feasibility to replace EMA SAP FIN tool, and assessment of other solutions ongoing
SAP HR replacement		2023	2025	– SAP HR on-premise migration	On track	Work started in Q4/2023
New Fee Regulation	Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency	Q4/2022	2025	– Analysis and impact assessment	On track	Analysis and impact assessment completed Long term implementation plan completed
E-procurement		Q4/2022	2023	– E-procurement suite	Achieved	PPMT e-procurement suite launched in Q1/2023 Several procurement procedures successfully prepared, launched and completed in PPMT Streamlined and improved process for publishing ex-ante advertisements and procurement procedures using an integration with eTendering
EU Network Training Centre (EU NTC)		Q4/2022	2023	– EU NTC website	Achieved	Public EU NTC Engagement Portal go-live in December
Intranet (new)		Q4/2022	2023	– New intranet – Archive old intranet	Achieved	New intranet launched on 15 March 2023 Migration from old to new intranet completed Training of new intranet editors completed Old intranet archived on 30 June 2023
Jira replacement (new)		2023	2023	– New solution for procurement, facilities	Achieved	Procurement ticket management solution go-live in November

Value Stream/ Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Status	Achievements/Results 2023
				management and PRE		Facilities ticket management solution go-live in September Procedures, Revenue and Expenses (PRE) ticket management solution go-live 3 January 2024
Ask EMA replacement (new)		2023	2024	– Ask EMA workflow management replacement	On track	Technology selection completed
DREAM replacement (new)		2023	2025	– Requirements analysis – Vendor assessment	On track	Requirements analysis completed Impact assessment completed Technology selection started
Technology Lifecycle Management and Information Security Value Stream (TLM VS)						**Budget 2023 (M€) 18.2**
Information Security		2022	2024	– Cyber and Information Security enhancements – Operational Security enhancements – Application Security enhancements	Achieved	Rollout of Service Now SecOps module for security incident investigations completed Rollout of Virtual Reality pilot (cybersecurity training) completed External and internal penetration tests to identify vulnerabilities completed Migration of applications to Azure AD authentication ongoing Better control and management of endpoints using Microsoft Intune solution ongoing Development of the Secure Development Lifecycle framework ongoing
Data Centre 2.0		2022	2023	– Migration from data centre to cloud provider	Achieved	Migration completed Decommissioning of physical data centre completed

2. (a) Management

2.1. Management Board

The Management Board (MB) is the European Medicines Agency's governance body. It has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.

The Board's operational tasks range from adopting legally binding implementing rules, to setting strategic directions for scientific networks, to reporting on the use of European Union (EU) contributions for the Agency's activities. The tasks and responsibilities of the Management Board are set out in the Agency's founding Regulation (EC) No 726/2004 of the European Parliament and of the Council.

Important milestones related to the EMA Management Board in 2023 included:

- **Mandatory use of CTIS from 31 January 2023 for all new clinical trial applications**
    - An ad-hoc Management Board (MB) meeting took place on 18 January 2023 where the Board was provided with an update on the improvements introduced in the system since December 2022 and progress made to prepare for mandatory use of CTIS from end of January 2023 for all new clinical trial applications. At the meeting, the Board noted the progress towards further improvement of the system in preparation for the mandatory use and in compliance with the relevant Clinical Trial Regulation (CTR) provisions from this date. Following this, a successful launch of the use of the Clinical Trials Information System (CTIS) took place on 31 January where it became mandatory for all new clinical trial applications.
    - The Board was updated at every subsequent MB meeting on the operational experience with CTIS and on the further enhancements implemented in the system throughout 2023. Updates on the monthly number of submissions of clinical trials through CTIS were also provided at each meeting. The Board welcomed EMA’s continued efforts to support stakeholders via workshops, trainings and regular communications. At the December MB meeting, the Board noted the CTIS planning for 2024, which continues to focus on improving the performance of the system and enhancing user experience.
    - At the October 2023 meeting, the Board adopted revised transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System (CTIS). The revision focused on the early publication of clinical trial data and documents that are most relevant for the public, including patients and the researcher community.

- **Activities of the joint HMA-EMA Task Force on Availability of Medicines**
    - The Management Board adopted the first version of the Union list of critical medicines, developed by HMA-EMA Task Force on Availability of Medicines (TFAAM) to enable EMA, the European Commission and the Heads of Medicines Agencies (EMA) to work together to ensure they can take proactive measures to avoid medicine shortages.
    - At the December 2023 meeting, the key deliverables from the HMA/EMA TFAAM was highlighted to the Board, including the HMA/EMA multistakeholder workshop on shortages in March 2023, the publication of Good Practice Guidance for industry for the prevention of medicine shortages in May 2023, the creation of Shortage Prevention and

Mitigation Plans (SPMP) templates, and the implementation of Good Practice Guidance for PC/HCPs organizations on the prevention of shortages of medicines.

- **Further implementation of EMA's extended mandate (Regulation (EU) 2022/123)**
    - On 2 February 2023, additional responsibilities of the Agency came into effect regarding the monitoring and mitigation of shortages of critical medical devices during public health emergencies. The Board was informed of the new provisions to be implemented of Regulation (EU) 2022/123 of EMA's extended mandate and that reinforces the Agency's role in the management of critical medicines and medical devices during public health emergencies. An update of the establishment of the Medical Devices Shortages Steering Group (MDSSG) to coordinate urgent actions related to critical medical devices during emergencies was provided to the Board at the March meeting.
    - The Management Board provided a favourable opinion of the Rules of Procedure of the MDSSG via written procedure.

The most significant issues discussed at the Management Board in 2023 included:

- **Update on 30 Churchill Place**
    - The Board was updated regularly throughout the second half of the year on the latest developments regarding the former EMA premises in London, in particular on how the financial situation of EMA's sub-tenant was impacting the Agency. Topic Coordinators were nominated by the Board to support the Agency and take decisions on behalf of the Board throughout the preparation of the building dossier for the Budgetary Authority. Following the Agency's discussions with the European Commission, the Board also adopted an amending budget to accommodate expenditure related to the post-Brexit premises in 2024.
- **Medicines Shortages Management**
    - At each MB meeting throughout 2023, the Board was updated on the efforts of EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to closely monitor critical shortages of medicines in the EU/EEA and strengthen the existing framework for management of shortages of medicines.
    - The Board received briefings on collaborative efforts between MSSG and the European Commission's Health Emergencies and Preparedness Response Authority (DG HERA). These initiatives involve actively engaging with key manufacturers to address manufacturing capacity and forecast demand for a specific group of critical medicines, including antibiotics.
    - The Board recognised the array of tools and measures developed by the MSSG, including the solidarity mechanism procedure enabling Member States to assist each other during critical medicine shortages, the MSSG Toolkit for addressing medicine shortages, and recommendations for averting shortages of crucial antibiotics for treating respiratory infections during the winter season 2023/24.
- **Accelerating Clinical Trials in the EU (ACT EU)**
    - At multiple Board meetings, the Board consistently received updates on the progress of the deliverables outlined in the ACT EU 2023-2026 workplan including the closed workshop on clinical trials in public health emergencies in June 2023. At the October

MB meeting, the Board also welcomed the agreed model for the ACT EU multi-stakeholder platform to ensure that the initiative is driven by the views of stakeholders.

- **EMA's Response to COVID-19**
    - The Board was updated throughout the year of 2023 on EMA's response to COVID-19, including the scaling back of pandemic-related activities following the end of the public health emergencies of international concern (PHEIC) declared by WHO for COVID-19 and mpox in May 2023. The Board was also informed of the discontinuation of the COVID-19 business continuity plans for EMA and the European Medicines Regulatory Network.
- **EMA's independence policies for competing interests of Scientific Committee members, Experts and Management Board members**
    - The Board endorsed the EMA 2022 annual report on independence in March 2023. The report provides facts and figures on controls carried out in 2022. It also gives information on initiatives taken during the year, notably the revision of the policy on the handling of competing interests for scientific committee members and experts and the separate policy for Board members related to the Agency's new responsibilities in the area of medical devices and its reinforced role in crisis preparedness and management.
- **Activities of the joint EMA-HMA Steering Group on Big Data**
    - The Board endorsed revised mandates the Big Data Steering Group (BDSG) aimed to clarify the scope, division of responsibilities, composition, and stakeholder engagement model of the group.
    - Additionally, the Board endorsed the workplan of the EMA/HMA Big Data Steering Group on AI at its December meeting. This initiative aims to leverage AI to enhance personal productivity, automate processes, gain deeper insights from data, and facilitate more robust decision-making for the benefit of public and animal health.
    - The Board also received regular, thorough updates on the activities aligned with the priority recommendations outlined in the Big Data Steering Group (BDSG) workplan, including areas on of data discoverability and data quality & representativeness.
- **Periodic reports from Chairs of Scientific Committees and Working Parties to the MB**
    - Chairs of relevant Scientific Committees were invited in 2023 to update MB members on the activities of the scientific committees and working parties and to engage in discussions with the Board regarding their respective initiatives. Johan Schefferlie, CVMP chair, highlighted advances in veterinary medicines regulation during COVID-19, including innovative authorizations. The CHMP Chair, Harald Enzmann, discussed CHMP's success in maintaining quality and speed during the pandemic, emphasizing upcoming challenges like AI integration. Dr. Sabine Straus, PRAC Chair, outlined PRAC's focus on AI and real-world evidence, stressing patient engagement for safer medicines. The Board recognized PRAC's crucial role in medicine safety during the pandemic.
    - The Board also heard an update from the Chair of Quality Innovation Group (QIG), Marcel Hoefnagel, regards the key achievements of QIG in 2023 and plans for 2024.

- **Review of activities of the Working Parties of EMA**
    - The Board was updated at its March meeting on the implementation of the new operational model of EMA's working parties was presented to the Board, focusing on the reorganisation of the working parties for the nonclinical, methodology and clinical domains. The Board agreed at the meeting on the expertise-based model that will be applied to the operations and revised structures of the Biologics Working Party (BWP) and Quality Working Party (QWP), including the proposed structure for the Working Parties membership.
- **Update on the implementation of Veterinary Medicinal Products Regulation**
    - At the December Board meeting, the Board welcomed a progress update on the implementation of the Veterinary Medicines Regulation, including guidelines on data requirements for veterinary medicines for limited markets and Union Product Database (UPD) public portal which was further improved throughout 2023.

Significant additional items adopted or decided by the Management Board in 2023 included:

- **Activities required by the EMA's founding and financial regulations**

  The Board's operational tasks include reporting on the use of the EU contributions for the Agency's activities. In 2023, these activities involved:
    - adopting the Board's assessment of the Executive Director's Annual activity report for 2022;
    - adopting the 2024-2026 Programming document, including the 2024 budget;
    - adopting the EMA's annual report for 2022; and
    - delivering an opinion on the Agency's final accounts for 2022.
- **Revised Fee Implementing Rules and Cooperation Agreement**
    - The Board adopted a revision of the Fee Implementing Rules coming into force on 1 April 2023. The revision concerned an increase in the levels of fees and the related remuneration to National Competent Authorities (NCAs) to adjust for the inflation rate of 10.4% for 2022.
    - In October, the Board endorsed the principles to establish a framework to renumerate external experts as per Article 93 of EMA Financial Regulation. High-level principles to remunerate external experts were presented with use-cases where it could be applied, e.g. supporting training, remuneration of patients and healthcare professionals in EMA's work.
- **Internal audit and advisory activities at the European Medicines Agency**
    - In June, The Management Board adopted a Decision on the establishment of a Management Board Audits and Risks Group (MBARG). This group will be assisting the Board to review the progress on the implementation of audit recommendations as well as providing objective and independent review and oversight of the EMA's strategic processes in relation to risk, internal controls and governance. At the December Board meeting, the Board also endorsed the proposed nomination of the representative of patients' organisations, Virginie Hivert, as Chair of MBARG.
    - The Board adopted at its December meeting the update of annual audit plan 2023, the EMA Audit strategy/plan 2024-2026, and a revision of the Internal Audit Charter of the

Audit Capability to reflect the Management Board's decision on the establishment of the MB Audits and Risks Group (MBARG).

- **3rd report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2019-2022) –** the Board's endorsement of the 3rd report on the performance of pharmacovigilance tasks by the EU Member States and the EMA from 2019 to 2022 via written procedure.

2.2. Major developments 2023

SAFe Agile Methodology transition

Following the Management Board's adoption of the Agile transformation in June 2021, EMA started using Agile principles and the Scaled Agile Framework (SAFe), which are widely regarded as industry best practices. Without sacrificing its fundamental values, the framework has been adjusted to EMA and its function as a regulatory organization promoting human and animal health in Europe. During 2023 the Agency completed the transition of its whole projects' portfolio under the Agile governance with the establishment of Value Streams structure, and the implementation of the Epics system.

Agency's former premises in London

In 2023, the situation regarding EMA's premises in London became increasingly challenging due to global macroeconomic changes and changing work habits of the population that had significant negative consequences in the UK office real estate market, i.e. the business of the current Agency's sub-tenant. The Agency's sub-tenant's parent company experienced financial challenges and initiated Chapter 11 bankruptcy procedures in the US. This placed EMA in a difficult and uncertain situation regarding the Agency's former premises in the UK in the post-Brexit scenario. The matter has a potential to impact on the Agency's capacity to focus on its core activities and to deliver its public and animal health objectives. As a result, the Agency has had to dedicate significant levels of resources to managing commercial real estate in a third country. It is important to underline that the Agency's continued responsibilities in the lease management of its former premises represent an anomaly in the Agency's core activities and entail a significant diversion from its core mission of promoting public and animal health. Despite these challenges, the Agency has diligently worked to stabilise the situation, emphasising the crucial necessity for EU funding to cover any budgetary requirements in relation to this activity so as not to impact the public health responsibilities of the Agency and of the National Competent Authorities. Therefore, the Agency also calls on EU institutions to find a long-term solution to this issue.

Revision of the EU Pharmaceutical legislation

The European Commission adopted in April 2023 a proposal for a new Directive and a new Regulation which revise and replace the existing general pharmaceutical legislation. The proposal adopted by the Commission revises and replaces the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). The Agency follows the development of the legislative procedure and will explore ways to implement the legislative proposal and use this opportunity to future proof medicines regulation in the EU and the work of EMA within the EU Medicines Regulatory Network.

WHO Listed Authority process

In 2023, EMA and the EMRN as a whole underwent the formal WHO (World Health Organisation) assessment for the identification of reference authorities. To be designated as a WHO listed authority, a regulatory body should undergo: i) a formal assessment with the WHO-Global Benchmarking Tool

(GBT) to demonstrate adequate maturity (ML3 as entry point) and ii) a performance evaluation (PE) process that complements the results of benchmarking, confirming consistency of advanced performance against international standards and best practices. Regulatory authorities that have reached a high-level regulatory capability and performance (WLA) may be used as a reference and to be relied on by other authorities, to avoid duplicating activities, foster better use of human and economic resources, increase oversight of the pharmaceutical products along the whole supply chain to ultimately enhance global access to high quality, efficacious and safe medicines and vaccines. The outcome of the assessment is expected to reach the Agency and the EMRN during 2024.

2.3. Budgetary and financial management

Budget overview

The total 2023 budget (revenues and expenditure), as adopted by the EMA Management Board on 15 December 2022, amounted to EUR 458,003,000, representing 8.58% increase compared to the 2022 budget (EUR 421,815,000).

One amending budget of EUR 9,400,000 was adopted by the Management Board in December 2023 to decrease revenue due to lower than anticipated application for evaluation of medicines than originally planned. This decrease was compensated by a reduction of the cost for evaluating medicines, as well as reductions in costs for interim staff, scientific studies, and business consultancy.

The draft financial outturn, a surplus of approx. EUR 20,939 represents 0.005% (2.52% in 2022) of total revenue (excluding R0 & CL), which is a positive result considering that 88% of the revenues derive from fee paying services. (more details can be found in Annex II).

Revenue (income from evaluation activities and EU contribution)

As stipulated in the Financial Regulation, budget revenue is based on cash received in terms of fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, contributions from the European Union, as well as for various administrative activities.

Total cash revenue (C1 & C11) entered in the accounts as of 31 December 2023 amounted to EUR 438,811,276.00 (2022: EUR 414,862,609.76).

Of total C1 income, 88.21% (2022: 87.95%) derived from the evaluation of medicines and other business-related activities, 11.43% (2022: 11.98%) from the European Union budget to fund various public health and harmonisation activities, and 0.36% (2022: 0.07%) from various sources.

Assigned revenue (external, R0, and internal, CL), which is handled outside the adopted budget, totalled EUR 22.7 million (2022: EUR 21.1 million).

Expenditure (commitments and payments)

Of the adopted budget, i.e. fund source C1, commitments totalled EUR 443,247,127.96 which represents 98.81% of the final appropriations (2022: EUR 408,324,836.93, or 96.80%). Payments totalled EUR 347,820,472.27, or 78.47% of the total commitments (2022: 301,496,618.72, or 73.84%).

Appropriations carried forward from 2023 to 2024

Automatic carry-forward

Automatic carry-forward to financial year 2024, C1 to C8, totalled EUR 95,426,655.69, or 21.51% of the total commitments (2023: 106,828,218.21, or 26.16%).

Non-automatic carry-forward

The Management Board approved a non-automatic carry-forward to 2024 of EUR 800,000.

Implementation of appropriations carried forward automatically from 2022 to 2023

Automatic carry-forward from financial year 2022 to 2023, i.e., fund source C8, totalled EUR 106,828,218.21 (2022: EUR 91,090,698.54). Payments against these appropriations were EUR 101,653,282.34, or 95.16% of appropriations (2022: 86,635,520.77 or 95.11%) and EUR 5,174,935.87 were cancelled (2022: EUR 4,455,177.77).

Appropriations from external and internal assigned revenue

The Agency's available appropriations in 2023 included external and internal assigned revenue. In accordance with its Financial Regulation, this revenue, matched by expenditure appropriations, is managed outside the adopted budget and under separate fund sources, i.e. R0 for external assigned revenue, and CL for internal assigned revenue.

External assigned revenue (R0) stems from inducements related to the Agency's new headquarters in Amsterdam, the planning and execution of an electronic Product Information pilot, to support regulatory systems at national and regional level in Africa, and in particular for the setting up of the African Medicines Agency (AMA) and various IPA and IMI programmes. In 2023, EUR 3,409,514.78 were received, and expenditure amounting to EUR 1,575,804.42 incurred (payments).

Internal assigned revenue (CL) stems from payments of rent, service and other charges received from the sub-tenant of the Agency's former headquarters in London. This revenue matches the payments made to the Agency's landlord in London. In 2023, EUR 19,303,776.46 were received (including amount carry forward from previous years), and expenditure amounting to EUR 23,256,171.15 incurred (payments).

While R0 and CL appropriations do not expire, the revenue and expenditure must balance over time.

Budget transfers

In line with Art. 26 of the Financial Regulation, the Executive Director may make unlimited transfers within a title and of up to 10% of appropriations from one title to another. Transfers *per se* are not an indication of deficiencies in budget management but are a necessary tool to adjust the budget in a changing environment, e.g. resigning staff members receiving allowances related to their departure rather than their salaries, inflation impact on utilities, adjusting activities to evolving business environment, increased expenditure due to exchange rate fluctuation, etc.

During 2023, no transfer exceeded the 10% ceiling for transfer between titles, thus requiring Management Board approval. Out of the ten transfers, nine involved expenditure appropriations and one revenue appropriations.

The transferred expenditure appropriations were primarily needed to cover additional commitments for staff costs due to the higher than expected salary adjustments and pension contribution, higher

expenditure for SLA with EC related to corporate website and staff, building expenditure to cover utility costs, canteen, security and reception expenditure, as well as the extension of an IT contracts for IRIS platform.

Cancellation of appropriations

Expenditure appropriations should be understood as estimates of requirements, and not as an entitlement to create the corresponding commitments. Being reliant on fee income, as the agency is, this means that the level of cancelled expenditure appropriations does not indicate delays in the implementation of the work programme, but it should rather be considered the result of stringent monitoring of actual revenue and adjustments to the expenditure.

Of the amended budget, expenditure appropriations totalling EUR 5,355,872.04 remained unused, which corresponds to 1.17% of final appropriations (2022: EUR 13,490,163.07, 3.20%).

The underuse of appropriations is within the acceptable range:

- title I (staff expenditure) - cancelled appropriation of 0.52%, (2022: 1.60%)
- title II (infrastructure and operating expenditure) - cancelled appropriation of 1.68% (2022: 5.45%)
- title III (operational expenditure) – cancellation of appropriation of 1.46% (2022: 3.64%).

Payment of interest on late payments

In compliance with Article 77 of the Financial Regulation, the terms of payment are 30/60/90 days upon receipt of a valid invoice or the approval of a report or certificate. If these terms are not respected, from the day following the deadline until the actual day of payment, default interest accrues at the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, increased by 8%[45]. The default interest accrued is paid automatically to the supplier/contractor if it amounts to more than EUR 200 at the time of payment of the valid invoice or the approval of a report or certificate.

In 2023, 898 payments (2022: 711) out of a total of 45,552, i.e. 1.97% of all payments, were made beyond the time limits foreseen by Article 77 of the Financial Regulation (2022: 35,157 or 2.02%). This resulted in default interest of EUR 1,593.18 being paid to suppliers and contractors (2022: EUR 2,242.88).

Procurement

In 2023, the procurement team, in line with the 4-year cycle of framework contracts, worked on the re-tendering of location-dependent contracts as the agency had moved into its current premises in January 2020, e.g. medical provider, interim staff, building security, restaurant, in addition to the procurement for operational activities, e.g. scientific studies, business- and ICT consultancy.

At the same time, in 2023 the team managed to reduce the number of 'very low value' procurement procedures whilst benefitting from an increased use of interinstitutional procurement procedures.

[45] Cf. Article 116 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

Procedure type	Closed 2023		Closed 2022	
Open procedure (GFR 164 (1)(a))	8	28%	4	10%
Competitive procedure with negotiations (Point 12.01, b (i) & (iii)	0	0%	1	3%
Negotiated procedure, middle value (Annex 1 - 14.2)	5	17%	3	8%
Negotiated procedure, low value (Annex 1 - 14.3)	1	3%	2	5%
Negotiated procedure, very low value (Annex 1 - 14.4)	1	3%	12	31%
Negotiated procedure, without prior publication (Annex 1 - 11.1)	0	0%	1	3%
Re-opening of competition	14	48%	16	41%
Total EMA-only procedures	**29**		**39**	
Interinstitutional EMA-led	1	8%	0	0%
Interinstitutional Non-EMA-led	11	92%	3	100%
Total interinstitutional procedures	**12**		**3**	

Cost and benefits of controls

In 2023, EMA allocated approximately 16.34 FTEs for control activities (amounting to 1.4M euros or 0.34% of the Agency's 2023 final budget). These activities were centred on the following areas: integrated quality management, audit, anti-fraud, finance and verification processes, corporate risk management and self-assessment activities. Considering the positive result of the ex-ante and ex-post control verifications, the opinion of the Head of Audit (ad interim), the well-established framework to manage exceptions and the regularity of operations, the overall balance between effectiveness, efficiency and economy of controls is reasonably satisfactory.

2.4. Delegation and sub-delegation of powers of budget implementation

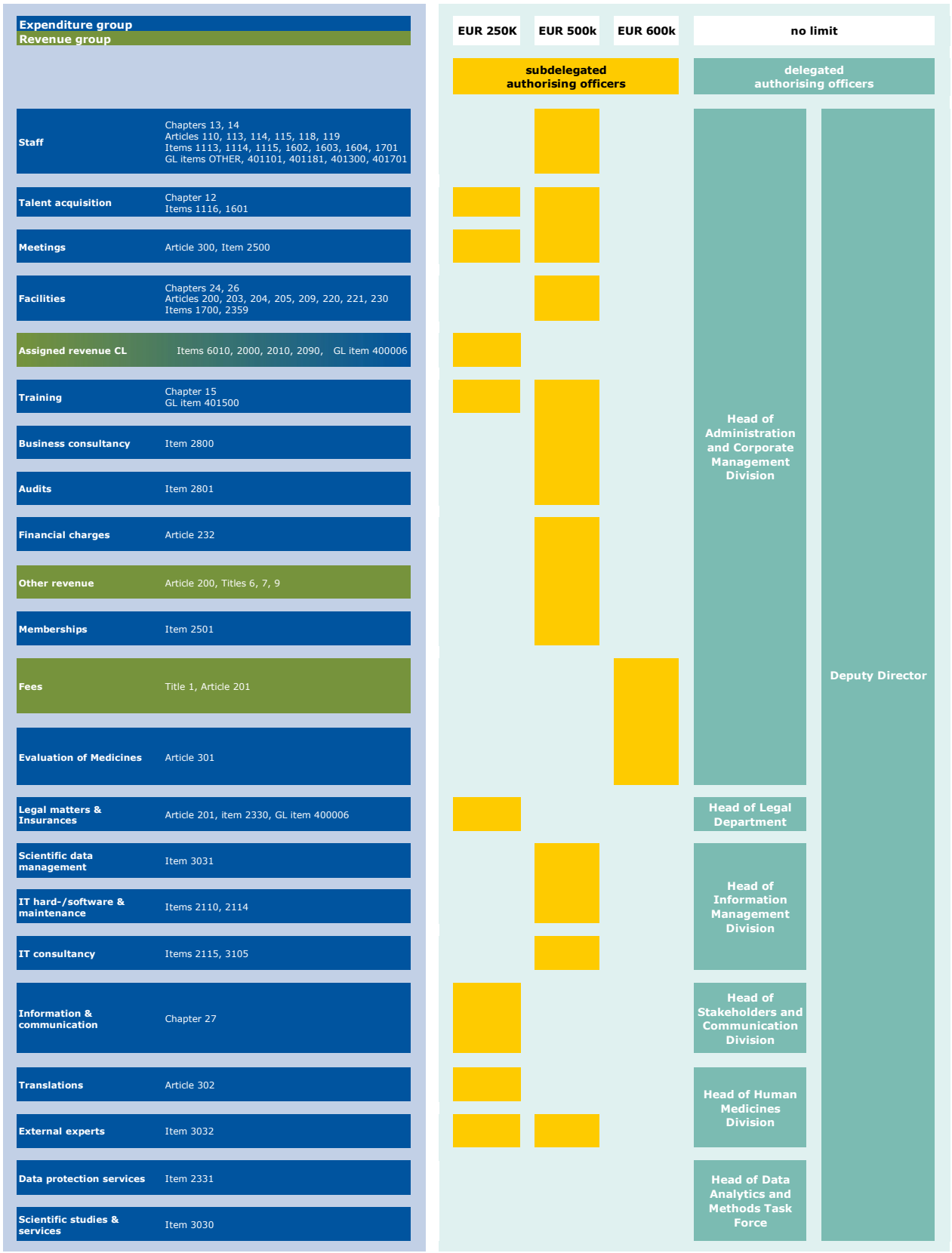
To enact the most effective management of the Agency, responsibilities are dispersed across various management levels to ensure proportionality and effective decision-making at the lowest possible level corresponding to the associated risks. To this effect, financial, operational and staff-related delegations have been put in place at the Agency, without prejudice to the Executive Director's power. These delegations are updated as required and to reflect any relevant organisational or staff changes.

The general principles for financial delegation and sub-delegation are set out in the Executive Decision on internal rules on the implementation of the budget of the European Medicines Agency and the Executive Decision on the charter of tasks and responsibilities of the Authorising Officer by delegation. The latter defines the conditions of delegations and sub-delegations, including reporting requirements and controls. The delegations and sub-delegations are linked to an organisational function and as such are issued by default for an unlimited time.

The authorising officer by delegation is required to sign a declaration of assurance, drawn up based on the assessment of the functioning of the management and internal control systems conducted for his/her area of responsibility. The declaration may contain reservations designed to highlight issues or weaknesses in the management and control systems associated with the operations and actions managed by the authorising officer by delegation. The declaration is an instrument of management accountability within the Agency and constitutes the basis on which the authorising officer takes responsibility for the management of resources by reference to the objectives set in the work plan and the efficiency and effectiveness of internal control systems, including an overall assessment of the costs and benefits of controls.

The Authorising Officers by Delegation, in line with the requirements of article 3.9 of the charter, provided their Declarations of Assurance to the Executive Director.

For the list of budget lines delegated by business area and subsequent sub-delegation, see table below:



2.5. Human resources management

In 2023, the key developments regarding staff and human resources management included:

- **Human Resources Strategy**

In 2023, the EMA HR community completed the development and preparation stage of the HR Strategy 2023-2025, and started the deployment of the HR Strategy which builds on the progress made over the past five years in improving ways of working in talent management. This includes the long-term strategic resources planning and initiatives supporting talent acquisition, onboarding, performance and development.

The HR Strategy 2023-2025 focusses on five ambitions with specific products and initiatives being developed and implemented for each ambition specifically:

- Sustainable Organisation (Resource Planning & Allocation)
- Optimised work environment (Managers' community, Peer recognition, Our workplace)
- Talent Management (Talent Reviews, Exchange & Rotation Programme, Development Day)
- Wellbeing (Wellbeing training, Social and employee assistance)
- One Agile Human Resources (Process review)

The HR Strategy was developed in close collaboration with the Agency's leadership team, managers and staff, to ensure its alignment with the real needs of the Agency (through consultations, focus groups and interviews). The HR Strategy was developed and defined in 2022 and an implementation plan for 2023-2025 was drawn up that undergoes periodic reviews every six (6) months. The first review and prioritisation exercise took place in December 2023. During this first prioritisation exercise, the backlog of products for the period until H1 2024 was decided by aligning with the Agency's strategic priorities, adopting a holistic approach. Urgency, need and resources capacity available were taken into consideration.

- **Continued modernisation of staff management processes and tools**

As part of the administration digitalisation programme, which aims to modernise processes and tools that EMA uses in staff management, finance and planning areas, the work undertaken in relation to staff management in 2023 included:

- In the first half of the year, the analysis to have a gradual replacement for SAP HR (which is set to run out of maintenance in 2027) took place as planned. More specifically, the draft roadmap for SAP Core HR replacement had been drafted and the first steps in the implementation of two modules began in Q4 2023.
- In September the work started on the SAP Fieldglass Contingent Workers module (currently used for the management of Experts) expansion for the management of interims and contractors. The effort to broaden Fieldglass's capabilities aims at process improvements through task automation, ensuring consistency, fostering transparency, and promoting collaboration.
- In December the work started on the 'Employee Central' module of SAP SuccessFactors, which enables the management of employee lifecycle. The integration of this module within the existing EMA Talent Hub is a pivotal step that will help to streamline core HR processes, improve operational efficiency and, in turn, enhance the overall employee experience.

- **Recruitment and selection**

  In 2023, in the area of recruitment and selection, the effort continued to fill vacant positions, and most importantly, to refresh reserve lists within core business, in particular, AD6 and AD8 that last were established in 2018 before EMA relocation. As a result, e.g. 4 new AD6 reserve lists were established with nearly 100 candidates placed on them, which will facilitate recruitment efforts in 2024 and beyond.

  Following the 2022 effort to revise, simplify and streamline the selection process, the new Hiring Manager Guide became effective as of 1 Jan 2023, followed by the online e-learning module for hiring managers and selection committee members on selection procedures process, interviewing skills and giving feedback.

  Talent Acquisition staff were also actively participating in three task forces of the EU Agencies Network establishing common practices and approaches for selection procedures (sharing of reserve lists), interagency mobility and EUAN staff exchanges programme (approved in Feb 2024 by Head of Agencies).

  Talent Acquisition also prepared 2 interagency tenders, to be launched in early 2024, attracting more than 30 participating agencies. Both tenders are designed to meet the imminent selection and recruitment needs in the areas of sourcing candidates (both active candidates (marketing plans/publishing) and passive candidates (active candidate search)) and assessment of candidates (covering Assessment Centres/Development Centre, assessments of applications, assessments design).

  Several HR implementing rules were adopted in 2023.

  The list of these can be found in Annex 4.

- **Positive IAS audit on Human resources management and ethics in the European Medicines Agency**

  IAS audit on Human resources management and ethics in the European Medicines Agency - The Agency underwent an internal audit from the Commission Internal Audit Service (IAS) during 2022. The final report, issued on 16 December 2022, commended the Agency's very well organised HR services, demonstrating a mature organisation with internal controls aspects of HR management well embedded into its culture and operations. The period audited coincided with the double challenge of relocation and of the Agency being on the spotlight and under an extremely high workload due to the pandemic. The IAS concluded that overall, the design of the internal control systems in place for the management of human resources and ethical standards was adequate and efficiently and effectively implemented in compliance with the regulatory framework and guidelines for EU bodies. The auditors identified only one area for improvement concerning the appraisal exercise. An action plan was developed and agreed at the beginning of 2023. All actions to improve the efficiency of the appraisal exercise have been carried out and evidence presented to the IAS by the agreed deadlines, with a final request to close this recommendation. The Agency is currently awaiting the confirmation from IAS.

- **Staffing**

  During 2023, the Agency recruited 93 statutory members of staff (50 TA and 43 CA).

  29 national experts were seconded to the Agency, 55 trainees and 145 new interim assignments provided services to the Agency.

The total number of joiners therefore amounted to 322.

During the same year, 36 statutory staff members (25 TA, 11 CA) and 7 SNEs left the Agency.

39 interim assignments were terminated, and 30 trainees ended their contract in 2023. The total number of leavers was 112.

Turnover for TA and CA was at the rate of 4.1%.

The occupancy rate amongst temporary agent staff was 97.4%.

2.6. Strategy for efficiency gains

The Agency has clearly demonstrated significant productivity gains over the past years, having managed to absorb the growing workload driven by the increase in pre- and post-marketing authorisation applications, while also dealing with specific COVID-related activities. During 2023, EMA continued the implementation of its strategy to achieve efficiency gains, maintaining the focus on two specific dimensions: a) process improvement; b) digitalisation.

As part of the process improvement dimensions, during 2023 the Agency worked on:

Agile governance

In 2023, the Agile transformation of the agency was completed. The entire portfolio of programmes and projects have been transitioned under the Agile governance. The Agency established a new Agile governance framework to facilitate the adoption of the Agile way of working. This resulted in a reduced number of steering committees, boards, and other organisations dedicated to a particular project. Steering committee reporting has been replaced by Agile "ceremonies," with critical decisions on priorities and major boundaries being made by the remaining governance bodies at the strategic and portfolio layers. The new governance encompasses five Value Streams which help to organise the portfolio into sub-portfolios that do not have to compete with each other and support long-term strategic goals.

IRIS platform developments

IRIS is a secure online platform that makes the management of product-related regulatory procedures more secure, efficient and user-friendly for EMA and its stakeholders. IRIS is integrated with other EMA systems, such as SPOR and EMA Account Management, to ensure data reuse and to prevent duplication of effort.

During 2023 the Agency launched in IRIS:

- The expert panels on medical devices and in vitro diagnostic medical devices (Expamed) lifecycle management tool: The new tool enables the collaborative assessment of the data provided within the context of the clinical evaluation consultation procedure (CECP) and performance evaluation consultation procedure (PECP) by both internal (EMA Expamed Secretariat) and external stakeholders (experts). This is facilitated through a single lifecycle management tool, to ensure efficient and robust consultation procedures on clinical assessments done by the notified bodies and performance evaluations done by in vitro diagnostics (IVD) manufacturers.
- The PRIME eligibility processes: Developers of human medicines must now use the IRIS platform to apply for PRIME eligibility and to transfer or request withdrawals of already granted PRIME eligibility. Received requests will be processed by the EMA PRIME team, using the customer relationship management (CRM) component of the IRIS platform. Members of the CHMP, CAT and SAWP will also use IRIS to access information and collaborate on documents related to PRIME eligibility.

As part of the digitalisation dimension, in 2023 the Agency focused on:

Digitalisation activities

During 2023 the Agency has continued to deliver on digital innovation, technology experimentation and automation through its Digital Innovation Lab (DigiLab) and the Analytics Centre of Excellence (ACE) including the following projects, several of which directly result in efficiency gains for EMA and its stakeholders:

- Launch of the new Certificates Process System: streamlining manual processes for the generation of certificates for human and veterinary medicines. With this new application, EMA is only issuing certificates for human and veterinary medicines that are signed and authenticated electronically, as of March 2020 and no longer issues paper certificates.
- Launch of the new EURD List Database: streamlining manual processes for the publication of the list of European Union reference dates and frequency of submission of periodic safety update reports
- Collection of more than 80 ideas for automation across the Agency with a focus on delivering efficiency gains
- Launch of more than 9 projects on automation:
    - NRG Checklist: Automatic generation of Name Review Group checklist
    - ESPDITE: Early screening of product documentation for input on techniques and evidence
    - INN Web Search: Scraping the web for INN information
    - New module in AVS (Art 61.3): Automating validation of Art 61.3 submissions
    - BURT - Batch update review tool: Application to modify template in batch
    - QRD Template validation: Application to validate documents submitted against the QRD Template
    - Generation of SAS Report: Develop a solution that could automatically trigger the SAS code every week
    - Automatic recording of VRA procedures: Automate the process to automatically register VRA procedures
    - PDF Vendor invoicing: Automate the process of invoice parking
- ChatGPT@EMA pilot to experiment with OpenAI capabilities at EMA: preparing EMA for strategic adoption of AI capabilities exploring the technology to understand EMA use cases and the technology limitations
- Launch of QR Code Business Card: A modern and paperless exchange of contact information
- New Early Notification System pilot finished: Preparing for a more digital and secure means of communication for ENS notification

2.7. Assessment of audit and ex-post evaluation results during the reporting year

Internal Audit Service (IAS)

In accordance with the IAS' Strategic Internal Audit Plan, the IAC coordinated the conduct of the following engagements in 2023:

- Internal audit on 'Information security management at EMA'
- Limited review on the 'adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to serious cross-border threats to health'

In addition, IAS conducted its three-year risk assessment leading to '2024 – 2026 strategic internal audit plan in EMA'.

Internal audit capability (IAC)

In accordance with its 2023 audit plan approved by the EMA Management Board, the Internal Audit Capability carried out the following engagements in 2023:

- Internal audit on 'Scientific advice'
- Internal audit on 'Scaled agile framework (SAFe) implementation and governance at EMA'
- Internal audit on 'EU NTC and capacity building within the EU Network'
- Internal audit on 'Environmental management at EMA' (fieldwork initiated in December 2023)
- Targeted Independent Review on 'EMA's whistleblowing activities'
- Targeted Independent Review on 'Records management at EMA'
- Targeted Independent Review on 'EMA's Internal Control Framework'.

Furthermore, the IAC coordinated in 2023 the fifth cycle of the Benchmarking of European Medicines Agencies which confirmed the high maturity of EMA operations and processes.

Finally, the IAC contributed to the establishment of the Management Board Audits and Risks Group (MBARG) to strengthen the oversight of audits and risks at EMA.

Based on the results of the internal audits carried out at EMA in 2023, including follow-up activities and independent analyses performed by the Audit Advisory Function and other sources of assurance, the Head of Audit *ad interim* believes the internal control systems in place at the Agency provide reasonable assurance regarding the achievement of the business objectives.

This opinion is issued with due consideration to the findings (including major recommendations) outlined in the audit reports issued in 2023, for which management has prepared improvement action plans and monitors the implementation continuously.

European Court of Auditors

Non-financial audits

The internal audit capability coordinated the fieldwork for the audit carried out by the European Court of Auditors on 'EU Agencies' response to the outbreak of COVID-19 pandemic'

Financial audits

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2022[46] on 19 September 2023.

In the report, ECA expressed an unqualified opinion on the reliability of the accounts and an unqualified opinion on the legality and regularity of the transactions underlying the accounts.

The report includes an emphasis of matter drawing attention to the uncertainty with the lease agreement for the Agency's previous premises in London, two observations on management and control systems and one observation on budgetary management.

None of the observations is considered critical. The Agency is putting in place corrective actions to address the procedural issues covered by the audit recommendations.

Observation on the management and control systems[47]	
Observation number	**Description**
3.19.9	The EMA contributes towards certain types of staff childcare costs, such as pre and after-school care in the Netherlands. For school meals, we found that EMA was not able to provide full evidence of the checks done to ensure that the costs of school meals were excluded, therefore putting into question whether such checks were systematically carried out. EMA's reply: Meals costs are excluded from school fees. Invoices, proof of payments and itemisation of additional charges are checked for each claim to ensure that only eligible costs are included in the calculation. The Agency takes note of the Court´s observation and will file the evidence that school meal costs are excluded from the calculation of the contribution.
3.19.10	As result of its relocation in 2019, the Agency leased a building in Amsterdam, which was fully fitted and furnished using the Dutch government's €15 million incentive scheme, including the donation of furniture and catering equipment. We found that the EMA had not assigned clear identification (such as labels with bar codes) to some of these assets, mainly furniture. We also noted that four inventory counts the EMA had carried since relocation repeatedly showed discrepancies (which, with time, decreased from €534 331 to €15 000) between the list of assets donated by the Dutch government, the EMA's asset register and the assets found on the premises. The absence of a complete and updated inventory list, specifying the location of tangible assets, goes against Article 87 of the Financial Regulation, and adversely affects the EMA's ability to ensure the safeguarding of its assets. EMA's reply: The Agency's inventory has been set up in January 2020 based on an asset value list provided by parties external to EMA. The accuracy of such list has been continuously finetuned via cyclical physical checks on the items delivered and installed in the premises. With a view to continuously improving its processes, the Agency will release an updated internal guidance for the management of its assets inventory, adopt a risk-based approach to the labelling of furniture and release a rolling physical checks plan to continuously confirm the accuracy of its inventory.

[46] Annual report on EU Agencies for the financial year 2022 (europa.eu).
[47] Ibid, page 178.

Observation on the management and control systems[47]	
3.19.11	For one audited payment of €2 million, the EMA authorised the related budgetary commitment only after the legal commitment was accepted. This goes against Article 73(2) of the EMA Financial Regulation. EMA's reply: The Agency is putting measures in place to avoid such cases reoccurring.

2.8. a Follow-up of recommendations and action plans for audits and evaluations

Internal Audit Service

Audit on 'Information security management at EMA'

In their audit on 'Information security management at EMA', while acknowledging the Agency's achievements in managing and controlling information security, IAS concluded that there are still significant improvements needed to ensure their effective and efficient implementation, in particular with regard to monitoring logical security, although the processes are adequately designed.

In addition, there are improvements needed as regards the information security management framework, the protection of information systems during their development lifecycle and the vulnerability management.

Limited review on the 'adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to serious cross-border threats to health'

IAS conducted a limited review on the adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to serious cross-border threats to health in Directorate-General for Health and Food Safety (DG SANTE), Health Emergency Preparedness and Response Authority (HERA), European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA). The auditors concluded that the audited services have, overall, put in place adequately designed mechanisms to support the effective and efficient cooperation and coordination in the prevention, preparedness, and response to serious cross border threats to health. Considering the overall positive results of the limited review, no final report has been addressed to the Agency and no recommendation is addressed to EMA.

Three-year risk assessment leading to '2024 – 2026 strategic internal audit plan in EMA'

In October 2023, IAS undertook its risk assessment based on a desk review of all key documentation and interviews of key EMA managers and staff. As a result of this exercise, the following high-risk areas were identified:

- Management of the lease of EMA's former office premises in London.
- The implementation of Clinical Trials Information System (CTIS)
- Quality and risk management in EMA
- Maintenance and obsolescence management of Legacy IT systems in EMA

The results led to the finalisation of the 2024 – 2026 strategic internal audit plan covering all auditable entities and a shortlist of audit topics. Such strategic internal audit plan will be subject to annual review while the topics may be adjusted or new topics may be added to reflect the results of IAS'

annual risk assessment updates, any new and emerging risks as well as significant changes in EMA processes. The next in-depth risk assessment is planned for 2027.

Implementation of recommendations related to the Audit on 'Human resources management and ethics in the European Medicines Agency' carried out in 2022

0 recommendation was open as of 31 December 2023 in relation to the Human resources management and ethics in the European Medicines Agency audit.

Internal audit capability (IAC)

Targeted Independent Reviews

Targeted Independent Reviews differ from Internal Audits in the sense that their main objective is to provide the Internal Audit Capability and EMA Management with a state of play of EMA processes, activities, tasks or systems through a targeted scope. No audit opinion on assurance or recommendation was issued.

Internal audits

In 2023, 30 major recommendations were issued (13 critical and 16 very important) by the internal audit capability.

- The **SAFe implementation and governance at EMA** audit included **13 Critical** and **10 very important recommendations**. These included to recommendations to strengthen the vision, composition of the network portfolio, better design of value streams, implementing Agile release trains, defining key results at all levels of the organisation (strategic portfolio, tactical and operational) and implement lean budgeting process. 2 of the critical recommendations were closed in 2023.
- For the internal audit on EU **NTC and capacity building within the EU Network**, the IAC issued **0 critical and 3 very important recommendations**. These pertained to establishing KPIs at board level for leadership EU NTC exploration to develop generic profiles with scientific knowledge for relevant curriculums and estimate value and measure effectiveness of training, e.g. via surveys.
- **The Scientific advice** audit resulted in **0 critical and 3 very important recommendations** including to implement ongoing security risk reviews of the IRIS platform, lessons learned on data quality issues identified during IRIS implementation and lessons learned on ETF scientific advice to be used for future ETF planning.

The current status of implementation of audit recommendations stemming from IAC audits includes 15 open critical recommendations and 32 very important recommendations for which the implementation of improvement actions remains ongoing: 1 from 2019, 1 from 2020 audits, 2 from 2021 audits, 16 from 2022 audits and 27 from 2023 audits.

Number of open major recommendations by year end						**Total**
Rating	**2019**	**2020**	**2021**	**2022**	**2023**	
Critical				4	11	15
Very Important	1	1	2	12	16	32
Total	1	1	2	16	27	47

Out of these open recommendations and similarly to the previous year, the following 2 recommendations are overdue at year-end:

- 1 recommendation (Critical) related to the internal audit on EMA's digitalisation refers to an Executive Decision needed to be signed to address the threshold and criteria for evaluations and to fully comply with Article 29 of the Financial Regulation,
- 1 recommendation (Very important) related to Agile SAFe methodology in which the Portfolio strategy should be reviewed continuously at each Strategic Portfolio Review Ceremony.

Major recommendations with "open" status by year-end			
Rating	On Time	Overdue	Subtotal
Critical	14	1	15
Very Important	24	9	33
Total	38	10	48

IAC recommendations implemented

In 2023, the IAC closed 13 major (4 critical and 9 very important) recommendations.

The implementation of the below recommendations led to improvements across the governance, risk management and internal control system across the audit universe pillars including operations, stakeholder and communications, administration and information management and security.

Pillar of Audit universe	Implemented recommendations
Operations[48]	N/A
Stakeholders and communication[49]	In 2023, implemented controls have sought to strengthen, streamline, and ensure confidentiality of communication material stemming from safety communication audit including: • EMA coordinated the update of GVP Module XV Safety communications and applicable templates, to ensure Direct Healthcare Professionals Communications are consistently described in all public documents. • EMA finalised and provided training on documentation describing the preparation, review and publication of Direct Healthcare Professionals Communication, outlining the interfaces with the

[48] This audit universe pillar on 'Operations' refers to supporting the governance, risk management and internal control system overseeing and managing medicines throughout their lifecycle; evaluating and monitoring of medicines, facilitating access and optimal use to produce patient-centred high-quality outputs to ensure patient trust.
[49] This audit universe pillar includes transparency, compliance, and reporting requirements whilst balancing security of the Agency's communication and interactions with stakeholders.

Pillar of Audit universe	Implemented recommendations
	management of product shortages as per the Agency's extended mandate. • S-Division established and documented controls to ensure EMA's stakeholders receive safety communication marked as 'Confidential' in accordance with confidentiality agreements. • S-Division established with EMA's stakeholders and partners some mechanisms to ensure the dissemination of EMA's safety communication-related documents marked as 'Confidential' with the access by individual recipients being granted at organisational level by relevant EMA's stakeholders and partners, in accordance with individually declared competing interests. • S-Division carried out regular ex-post controls to ensure safety communication marked as 'Confidential' are disseminated in accordance with applicable confidentially agreements. • EMA conducted an assessment with the EU Network whether GVP Module XV on safety communications should be updated to reflect any improvements or lessons learnt from Covid-19 safety issues.
Administration[50]	To address the impact of staff during both the relocation and covid-19 in 2023, the Agency-wide was successful at addressing overtime and sick level which involved routine monitoring by EXB with routine follow up of action plans being devised to support staff.
Information management and security[51]	• To ensure greater value for money addressing Agency and portfolio needs an IT sourcing strategy was established including an IT Spend Analysis: category management strategies and Market Intelligence was utilised. • In support of the implementation of Agile SAFe methodology at the Agency, recommendations were implemented to better support the delivery of business value optimise and advance the Architectural runway and foster a culture of continuous

[50] This audit pillar focuses on the Agency's resources management including revenue, expenditure, and accounts according to existing rules and regulations, recruiting and managing staff and contractors and providing and running the necessary facility services and physical security for an effective functioning of the organisation.
[51] This audit pillar provides the Agency and stakeholders with a core set of business applications, IT systems and services to support their activities related to the regulation of human and veterinary medicines in the European Union. Recommendations therefore would focus on customer advocacy and delivery, developing strategic platforms and ensuring security of core IT service.

Pillar of Audit universe	Implemented recommendations
	improvement. These recommendations required further defining epics, requiring greater leadership in defining the objectives and vision at strategy level, participating in portfolio strategy and investment decision-making processes, removing impediments and monitoring metrics. • With regard to business continuity and IT disaster recovery, a communication channel was established for crisis) communication team 'for all critical incidents, a new priority P0 was defined for critical IT incidents [based on the IT Business Impact Analysis (BIA)], which could have a serious disruption across the Agency. A detailed escalation procedure to raise these incidents to the Executive Director was developed and to support its implementation business continuity scenarios (including in case of a ransomware altering part of applications and data) were devised.

European Court of Auditors

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2022[52] on 19 September 2023.

The report includes a follow up of five previous years' observations for which corrective actions have been put in place by the Agency, leading to the closure of all observations.

Follow-up of previous years' observations[53]			
Year	**Court's observations**	**Summary of corrective action taken and/or relevant developments**	**Status of the observation (Open/Closed)**
2016- 2017-2018	The EMA has been tasked by Parliament and Council with the implementation of the Regulation on Clinical Trials (536/2014), requiring the development and implementation of a major pan-EU IT system. In the absence of the necessary own internal resources, the EMA used consultants to an extent that it became critically dependent on external expertise. There was no adequate control over project development and implementation and project delays and costs escalated.	The Clinical Trials Information System was launched on 31 January 2022, delivering the functionalities required and was further stabilised in preparation for its compulsory use as from 31 January 2023. For the management of its Network Portfolio of IT systems and services, the EMA has put in place a bespoke Agile governance model.	Closed

[52] Annual report on EU Agencies for the financial year 2022 (europa.eu).
[53] Ibid, page 179-181.

Follow-up of previous years' observations[53]			
2019	EMA signed a framework contract with three companies for the supply of temporary workers. The price element of the tender specifications had to include an all-inclusive hourly rate conversion factor applied to the gross hourly remuneration of the temporary workers in specific staff categories. However, the Agency did not provide us with any breakdown of the estimated gross staff cost for the interim workers in each requested staff category. As a result, the EMA was not in a position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts.	In the recently concluded new tender for the supply of temporary workers, the Agency has enhanced the design of the costing sheets and the technical specifications providing a more comprehensive representation of the constituent elements of the price paid to temporary workers' agencies.	Closed
2019	EMA granted an additional travel allowance to its staff for their move from London to Amsterdam premises. The amount was calculated based on the cost of a business-class ticket instead of the economy-class fare. We conclude that the EMA gave little consideration to the principle of economy in calculating the amount of the additional travel allowance.	The exceptional travel social measure ended with applications received by 30 June 2022. There have been no further applications for payments accepted after that date.	Closed
2021	Some deficiencies were found in two recruitment procedures mainly related to: a. The vacancy notices did not clearly link the selection criteria with the phase of the procedure. b. The evaluation report did not describe how the conflict of interest were handled when appealing. c. The selection committee had opted not to evaluate all the published selection criteria.	The Agency has developed internal Hiring Manager Guidelines addressing the weaknesses identified. In addition, Career at EMA is a document published on the EMA website, which is publicly available to candidates. A new evaluation report template has been designed, documenting conflicts of interests (if any) and how they have been addressed.	Closed
2021	Due to the overestimation of the contract value in a procurement procedure, the EMA set the financial and economic capacity requirement at a level exceeding the limits set in the Financial Regulation.	The Agency updated its internal guidelines for the evaluation of the financial capacity of the tenderers, outlining more clearly the aspects to be taken into consideration with respect to the establishment of an adequate turnover threshold.	Closed

Management Board on Audit and Risks Group (MBARG)

In June 2023, the Management Board adopted a Decision on the establishment of a 'Management Board Audits and Risks Group' (MBARG). This group consists of Board members tasked with assisting the Board to review the progress on the implementation of audit recommendations as well as providing objective and independent review and oversight of the EMA's strategic processes in relation to risk, internal controls and governance. The MBARG plays a critical role in ensuring that the organisation operates ethically, effectively, and in accordance with established standards and regulations while managing risks appropriately.

2.8. b Follow-up of recommendations issued following investigations by OLAF

No recommendations were issued as of 31 December 2023 following any OLAF investigation.

2.9. Follow-up of observations from the discharge authority

As a follow-up to the discharge decision for 2021, EMA reported in September 2023 on the measures taken in light of the observations made by the Discharge Authority in its annual report under Article 106 of the Framework Financial Regulation. Many of the recommendations made by the European Parliament have been or are being implemented. The Agency is not experiencing any significant delay in the implementation of the observations.

The full report describing the observations made by the Discharge Authority and the Agency's responses and measures taken, is publicly available on the website of the European Parliament.

2.10. Environment management

In 2023, the Agency continued its work towards EMAS registration in accordance with the EMA Environmental Policy and Environmental Management Roadmap 2020 to 2024.

The carbon emissions from the Agency's activities were monitored and calculated in accordance with the Greenhouse Gas Protocol Scope 1, 2 and part Scope 3 with actions to support by selecting energy efficient equipment, and removing single-use materials from the EMA catering facilities. By monitoring consumption data, it was confirmed that despite the return to office-based work in 2023 the level of printing and the generation of waste are being well maintained and kept well below the level in 2020 when the office was used mainly during the first quarter. Some data such as electricity and water show increased consumption in 2023 which is connected to the return to the offices and for water also to the high number of staff cycling to work on a regular basis.

During 2023, the Agency maintained a flexible approach to on-site work requiring a minimum of 40% work from the offices, on a monthly basis. Throughout the year staff were able to work one week per month outside of the Netherlands.

In June/July the new draft guidelines for staff Mission Rules were received. Once finalised, there will be an implementation period, expected to be completed towards the end of 2024. Until new Rules are in place the temporary rules from 2022 remains in place.

For the scientific committee meetings and working parties the previously made decision to perform every other meeting in a virtual setting after physical meetings was maintained, to manage the impact and contribution of delegate's travel on the Agency's carbon footprint.

Starting September 2023, Senior Managers have visibly demonstrated their strong support, leadership and commitment to environmental management and implementation of sustainability focus at EMA through communication activities with personal blogs and info-screen messages focussing on different topics where EMA have a direct and indirect environmental impact. This campaign will continue well into 2024.

Towards the end of 2023, the awaited Internal Environmental Audit was performed by the EMA Audit Advisory Function (AF-AUD) with support from an external provider, KPMG. The audit outcome confirmed the EMA EMS to be compliant with the EMAS regulation and thereby ready to pursue external verification to the ISO 14001:2015 and EMAS management standards, with only one minor non-conformity and some additional observations for further improvements.

During 2023, the EMA Green Group has promoted more than 20 topics on the Viva Engage 'Go Green with EMA' community to raise staff awareness and engagement.

EMA participated in an inter-institutional tender procedure led by ECHA for procurement of Management Standard Certification Services that was awarded in mid-January 2024.

More details of the outcome of the EMA Environment Management activities towards objectives, targets and actions can be found in Annex 7.

2.11. Assessment by Management

Based on the information provided in the previous sub-sections of this report, EMA Executive Director is of the opinion that overall, suitable controls are in place and working as intended, risks and opportunities are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented and that no significant weaknesses that may have a potential impact on the declaration of assurance of the authorising officer were identified.

2.(b) External evaluations

The latest evaluation of the Agency's operation pursuant to Article 86 of the Regulation (EC) No 726/2004 [EMA's founding Regulation] was published on 31 August 2021 and is available in the form of a 'Report from the Commission to the European Parliament and the Council on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use (COM/2021/497 final)'. The study assessed the extent to which the current marketing-authorisation system for medicines met its objectives in the period 2010-2017.

A number of studies to evaluate legislative frameworks and other activities implemented by EMA have been performed for the European Commission in preparation of the revision general pharmaceutical legislation, which was published on 26 April 2023. These are the following:

- **European Commission's evaluation of experience with the operation of the Orphan and Paediatric Regulations**, whose results were published by the European Commission on 11 August 2020.
- **Evaluation of experience with shortages of medicines,** based on the study on medicines shortage (December 2021) which reviews activities carried out by EMA and National Competent Authorities in this area between 2004 and 2020.
- **Studies in support of the evaluation and impact assessment of the EU general pharmaceuticals legislation**, which include an Evaluation report, an Analytical report and Impact Assessment Report, which were all published in April 2023.

- **Evaluation of the EMA fee system**, which was finalised in 2019 in preparation of the legal proposal for the revised EMA's fees regulation published on 14 December 2022.

There are no conclusions or actions from these evaluations which are specific for EMA to follow up, as these evaluations were mainly aimed at informing and preparing future legislative initiatives of the European Commission.

3. Assessment of the effectiveness of internal control systems

3.1. Effectiveness of internal control systems

Internal control framework review

The framework is comprised of 17 internal control principles that cover five core components of the internal control framework: control environment, risk assessment, control activities, information and communication, and monitoring activities.

The framework is based on a principle-based system, whereby the managers are offered the necessary flexibility to adapt to their specific characteristics and circumstances while ensuring a robust internal control with a consistent assessment throughout the Agency.

To assess the implementation, functioning, and improvement of the 17 principles, a questionnaire was prepared. The questionnaire was then addressed to the managers and staff members in charge of specific principles or elements of the internal control framework. This year, like in previous years, several individuals with topics that needed elaboration were interviewed for further clarification of the questions/principles.

Regarding the functioning of the internal control system and its principles, the overall conclusion is that the internal control system, its components and principles are in general present and functioning reasonably well. Several principles were noted to benefit from minor clarifications or additional information, and/or some adjustments and improvements that would enhance the efficiency and effectiveness of the principle and its elements.

Ex-ante financial control system and register of exceptions

Ex-ante verifications

The day-to-day ex-ante verification is the financial control, based on the subjective evaluation of risks where sound judgment applies. The Agency has decentralised the verification for fee revenue and expenditure, as these are standardised transactions requiring either an operational expertise or specific controls. The aim of the financial ex-ante verification is to assure the Authorising Officer that the budget implementation does respect the budgetary principles, focused on legality and regularity including sound financial management and transparency.

The financial verifying agents, as a general policy, perform checks focusing on medium/high-value commitments, sensitive contracts or complex procurement procedures where higher risks have been identified. Transactions are checked by applying appropriate checklists in line with the EMA's internal control framework, the Financial Regulation and the Charter of the Verifying Officer.

EMA’s internal control system also relies on the segregation of duties and the corresponding mapping in the underlying IT system (SAP). Two segregated teams are responsible for initiation and verification.

Comparison between verified and rejected transactions	2021	2022	2023
Number of transactions verified	38,447	27,151[54]	37,874[55]
Number of transactions rejected	511	513	421
Rejections triggered by formal considerations or technical malfunctioning	119 (23%)	301 (59%)	164 (39%)
Rejections triggered by errors in the transaction (incorrect data, insufficient justification)	392 (77%)	210 (41%)	258 (61%)
Overall rejection rate	1.3%	1.9%	1.1%

Register of exceptions

As per the Agency's Internal Control Framework as well as internal procedures, Exception and non-compliance reporting is one of the management tools used to draw conclusions about the effectiveness of internal control and/or the changes needed in the internal control system. In 2023 altogether 29 events were registered in total.

- Exceptions: 8
- Non-compliances: 18
- Combined Exceptions & Non-Compliances: 3

The exceptions related to procurement, delegate reimbursement, fee and financial regulation. Of the non-compliances, twelve related to budgetary commitments a posteriori, the other each to a contract overconsumption and omittance of contract amendment.

In 2023, the internal procedure of handling of exceptions and non-compliances was revised. The Executive Director delegated the authorization of events (granting or rejecting) to the relevant Authorizing Officer by Delegation. Nevertheless, an annual report is prepared and submitted to the Executive Director and all Authorising Officers by Delegation, reporting on the status of the implementation of the mitigating actions stemming from exceptions and non-compliances.

Ex-post control system

Ex-post controls are part of the management and internal control procedures; they are required under Article 45 of the Financial Regulation. The purpose of ex-post controls is to detect and correct errors and irregularities of operations after they have been authorized. Such controls may be organized on a sample basis according to risk and shall take in account of the results of prior controls as well as cost-effectiveness and performance considerations.

Agency-wide ex-post controls are conducted once a year on three types of activities:

- Financial non-fee related
- Financial fee related

[54] Due to automated processing, the number of verified transactions dropped by approximately 11,000.
[55] Verification increased by approximately 10k transactions, because pharmacovigilance Annual Fee and PSURs switched to long workflow following technical issues (~6,000); sales orders for Certificates migrated to another system, requiring temporary long workflow processing (~3,300).

- non-financial procedures and processes

Financial, non-fee related

Financial, non-fee related ex-post controls are performed on transactions that did not undergo an ex-ante verification, in line with the Executive Decision on financial circuits as well as the Methodology for conducting ex-post controls for financial transactions.

The ex-post control yielded errors in the implementation of the BL1300 mission budget due to a technical error in SAP with the calculation of the Daily Subsistence Allowance. Mitigating measures were put in place and the BL1300 reverted to ex-ante verification on 1 July 2023. Following a recommendation of the Verification Service, the mission office now requests the line manager's explicit approval for derogations from the mission rules.

Regarding the BL3000 and BL3003, based on an observation from the ex-post control, a new section in the Guidance for Meeting organisers will be added in relation to pre-meeting/welcome registration events prior to the meeting. The ex-post controls on BL3020 and BL3021 did not raise any observations.

Financial, Fee related

Following a calculation of comparative risk, EMA selected scientific services & PMF, Renewals and Type IB variation for the ex-post controls.

Operational

Agency-wide ex-post controls are conducted once a year on selected financial and non-financial procedures and processes. The areas to be subjected to ex-post controls are proposed by the divisions and a delegated group of senior managers decides on the specific ex-post controls to be carried out, based on the risk assessment and the results of previous controls of these proposed areas.

The following areas were assessed in 2023:

- Handling of procurement procedures in Facilities Support Services
- Handling of declarations of interests of experts
- Parallel Distribution
- Handling of Validation and classification of SA procedures (V)
- Handling of Validation and classification of MRL procedures (V)
- Enterprise Architecture: the functioning of the EMA's Enterprise Architecture Board – EAB
- Handing of declarations of interests by MB members

Conclusion on ex post controls:

Overall, the ex-post controls highlighted some weaknesses, but these are being addressed by specific improvement action plans and the re-assessment of the effectiveness of the actions has been recommended in the next ex-post controls cycles.

Annual review of sensitive functions

As in any organisation, certain Agency staff members are required to carry out functions involving a considerable amount of autonomy or executive power, implying a risk that such powers or influence may be misused for personal gain (financial or otherwise). Consequently, the identification and management of such functions, defined as sensitive, form an important part of the EMA internal control system as they aim at preventing fraud and corruption, as well as at protecting the Agency's interests.

In line with the EMA 'Guidance on sensitive functions', a risk assessment to identify the Agency's sensitive functions was carried out in 2023. In total, 45 posts were identified as sensitive in 2023, compared to the number of sensitive functions in 2022 (41), specifically all senior management roles (Executive Director, Heads of Divisions and Task Forces, and Head of Legal Department) are by default considered sensitive due to the considerable level of decision-making power and influence attached to these roles. Similarly, middle-level management roles (Heads of Department) are also considered sensitive, with the exception of four positions that hold mainly administrative responsibilities and/or less pervasive levels of decision-making power and influence: Head of Surveillance and Regulatory Support in Veterinary Division; Head of Strategic Planning and Governance in Administration Division, and Head of Public and Stakeholders Engagement and Head of Documents Access and Publication in Stakeholders and Communication Division.

The lower-level management roles (Heads of Service/Office and Task Force Work-Streams) are in general considered to have less pervasive levels of decision-making power and influence in combination with sufficient control and oversight from staff holding posts to which such lower management roles directly report to deem these functions non-sensitive. As an exception to this general rule, certain positions at this managerial level are deemed sensitive due to specific aspects of their roles, such as, by way of example, significant involvement with procurement, handling sensitive data, handling of anti-fraud activities, financial or staff-related decisions.

Advisory Committee on Procurement and Contracts (ACPC) and procurement management

The ACPC has been set up as part of the internal control system of the Agency and provides an opinion, in an advisory capacity, on the compliance with the Financial Rules regarding procurements and contracts. The ACPC review is mandatory if the contract amounts to €1,000,000 or above.

In 2023, the committee reviewed 10 cases and expressed 8 favourable opinions, and 2 favourable opinions with recommendations.

Reconciliation of information in financial systems

Most of the Agency's operational systems are interfaced with the SAP system. During 2023, reconciliations for 100% of the data between the product- and procedure-tracking systems and SAP were carried out on a regular basis, including data from the newly interfaced IRIS system. A finding was detected in 2023 due the migration of several inspections during the decommissioning process of CorpGxP database in 1Q2023 that transitioned from this system to the new inspection management system (IRIS). The inspection fees migrated in 2023 were due in 4Q2022 but due to the migration strategy, only available later in 2023 in SAP. This resulted in a delayed recovery of fees and the budget booking for the following year (2023 instead of 2022).

Data protection

EMA processes personal data in accordance with the rules laid down in Regulation (EU) 2018/1725, the European Union Data Protection Regulation (EUDPR) (applicable as of 11 December 2018) and is subject to the supervision of the European Data Protection Supervisor (EDPS). National Competent Authorities in Member States and EMA's other stakeholders in the EEA are subject to Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR).

In 2023, EMA continued to pursue the implementation of the EUDPR at full speed. The Data Protection Officer (DPO), in consultation with the internal controllers, developed a data protection action plan focusing on delivering:

- An annual data protection work plan,
- A methodology for the risk categorisation of data protection activities with a view of prioritising tasks,
- Enhanced data protection training for EMA staff, contractors and the EU Medicines Regulatory Network and
- A quarterly report on the Agency's data protection activities addressed to the Executive Director and Internal Controllers.

To address organisational matters and discuss recent EDPS/EDPB guidance on specific data protection topics, the DPO organised a total of six meetings with the Agency's appointed Data Protection Coordinators (DPCs). Furthermore, the DPO attended the two annual meetings of the EUIs DPOs Network and the joint Network meetings with the European Data Protection Supervisor (EDPS). These meetings provide an important forum to exchange experience, discuss practical approaches on how to address specific data protection matters and to interact with the supervisory authority on the application of the EUDPR. The output of these meetings feed into EMA's data protection procedures where applicable. This is reflected as part of the detailed review of the Annexes to the Internal Guidance on Data Protection (Ref. 0055-2020). Following consultation of the DPCs in Q3 2023, these annexes are subject to finalisation early 2024. Work on new topics such as data protection steps to be followed as part of the Agency's technology selection and procurement procedure is being continued in 2024.

In response to the EDPS consultation on international transfers of unredacted case narratives originating from EudraVigilance by certain MAHs which EMA initiated in September 2022, the EDPS conducted an on-site audit on EudraVigilance in March 2023. In this regard EMA was asked to demonstrate adherence to the integrity and confidentiality principle as part of the stakeholders' access to EudraVigilance, the data protection by default and design principle including the technical and organisational measures implemented, the data minimisation principle and the anonymisation and pseudonymisation methods applied. EMA also supported on the spot checks in response to the potential data breach by a MAH as notified by NOMA in 2022 and outlined the international transfer mechanisms applied by EMA in accordance with chapter V of the EUDPR. The audit minutes were agreed in July 2023, the final audit report is being awaited by EMA upon which further improvement actions may be required.

The consultation of the German Data Protection Authority as advised by the EDPS, which was initiated in October 2022 by EMA, is still ongoing.

In March 2023, the EDPS launched a coordinated enforcement action focusing on the role, responsibilities, and tasks of data protection officers in EUIs. To support this work, the DPO responded to the EDPS questionnaire targeted at compliance checks with the applicable data protection law, Regulation (EU) 2018/1725. This involved verifying data protection officers' independence; how their

advice is followed; and how they carry out their duties to ensure compliance with the applicable rules whenever EUIs are processing personal data. The results of the Coordinated Enforcement Action on data protection officers was published by the EDPS on 18 January 2024.

During 2023, the DPO continued to assist and guide Internal Controllers and DPCs regarding data protection obligations. This related to areas such the discussion and review of arrangements with health data providers and access to document requests in accordance with Regulation (EC) No 1049/2001. Details are further reflected in the quarterly reports.

In collaboration with the DPCs, the DPO continued to coordinate the performance of EMA's transparency obligations. This includes the preparation and publication of data protection notices and records of processing operations (the latter in accordance with Article 31 of the EUDPR).

As part of the technology selection and acquisition process and the procurement and tender procedures, efforts were specifically devoted to the data protection risk assessment of the potential data processors of the Agency and the negotiations of the relevant contracts with the successful vendors. This included a review of the Cloud security and data protection risk assessment questionnaires as applicable, providing support in performing Transfer Impact Assessments (TIAs) to assess whether it is possible to transfer data to a third country by checking whether the destination country provides for an essentially EUDPR/GDPR equivalent level of data protection and to review the effectiveness of supplementary measures put in place by the processors to mitigate risks to data subjects.

Based on the data protection by design principle, two Data Protection Impact Assessments (DPIAs), were updated (DARWIN EU and Lifecyle Regulatory Submissions Raw Data Pilot). The DPIA dedicated to the EHDS pilot 2 was completed for review and comments by French Healthcare acting as the data access body for this pilot. Furthermore, the drafting of the following DPIAs is ongoing or near completion: IRIS for product-related scientific and regulatory procedures at EMA, the Security Operations Center (SOC), the Data Analytics Platform (DAP), the EMA Cloud strategy implementation and the French Health Data Hub (HDH). A draft DPIA for Signal and Safety Analytics (SSA) forming the basis for a contractual deliverable in 2024 by the vendor.

The management of security incidents including personal data breaches were supported throughout 2023 with a reduction of personal data breaches by nearly 50% compared to 2022. Such reduction can be associated with the enhanced data protection training offered to EMA staff and contractors during 2023. This included the development of a dedicated training programme on the secondary use of health data (5 modules) targeted at data scientists of the Medicines Regulatory Network and EMA, which attracted more than 400 participants. A training on data protection and EudraVigilance was delivered to the PhV Inspectors Working Group and to external stakeholders. For I-Division, two training sessions were provided on data protection basics and principles (target audience IT specialists and contractors), for A-Division a training session on data protection in purchasing IT solutions and services was organised (target audience procurement experts), and for all EMA staff data training on protection topics of special interest and data breach management as delivered.

The topic of international data transfers possibly carried out by the Agency when performing its activities continued to be of importance in 2023. The negotiations with Health Canada to enter an administrative arrangement pursuant to Article 48(3)(b) of the EUDPR continued including further interactions with the EDPS in the frame of the necessary prior authorisation to enter into this arrangement. This included a bilateral meeting between the EDPS and EMA to address their specific authorisation comments and a trilateral meeting including Health Canada as a party. EMA and Health Canada are awaiting further EDPS clarifications on specific action areas allowing for the finalisation of the agreement.

In addition, EMA and the Council of Europe agreed on the use of the model contractual clauses for the transfer of personal data (COUNCIL OF EUROPE CONVENTION 108+) for the purpose of the renewal of a contract for the sampling and testing cooperation agreement between EMA and EDQM with a view to finalise the clauses in Q2 2024.

Prevention, detection and correction of fraud

EMA is committed to ensuring that its staff, members of committees and all external contractors pursue the highest ethical standards of honesty and integrity in the exercise of their duties and has a 'zero tolerance' approach to fraud.

To improve prevention, detection and the conditions for investigation of fraud, and to pursue adequate deterrence and reparation with proportionate and dissuasive sanctions, the Agency adopted its Anti-Fraud Strategy (AFS) in December 2014. The AFS is accompanied by a 3-year action plan. Both the strategy and the action plan are reviewed and updated every three years. The last update of the AFS was adopted by the Management Board in March 2021, together with the action plan for 2021-2023. The next revision will take place in March 2024.

The AFS and action plan address specific risks that have emerged at the Agency's level, as also reflected in the annual fraud risk assessments.

Prevention and awareness-raising are the most important objectives of the AFS since its adoption back in 2014. This aspect has remained unchanged in 2023. New staff members are required to take a mandatory anti-fraud e-learning training that was updated in 2021. Presentations on ethics and anti-fraud were prepared for staff members to attend, including information on EMA's code of conduct and conflict of interest.

No administrative inquiries were opened in 2023.

Handling of information from external reporting persons

The Agency's main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. EMA is strongly committed to carry out all of its responsibilities and to adhere to the highest standards of professional and personal integrity. In this regard, receiving and considering information provided by external persons reporting concerns about EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities is essential in safeguarding the public interest and in promoting a culture of public accountability and integrity.

A policy to handle allegations of breaches communicated by any external reporting persons is in place since March 2017, complementing the policy on whistleblowing which applies to the Agency's staff. The goal of the policy is to create an environment where individuals from outside the Agency feel confident to raise their concerns.

This policy outlines EMA's approach to the handling of any reporting by external persons which contain allegations of breaches relevant to EMA's sphere of competence. "Breaches" are defined as acts or omissions that are unlawful or defeat the object of the purpose of the authorisation, supervision and maintenance of human and veterinary medicinal products and which are within the competence of EMA, i.e., any conduct or omission amounting to a violation of any legal provision governing the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use, or any other EMA activities.

The policy sets out the key principles underlying the handling of the information received from external reporting persons and helps EMA assess these reports and coordinate any further investigation in a

structured way, while also protecting the identity of the reporter. The key principles relate to the confidentiality of the information received (including the management and processing of any personal data), the acknowledgement of receipt, the treatment of the information, the interaction (if any) with the EMA Anti-Fraud Strategy, analysis of the competence, the transfer of information to other authorities and the notification to the external reporting persons. A dedicated inbox has been created for external reporting persons to report breaches to the Agency (reporting@ema.europa.eu).

The standard operating procedure (SOP) on handling information submitted by external reporting persons is effective as of 1 August 2017 and establishes a procedure providing for uniform, structured and confidential handling of information from external reporting persons disclosing allegations of breaches reported to the Agency. The procedure can be divided into six main sub-processes: receipt of information, triage of the information, initial evaluation of the information, assessment of the allegations, closure of the case and information to the external reporting person, and archiving.

Both the Policy and the SOP have been revised in 2022, taking into account the Regulation (EU) No 1725/2018 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, offices and agencies and the Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of person who report breaches of Union law.

EMA received 38 (thirty-eight) external whistleblowing reports in 2023 and followed-up on each of these cases in accordance with the Policy and SOP.

26 (twenty six) cases have been closed, in 12 (twelve) cases the assessment is ongoing. For 30 (thirty) cases, EMA was not competent on the matter (e.g. manufacturing sites not involved in centrally authorised products, supervision of ongoing clinical trials, medical devices) and handed the case over to the concerned NCAs. In 7 (seven) cases EMA coordinated the investigation with the involvement of the relevant NCAs/Rapporteurs. Once case, although falling within the EMA remit as per the initial report, was not assessed further as no sufficient information was provided by the reporter.

For the reports in EMA remit, there were 3 (three) cases of GCP non-compliance and 5 (five) cases of GMP non-compliance.

Management of competing interests

In order to preserve impartiality and objectivity in every aspect of the Agency’s work, a number of policies and rules on management of competing interests have been put in place, covering the different groups of people involved in and contributing to the Agency’s work.

Management Board

The updated policy (0058) governing the Management Board's management of conflicting interests took effect on January 1, 2023. It now encompasses the new responsibilities of the EMA concerning medical devices and in vitro medical devices, as well as the agency's enhanced role in monitoring and addressing shortages of medicinal products and medical devices. Additionally, the revised Breach-of-Trust procedure for Management Board members, harmonised with the updates to policy 0058, also became effective on January 1, 2023

EMA requires Management Board members to sign a declaration of interests (DoI) and submit a curriculum vitae (CV) when they join the Management Board. Members have to re-submit these documents at least on an annual basis, or when a change in their interests occurs.

Since 2016, an ex-ante control has been carried out systematically on all DoIs submitted by Management Board members to compare the details contained in each new declaration with the

previous declaration, and with the CV provided. Members are required to undertake training before their declaration of interest can be submitted.

The involvement of members and alternates in Management Board activities takes into account several factors, namely, the nature of the declared interest, the timeframe of the interest, the type of Management Board activity/topic, and the likelihood of impact on the industry (the pharmaceutical/medical device industry or any other industry related to any declared personal interests), as well as the action requested from the Management Board (i.e. adoption or endorsement).

Moreover, members are informed in writing and ahead of each meeting, of the perceived competing interest which has been identified, and the applicable restriction to their involvement at the meeting. At the start of each meeting, members are further asked to declare any specific interests which could be prejudicial to their independence with respect to the items on the agenda. The names of members having declared competing interests which could affect their impartiality, with regard to specific items on the agenda, are noted in the MB minutes.

Declarations of interests of all Management Board members are published on the Agency's website.

No breach of trust procedure had to be initiated for a Management Board member in 2023.

The Agency publishes each year an Annual Report on Independence that is submitted to the Management board and which sets out how its policies on completing interests are implemented, monitored and any new activities undertaken during the year.

Scientific committee members and experts

The policy on the handling of competing interests of scientific committees' members and experts (policy 0044) was last revised in December 2022, with effect from 1 January 2023.The revision resulted from:

- the additional responsibilities for the Agency, following its involvement in certain medical device and *in vitro* medical device procedures, as set out in Regulations (EU) 2017/745 and 2017/746, which requires members and experts now to declare also interests in the medical device industry which could affect their impartiality;
- the Agency's extended mandate in accordance with Regulation (EU) 2022/123, which reinforced its role in crisis preparedness, and which established new bodies within EMA (Emergency Task Force (ETF), Medicines Shortages Steering Group (MSSG) and Medical Devices Shortages Steering Group (MDSSG)) to which the policy also applies.

The Agency takes a proactive approach to identifying cases where the potential involvement of an expert as a member of a committee, working party, body or other group, or in any other Agency activity in the context of the evaluation, supervision and maintenance of medicinal products for human or veterinary use, procedures regarding medical devices, public health emergencies on medicinal products or medical devices or shortages of medicinal products and medical devices, needs to be restricted or excluded, due to interests in a pharmaceutical company or a medical device company (or the biotechnology sector for CAT members and alternates).

The Agency requires experts to provide a declaration of interests (DoI) every year, or when a change in their interests occurs, to ensure that they do not have any financial or other interests in the pharmaceutical/medical device industry that could affect their impartiality. The Agency also requires the experts to submit an up-to-date curriculum vitae (CV).

For the handling of DoIs submitted by members and experts of scientific committees' and the Agency's other bodies, a 2-step procedure applies: firstly, an interest level is automatically assigned to the DoI

based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Subsequently the level of participation in the Agency's activities is determined by active screening of the DoI by the Agency's secretariat for each procedure or activity where the relevant expert would be involved.

Involvement of an individual member or expert in the Agency's activities is determined taking into account 3 factors:

- the nature of the declared interests;
- the timeframe during which such interest occurred;
- the type of activity that the expert will be undertaking.

The policy reflects a balanced approach and aims to effectively restrict the involvement of experts with possible competing interests in the Agency's work, while maintaining EMA's ability to access the best available expertise. It includes a number of measures to take into account the nature of the declared interest, before determining the length of time for which any restrictions may apply.

Requirements for members of scientific committees, ETF, MSSG and MDSSG are stricter than for experts participating in advisory bodies and ad-hoc expert groups. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than for the other members.

The Agency has a Declaration of Interest/Conflict of Interest community composed of EMA staff members with experience in handling of competing interest, who can provide advice on the evaluation of DoIs of members and experts.

On 22 June 2023, the Court of Justice set aside the first-instance judgment of 28 October 2020 in Case T-594/18, Pharma Mar v Commission. The case concerned whether a university hospital may be classified as a "pharmaceutical company" for the purpose of EMA's Policy on the handling of competing interests of scientific committees' members and experts (Policy 0044). Consequently, the implementation measures which were introduced for Scientific Advisory Groups and Ad Hoc Experts Groups following the delivery of the first-instance judgment have been discontinued.

In its appellate judgment, the Court of Justice took note of the fact that Policy 0044 seeks to ensure an appropriate balance between the requirement of impartiality of experts involved in EMA's activities and the requirement of scientific excellence. After reviewing Policy 0044, the Court of Justice found that a university hospital should not be qualified in its entirety as a pharmaceutical company, even when there is an entity within that organisation that would satisfy the definition of a pharmaceutical company under this Policy.

In that connection, the appellate judgment recognised the important contribution that the staff of a university hospital represent in the context of EMA's scientific evaluation procedures.

Following the setting aside of the first-instance judgment, the Court of Justice referred the case back to the General Court so that it can examine the remaining elements of the case. EMA is a party to those proceedings (Case T-594/18 RENV); and a judgment might be expected in 2025.

All members proposed for the Agency's scientific committees, ETF, MSSG and MDSSEG have their DoI screened before their formal appointment to the committee or body. In cases where the nominating authority appoints a member or alternate to a scientific committee, body or other forum, or an expert for participation in an Agency's activity where the expert has declared interests incompatible with involvement in Agency's activities in accordance with the policy, the Agency would not allow this expert to participate and inform the nominating authority accordingly.

Pre-meeting, meeting, and post-meeting arrangements are applied to ensure application of the policy, and to provide documented evidence. The outcomes of the evaluation of DoIs, and restrictions applicable to meeting participation, are included in the meeting minutes. The meeting minutes of all scientific committees are published on the Agency's website.

DoIs, their interest levels, and the CVs of scientific committees' members and experts, are published on the Agency's external website for transparency purposes. The European experts' list on the Agency's website includes only those experts who have a valid DoI and CV. The Agency removes from the list the experts whose DoI is older than a year, until they submit an updated DoI.

EMA has a breach of trust (BoT) procedure, which sets out how it deals with incorrect or incomplete DoIs by scientific committees and other bodies' members and experts, as well with disclosure of confidential information. The BoT procedure was last revised in December 2022 (EMA/154320/2012 Rev 3) to align it to the latest changes to policy 0044.

No BoT procedure was initiated in 2023. One procedure initiated in 2022 was concluded in 2023. The case concerned a committee member who did not declare a close family member's interest in a pharmaceutical company. It was found that the failure to declare the interest constituted negligence to comply with the EMA policy, but it did not occur through gross negligence. The committee member was not allowed to be involved in EMA activities for a period of 9 months and a new member for the committee concerned was appointed by the nominating body. The Agency immediately restricts scientific committee members, as well as any other experts, from any further involvement in the Agency's activities, from the date they inform the Agency that they intend to take up employment in a pharmaceutical company. In 2023, 10 delegates (6 scientific committee members: 2 CHMP, 3 CAT, 1 PRAC; 4 working party members: 2 SAWP, 1 BWP, 1 inspectors working group) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector (EMA/267183/2015 Rev 1), the members were immediately fully restricted from further involvement in any Agency activity. The imminent employment in a company did not constitute a conflict for any of the ongoing assessment procedures. The Guidance has been updated in July 2023 to align it with the revised Policy 0044.

In 2023, 826 DoIs of new experts were checked and an error was noted in 12 DoIs (1.5%). The nature of the errors in 2023 was that 5 of these experts failed to declare in their DoI their recent employment (in the past 3-year period) within a pharmaceutical company. EMA asked the experts to correct their DoI, resulting in a higher or same interest level being assigned to their DoI. This EMA ex ante/preventive check of each new expert is important and is maintained to ensure a low number error on the first DoIs of new experts.

On 29 March 2023, the Agency launched its new Experts Management tool to replace the old Experts database. The tool holds the DoIs and CVs of all scientific committees' and other bodies' members and experts involved in EMA's medicines and medical devices related activities falling under Policy 0044. Information from existing experts was migrated from the old database to the new tool and all experts were requested to update their DoI in the new tool by 1 July 2023 in line with the revised policy. The tool includes also the DoIs and CV of Management Board members falling under Policy 0058 and those of the EXPAMED members falling under the applicable EC Policy.

The new tool is user-friendly for new experts to register in the tool, i.e. to provide their contact details, areas of expertise, DoI and CV, and for existing experts to submit an annual DoI or to update their information. The tool also facilitates the evaluation of DoIs of members and experts involved in EMA activities, as well as the management of memberships in committees, bodies and other groups.

The Agency publishes each year an Annual Report on Independence that sets out how its policies on independence are implemented, monitored and any new activities undertaken during the year.

Expert panels in the field of medical devices (EXPAMED)

The European Commission's Joint Research Centre (JRC) created the expert panels in the field of medical devices (EXPAMED) according to the mandate from the Medical Device Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). The expert panels were transferred to the EMA on 1 March 2022, following the applicability of the Extended Mandate Regulation (EU) 2022/123 on the reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

The expert panels support the conformity assessment of high-risk medical devices by Notified Bodies through the opinions for the clinical evaluation consultation procedure and for in vitro diagnostics through the views from the performance evaluation consultation procedure. The expert panels also provide advice to manufacturers in the field of high-risk medical devices. The experts can be assigned one of 5 roles: Chair, Vice-chair, Rapporteur, Co-Rapporteur and reviewer. The Agency provides administrative, technical and scientific support to the expert panels.

According to Article 106 and Article 107 of the MDR, expert panel members shall perform their tasks with impartiality and shall not have financial or other interests in the medical device industry which could affect their impartiality. To this effect the European Commission adopted a Policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices.[56]

Interests from members of the expert panels are declared and evaluated by EMA in accordance with this policy: a DOI needs to be completed by all candidates applying to the call for expression of interest for expert panels on medical devices and in vitro diagnostic medical devices. Moreover, a DOI needs to be completed and regularly updated by all advisors appointed as expert panel members. The DOI should be updated without delay if there is a change of interests or new interests declared during the course of the term.

The handling of declared interests is based on a two-step procedure. Following receipt of the DOI an interest level is assigned based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Subsequently, the level of participation in the expert panel activities is determined taking into account the assigned interest level, the task at hand, the envisaged role of the expert as well as the relevant interest and resulting restrictions.

The DoIs and the CVs of all expert panel members are published on the European Commission's website.

Agency staff

The Staff Regulations (Article 11, 11a and 13) and in addition, Agency's Code of Conduct extends the requirements for impartiality and the submission of annual declarations of interests to all staff members working at the Agency, including temporary agents, contract agents, seconded national experts, interims, visiting experts, collaborating experts and trainees. Staff must therefore complete a declaration of interest prior to the start of their contract, at the start of their contract and update their declaration annually. Equally, staff members must update their declaration if their circumstances change.

[56] EXPAMED document D4.3: https://health.ec.europa.eu/system/files/2023-04/policy-mngt-conflicts_en.pdf.

Following the completion of a declaration of interests, and depending on the nature of the declared interests, if any, an interest level (1-3) is assigned to the staff member and/or candidate by the reporting officer evaluating the declaration. Staff members and/or candidates with interest level 2 or 3 are subject to a documented risk-based assessment, which includes mitigating actions, where required, to reduce the risk. The decision is based on:

- the nature of the declared interests;
- the timeframe during which such interest occurred;
- the staff member's specific role and responsibilities (this includes the following aspects: the nature of the staff member's duties, the nature of the staff member's input to the Agency's activities and the degree of influence that may be exerted on the final administrative or technical proposal, opinion or decision).

Staff declarations are available internally in SAP HR and for consultation by external persons upon request. CVs and DoIs of the Executive Director and all EMA managers are published on the Agency's corporate website.

With regards to selection procedures and procurement, any competing interests must be declared by selection committee members and procurement evaluation committee members, and action taken accordingly.

Staff must request prior authorisation for outside activities during active service, in accordance with the Commission rules on outside activities and assignments of 2018, applicable to the Agency by analogy. In 2023, the Agency received 27 requests for an outside activity during active service. All requests were granted; 26 requests were authorised in 2023 and 1 request was authorised in January 2024.

Post-employment

Staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. National experts are also required to seek permission, although the period is restricted to the equivalent duration of the secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

It is important to note that in accordance with the current rules on outside activities and assignments and on occupational activities after leaving the service, taking up employment at a European Union institution does not trigger the obligation to inform the Agency as working for another EU institution does not lead to leaving the service of the Union for the purpose of applying Article 16 of the Staff Regulations. Therefore, any staff member leaving the European Medicines Agency to take up employment with another EU institution is not required to seek prior authorisation.

For the period from 1 January 2023 to 31 December 2023, staff made a total of 16 applications to engage in an occupation after leaving the service. 15 applications were finalised within 2023 and this resulted in 4 authorisations with restrictions. The remaining application was finalised in 2024.

Restrictions (that are grade and role related) imposed include a distance clause, whereby the former staff member may not contact individual Agency staff for a certain period of time, e.g. 6 - 24 months.

Since November 2020, the Agency publishes on EMA's corporate website a specific register for senior staff leaving the Agency. For the purposes of this register, a 'senior staff member' includes the Executive Director, the Deputy Executive Director, Heads of Division, Advisers, Heads of Task Force

and the Head of the Legal Department. The register includes the name of the senior staff member concerned, date of departure, type of post held at the Agency, name of the intended future employer, the job title (or brief description if self-employed) and the date of the decision and restrictions applied. The data will be removed from the register two years after the departure of the staff member.

More information on restrictions applied to applications in 2023 is given in Annex 9.

External consultants and contractors

Competing interests for external consultants and contractors are covered by the standard framework contract provisions (section II.7), specifically:

The contractor shall take all necessary measures to prevent any conflict of interest or professional conflicting interest, i.e. any situation that could compromise the impartial and objective implementation of the contract. Such conflicts of interest or professional conflicting interest could arise, in particular, as a result of family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the contracting authority or any third party related to the subject matter of the contract.

In the event of any such conflict, the contractor must notify the contracting authority in writing as soon as possible of any situation that could constitute a conflict of interest or a professional conflicting interest during the implementation of the contract. The contractor must immediately take action to rectify the situation.

The Agency may do any of the following: verify that the contractor's action is appropriate; require the contractor to take further action within a specified deadline; decide not to award a specific contract to the contractor.

The contractor must pass on all the relevant obligations in writing to its personnel, any natural person with the power to represent it or take decisions on its behalf, third parties involved in the implementation contract, including subcontractors. The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

Furthermore, in compliance with section II.8 of the standard framework contract (provisions regulating confidentiality), the contractor has the obligation to treat with confidentiality any information or documents, in any format, disclosed in writing or orally, relating to the implementation of the contract and identified as confidential. In particular:

The contractor shall not use confidential information or documents for any purpose other than to perform its obligations under the contract without the prior written agreement of the other party;

The contractor shall ensure the protection of such confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence;

The contractor shall not disclose, directly or indirectly, confidential information or documents to third parties without the prior written agreement of the other party.

Additionally, the Agency has measures in place to mitigate the risk of project-related, commercially confidential information (CCI) being disclosed to non-EMA staff, such as consultants and contractors. CCI includes rates for payment of contracted services, quotations for delivery of contracted goods or services, and services and goods quoted in tender procedures. An internal guidance document provides information on how project related CCI should be handled, as well as practical measures that should be taken to avoid disclosure.

3.2. Conclusions of assessment of internal control systems

Detailed assessment of the internal control system is carried out at the beginning of each calendar year, with the results included in the Annual activity report. Based on the assessment of internal controls 2023, the Agency concluded that the internal control systems in place, both in terms of the individual elements, and the system as a whole, are effective overall, with some improvements needed to further enhance the effectiveness of specific elements of the system. Nonetheless, the internal control systems in place are considered to provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

3.3. Statement of the manager in charge of risk management and internal control

I, the undersigned, Mario Benetti, Head of Quality and Risk Management Service within the European Medicines Agency, in my capacity as Manager in charge of risk management and internal control,

- declare that in accordance with the European Medicines Agency's Internal Control Framework, I have reported my advice and recommendations on the overall state of internal control in the Agency to the Executive Director.
- hereby certify that the information provided in the present Consolidated Annual activity report and in its annexes is, to the best of my knowledge, accurate, reliable and complete.

Amsterdam, 24 May 2024

[signature on file]
Mario Benetti
Head of Quality and Risk Management Service

4. Management assurance

4.1. Review of the elements supporting assurance

Taking into account the review of the elements supporting assurance, the Executive Director is of the opinion that the management and control systems in place at the Agency are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

4.1.1. Assurance from the authorising officers by delegation

In accordance with the charter of tasks and responsibilities of authorising officer by delegation, and in support of the Annual activity report, all authorising officers by delegation were asked to confirm their reasonable assurance for their areas of responsibility.

The authorising officers by delegation confirmed their reasonable assurance that, overall, suitable controls have been in place and have been working as intended; identified risks have been appropriately monitored and mitigated, and necessary improvements have been implemented.

4.1.2. Conclusions

Given the review of the elements supporting assurance, the Executive Director confirms that the management and control systems in place at the Agency are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

4.2. Reservations

Based on the assurance provided by the control system results, the Executive Director sees no reason that would justify or require a reservation.

4.2.1. Materiality criteria used

In line with the suggestion of the guidelines on the preparation of the Annual activity report, the Agency used the qualitative and quantitative materiality criteria described below to assess if issues identified merit a reservation.

4.2.2. Qualitative criteria used

The Agency would consider as significant the weaknesses in the internal control system that fall under the following qualitative criteria:

- significant errors detected during the control or supervision exercises;
- significant weakness in one of the control systems;
- situations where the Agency does not have sufficient evidence from internal control systems or audit coverage to be confident of providing the necessary assurance;
- situations where a major issue has been outlined by the European Court of Auditors or the Internal Audit Service of the Commission (critical audit recommendations for underlying weaknesses relevant to the area covered by the declaration of assurance that are not adequately addressed by other internal controls and where the materiality threshold is exceeded);
- situations revealed through own control work or audits where significant risks remain unmitigated;
- significant reputational risk.

4.2.3. Quantitative criterion used

According to the Commission guideline on preparation of Annual activity reports, the Court of Auditors uses a 2% materiality threshold. The Agency has therefore set the quantitative criterion of materiality at 2% of its total budget, as the Agency's tasks can be considered a policy area. This enables the Agency to apply the materiality criteria to the data and results of various control activities.

5. Declaration of Assurance

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the Court of Auditors on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Agency can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

Emphasis of Matter

Without calling into question the overall conclusions on assurance, the attention is drawn to the following important matter:

The lease on EMA's former office premises in London runs until 2039 and does not contain a break clause. The Agency's premises in the United Kingdom were not included in the EU-UK political negotiations on the Withdrawal Agreement. Further to the ruling of the High Court of Justice of England and Wales of February 2019, stating that Brexit is not a cause for frustrating the lease agreement, EMA sought contractual possibilities to dispose of the premises and mitigate the financial burden on the EU budget, subletting its former office premises to a sub-tenant from July 2019, under conditions that are consistent with the terms of the head lease.

The sub-tenant's parent company filed for Chapter 11 bankruptcy protection in the US in November 2023 following the impact of the pandemic on the use of office spaces and the changed situation in the post-pandemic period. The parent company's liquidity situation directly affected the sub-tenant, who approached EMA to renegotiate the sub-lease agreement in order to be in a position to remain in the premises. The negotiations, concluded in March 2024, will enable the sub-tenant to remain in the premises, paying a fixed rent, a rent linked to turnover and all the other building charges.

It should be noted that the London office market and rent levels, particularly in the area where EMA's former office premises are located have significantly deteriorated post pandemic due to many factors including increased hybrid work, higher interest rates, growing vacancies in the second-hand real estate market.

The revised lease agreement has been supported by the Budgetary Authority. EU funding will cover the difference between the cost of the lease and the revenue received from the sub-tenant. This EU funding is essential to protect the public health activities of the Agency and of the national competent authorities.

It must be noted, however, that since EMA remains a party to the head lease, it is financially responsible for running its former premises in the UK. This long-term liability forces the Agency to continuously divert some of its human resources away from its public health remit to manage a commercial property in a third country (an activity not foreseen in the Agency's founding regulation), for which neither the Agency nor the EU have business use. Furthermore, the Agency is liable for the entire remaining amount payable under the contractual obligations of the head lease if the sub-tenant fails to meet its obligations. As of 31 December 2023, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by EMA up to the end of the lease term is €375 million. If premises were to remain vacant, there would be further costs until such time as the floors would be rented out to new sub-tenant(s). Such costs would include, for example, UK government taxes and/or VAT and operating costs and utilities.

The EMA Management Board has stressed on numerous occasions the unsustainability of this situation in the long term and urged EU institutions to resolve this matter at the highest political level. The

persistent volatility of global - and UK - economies, caused by the pandemic and exacerbated by geopolitical tensions, underlines the need for a political resolution of this issue, to enable the Agency to fully focus its resources on the implementation of its recently expanded mandate and on the Union's efforts to address public health crises.

Declaration of assurance

I, the undersigned Emer Cooke, Executive Director of the European Medicines Agency, in my capacity as authorising officer,

- Declare that the information contained in this report gives a true and fair view.
- State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.
- This reasonable assurance is based on my own judgement and on the information at my disposal such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service, the work of the Internal Audit Capability and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.
- Confirm that I am not aware of anything not reported here which could harm the interests of the Agency.

Amsterdam, 24 May 2024

Emer Cooke

Executive Director

[signature on file]

Annexes

Annex 1. Core business statistics

Business statistics can be found in Part I.

2023 key figures

1. Human Medicines

1.1. Supporting research and development

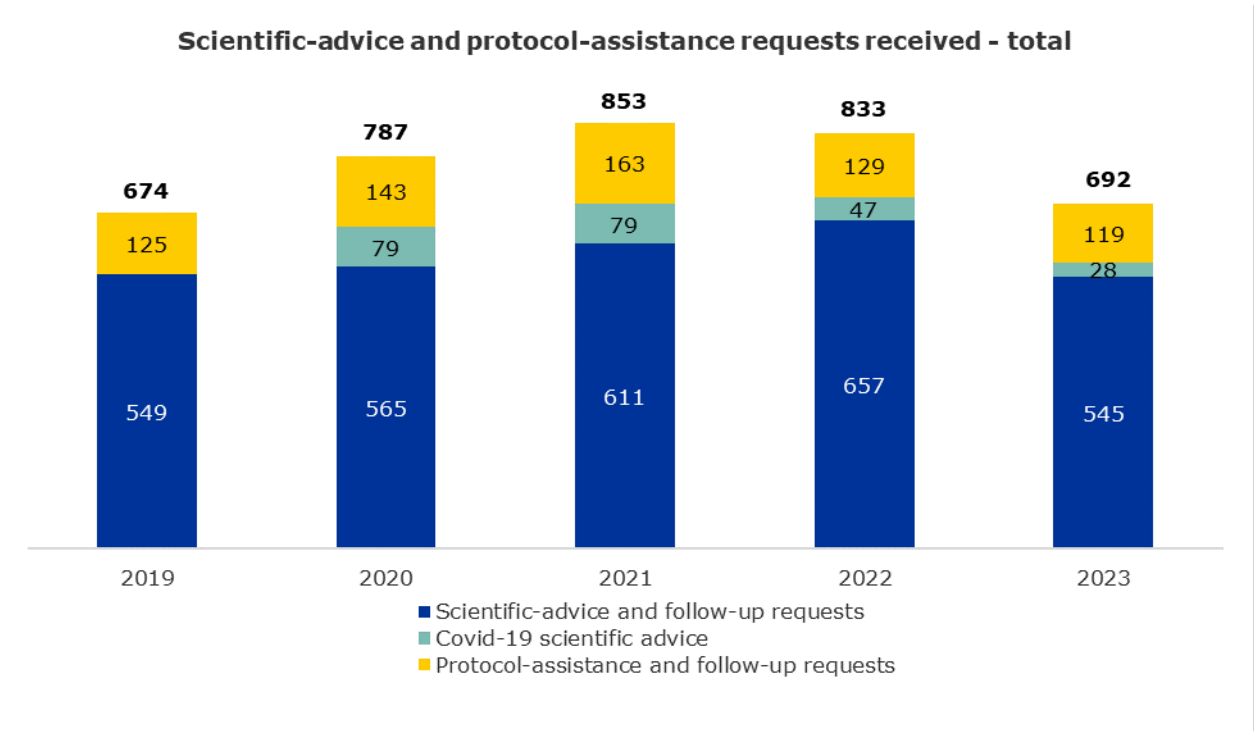
EMA provides guidance and support to medicine developers. This includes scientific and regulatory information on how to design and run clinical trials, compliance standards and obligations and incentives for developers of specialised medicines.

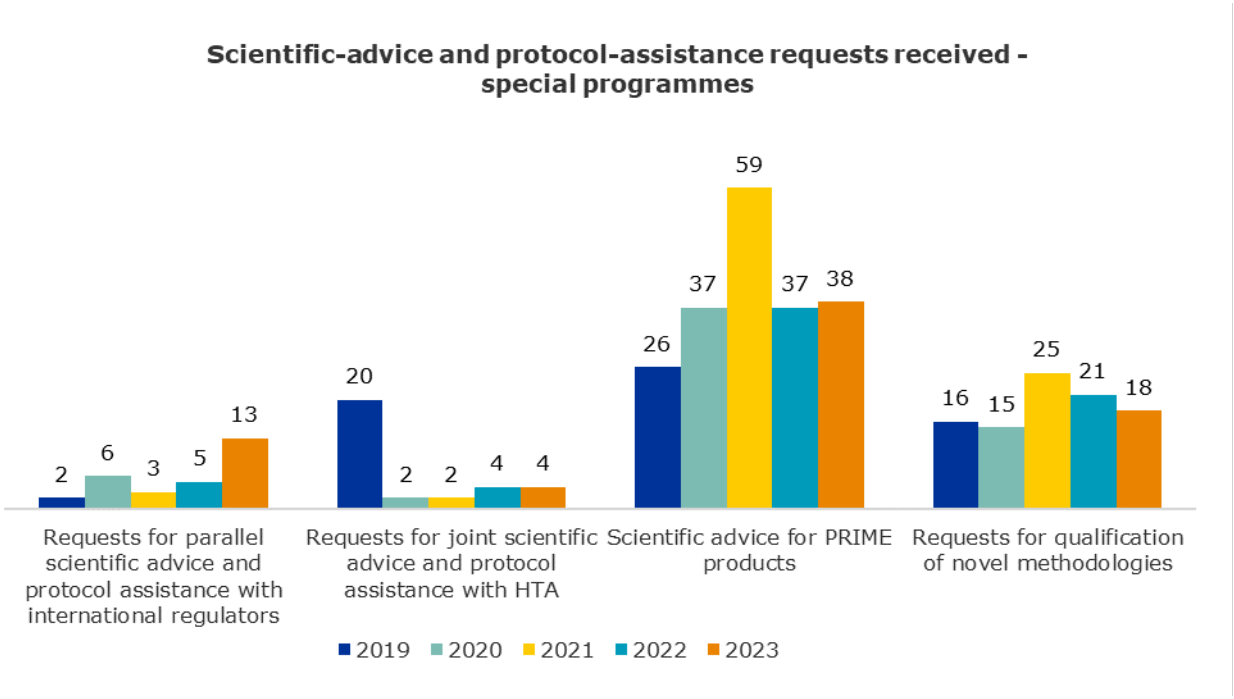
Scientific advice

During a medicine's development, a developer can request guidance and direction from EMA on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. This is known as scientific advice.

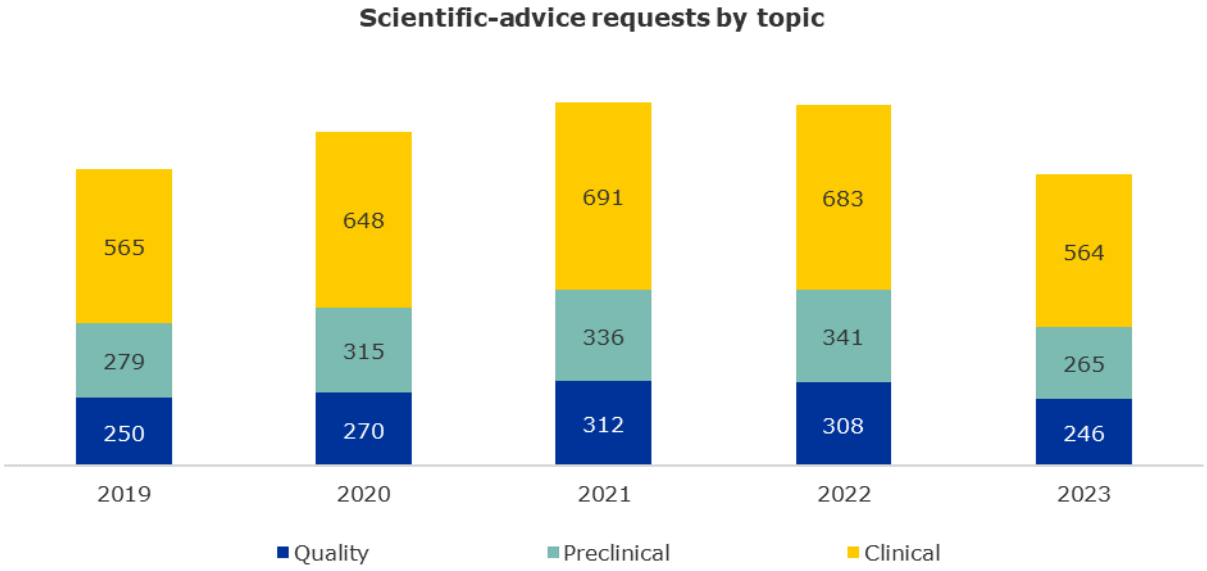
Scientific advice is one of the Agency's key instruments for supporting the development of high-quality, effective and safe medicines, for the benefit of patients. Early dialogue and scientific advice lead to better development plans, promote the collection of high-quality data and, most importantly, help to ensure that patients only take part in those clinical trials that are likely to be robust enough to generate data that are relevant to support the evaluation of a marketing authorisation application or extension of indication.

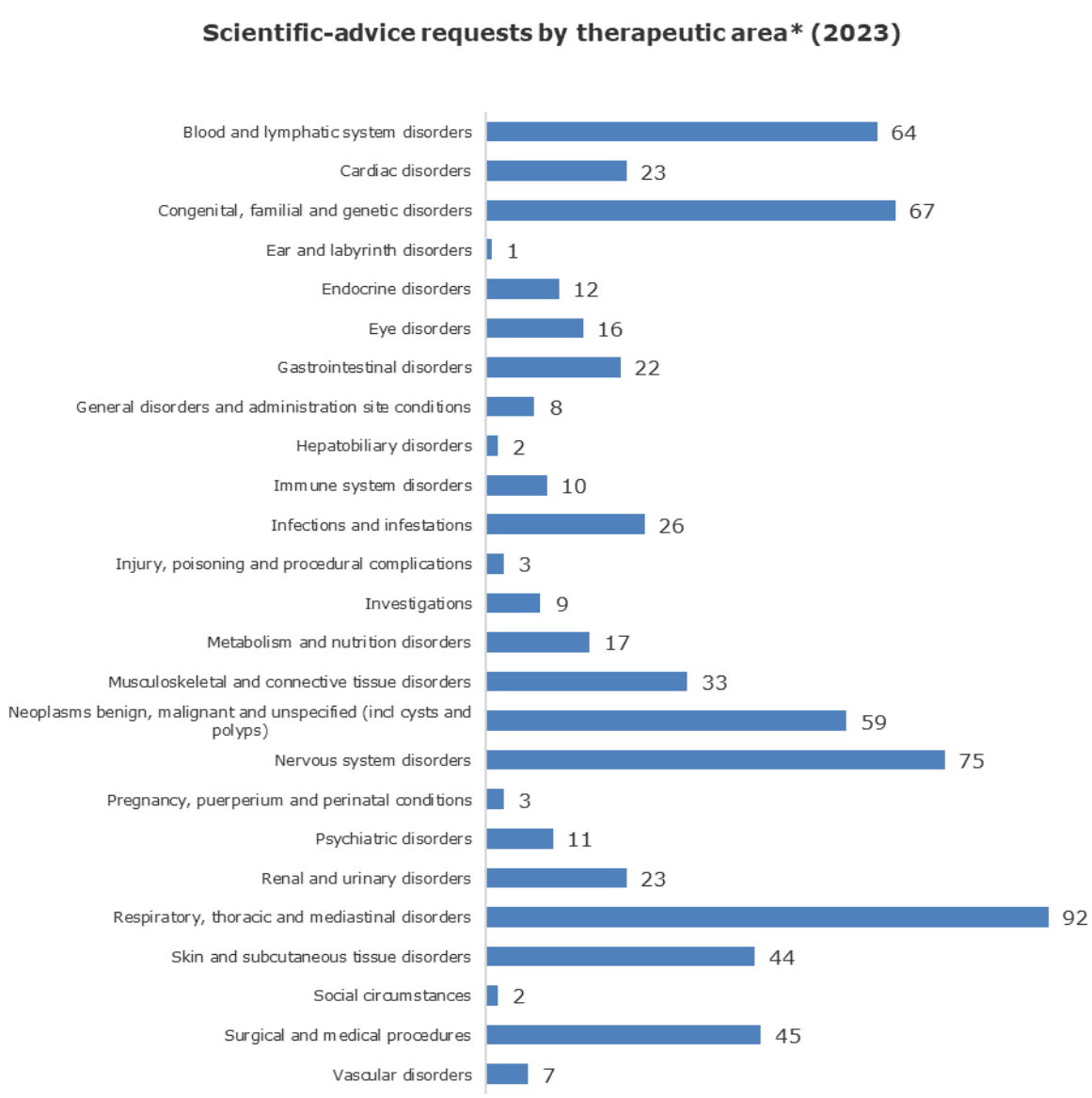
Protocol assistance is the special form of scientific advice for developers of designated orphan medicines for rare diseases.



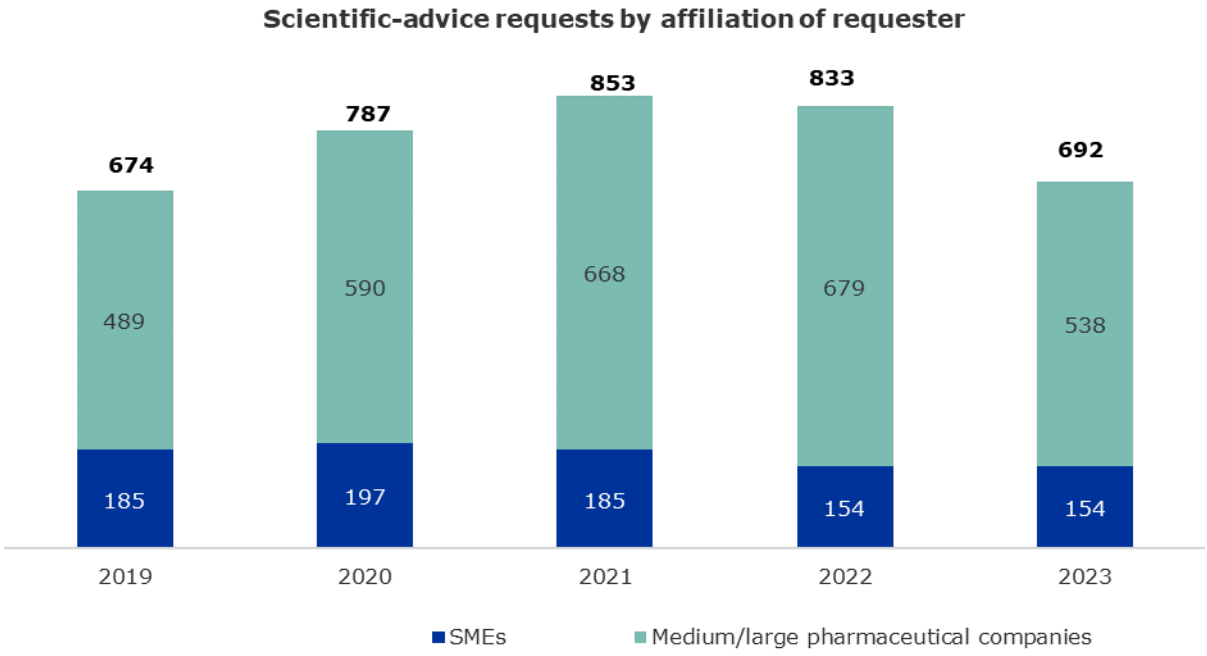


Scientific advice is the core of many of EMA's special programmes to encourage development and availability of new and innovative medicines.





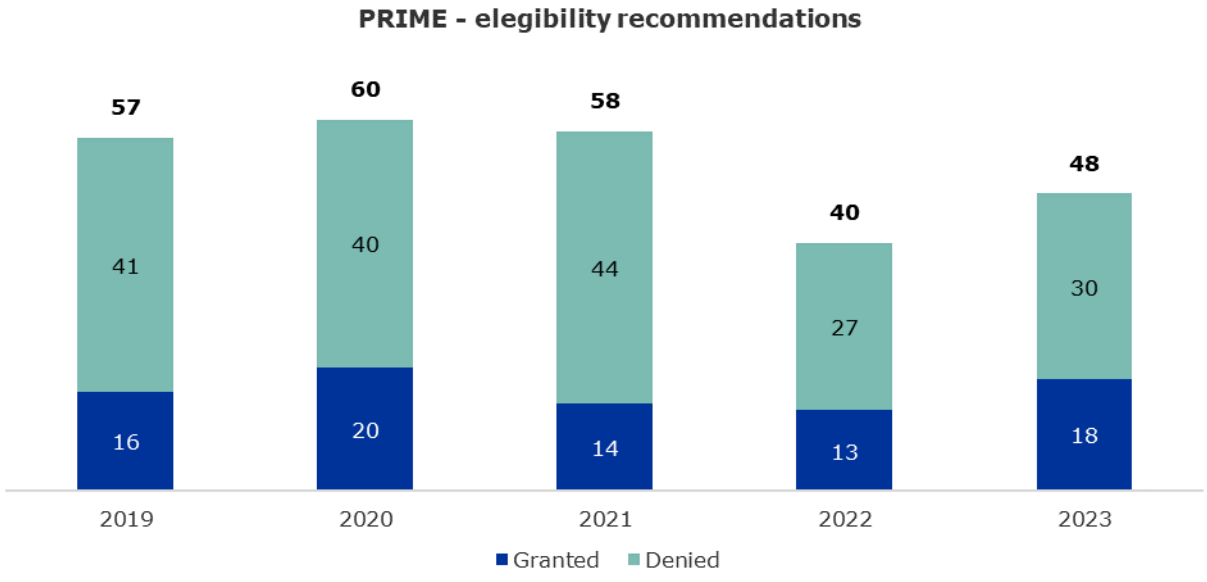
*excludes biomarkers



PRIME

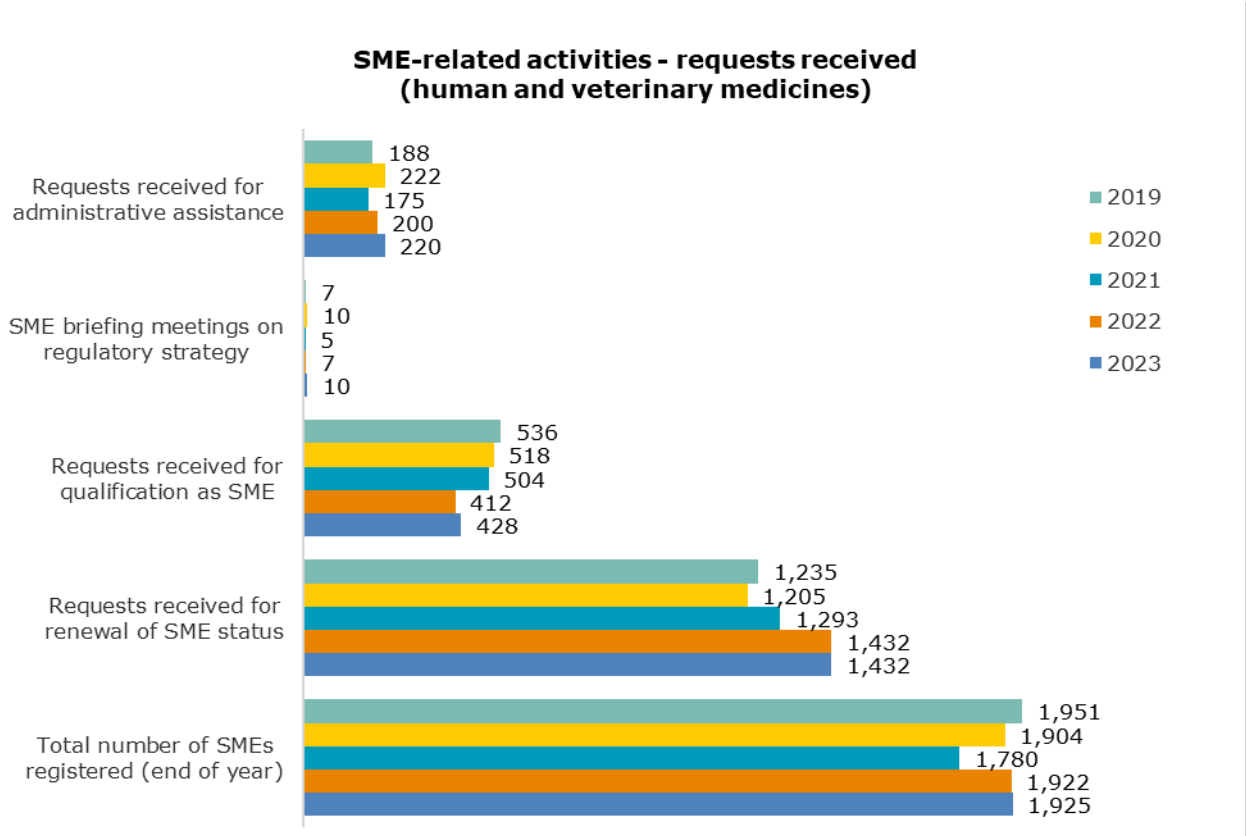
Launched in March 2016, PRIME aims to support and optimise medicine development so that patients who have no or only unsatisfactory treatments for their disease have access to new medicines that enable them to live healthier lives.

PRIME is meant for the most promising medicines and EMA focuses its attention on medicines that have the potential to bring a major therapeutic advantage. That is why, based on PRIME criteria, only a limited number of applications are accepted into the scheme.



Support for SMEs

SMEs are recognised as a driver of innovation in the EU. The Agency promotes innovation and the development of medicines by SMEs through regulatory and administrative support to these companies. The Agency's SME office provides advice and guidance, organises topical workshops and produces a dedicated newsletter for SMEs registered with EMA. These companies also have access to various fee incentives to enable access to regulatory procedures and advice.

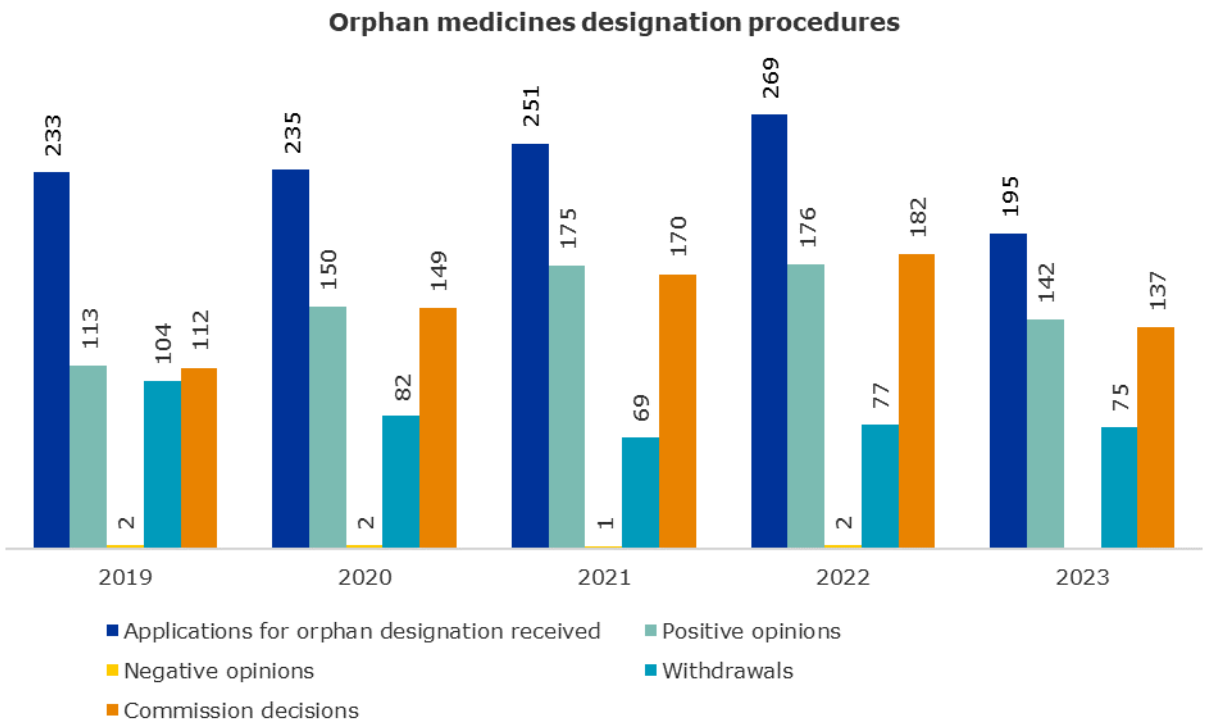


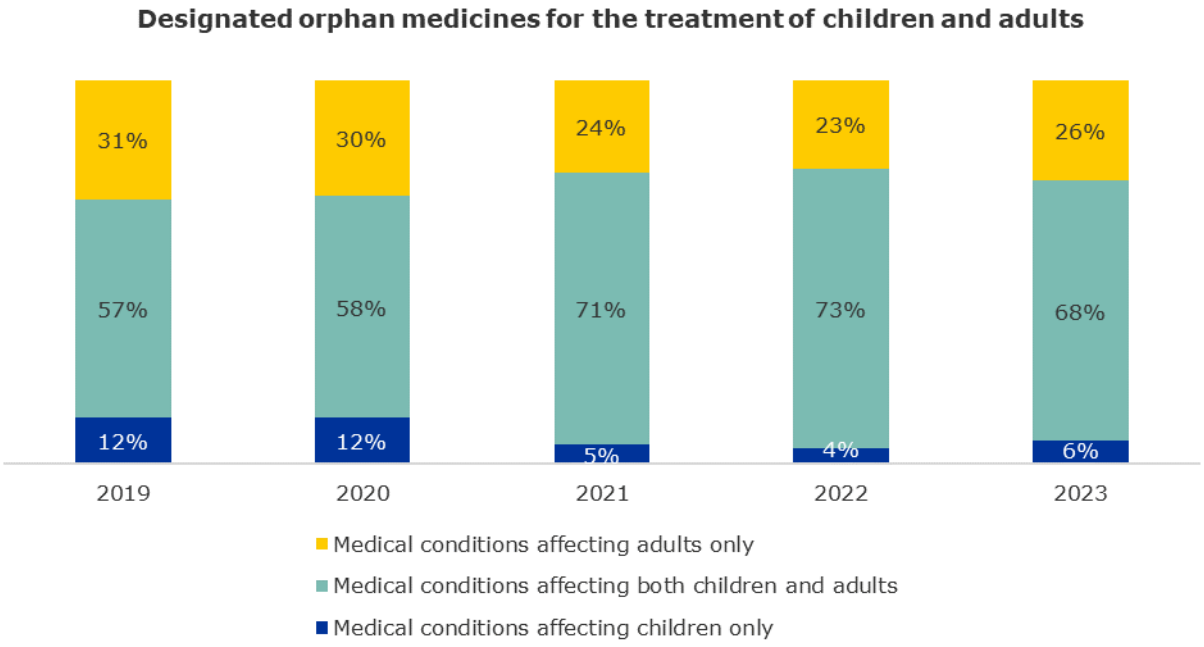
Initial evaluation application and SMEs (human medicines)	2019	2020	2021	2022	2023
Initial MAAs submitted by SMEs	24	23	10	13	10
of which orphan medicines MAAs	13	13	4	5	4
Positive opinions	8	16	11	5	9
of which new active substances	4	8	8	1	3
of which orphan medicines	0	8	4	2	3
Negative opinions	1	1	0	4	1
Withdrawals	3	1	4	3	2

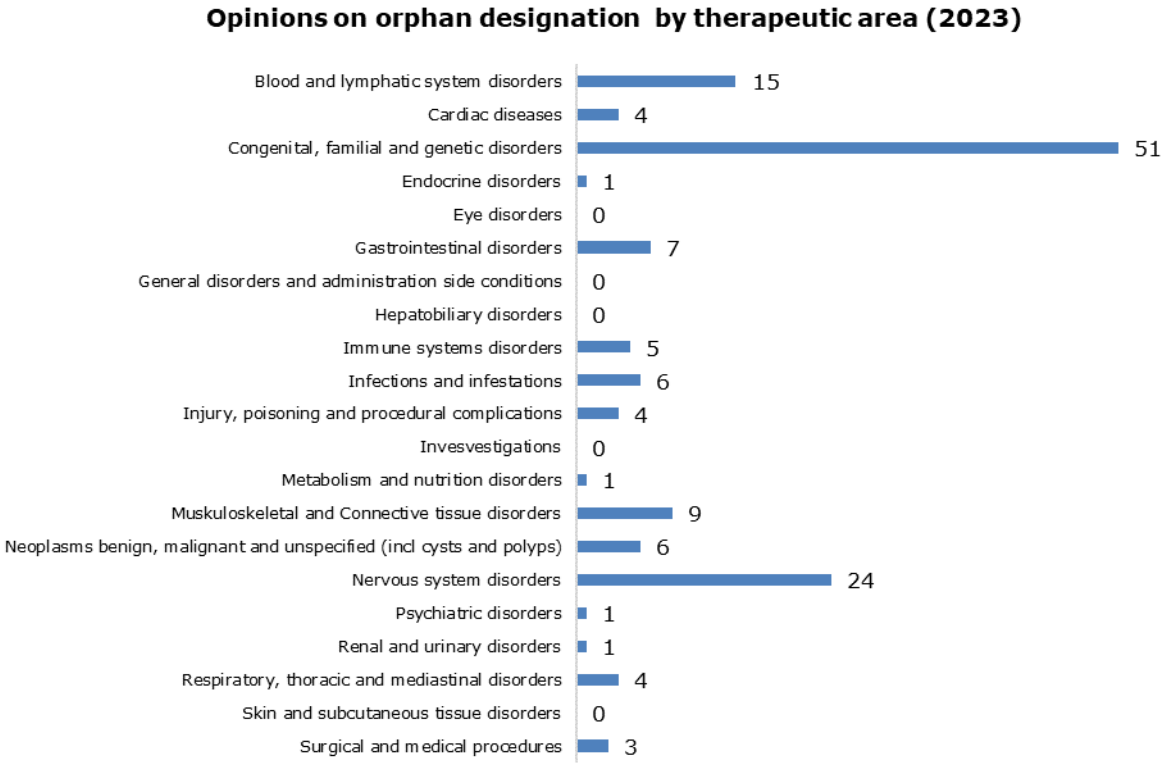
Orphan medicine designation

The EU framework for orphan medicines aims to encourage the development and marketing of medicines for patients with rare diseases by providing incentives for developers.

Medicines with an EU orphan designation benefit from ten years of market exclusivity if they are granted a marketing authorisation and continue to fulfil the criteria for orphan designation. During the development of an orphan medicine, other incentives such as a fee reduction for scientific advice (protocol assistance) are also available for medicine developers. EMA's Committee for Orphan Medicines (COMP) is responsible for assessing orphan designation applications.





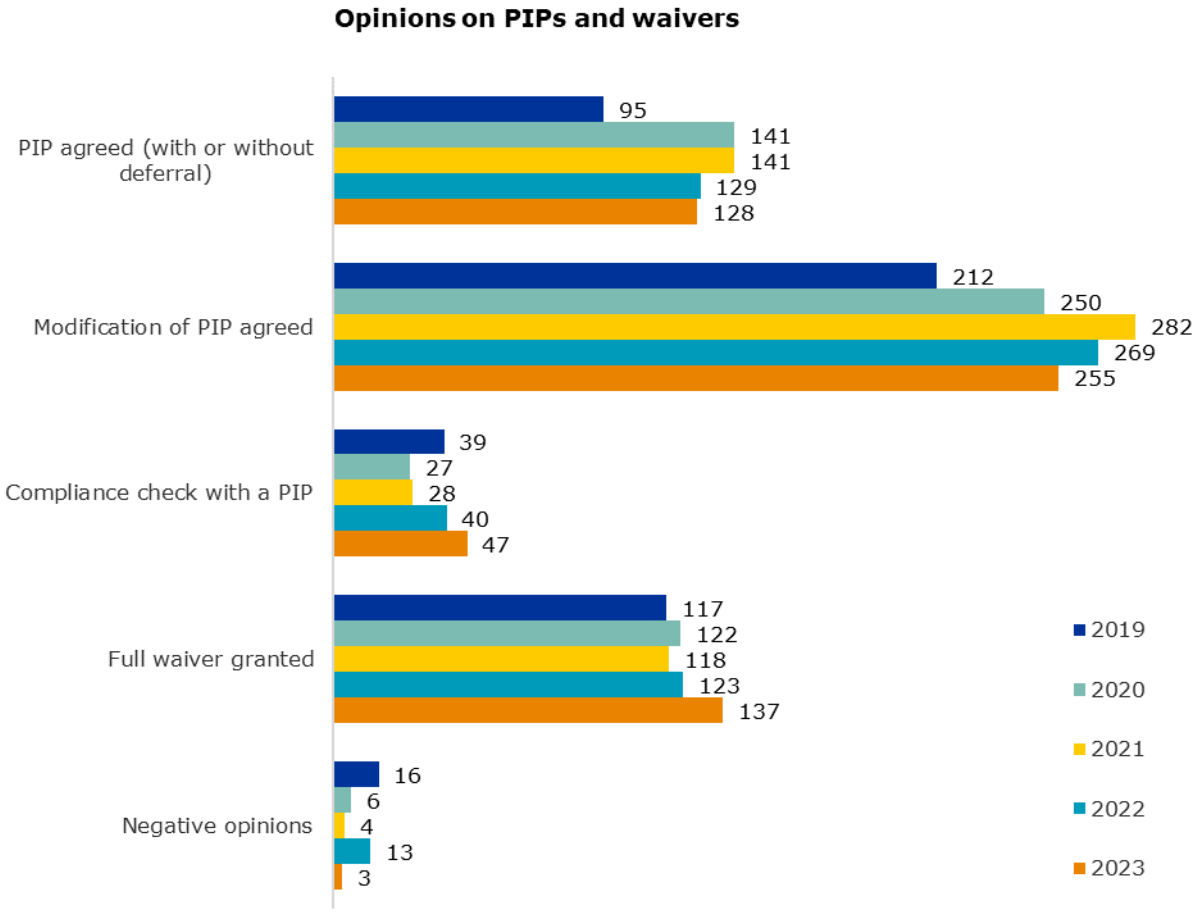


Total 2023: 142

Medicines for children

The Agency also promotes the development of medicines for children. EMA's Paediatric Committee (PDCO) assesses and agrees paediatric investigation plans (PIPs) as well as PIP waivers for medicines that are unlikely to benefit children. The committee also checks compliance with a PIP at the time of the submission of a marketing authorisation. To support research and development of medicines for children, EMA provides the secretariat for the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA).

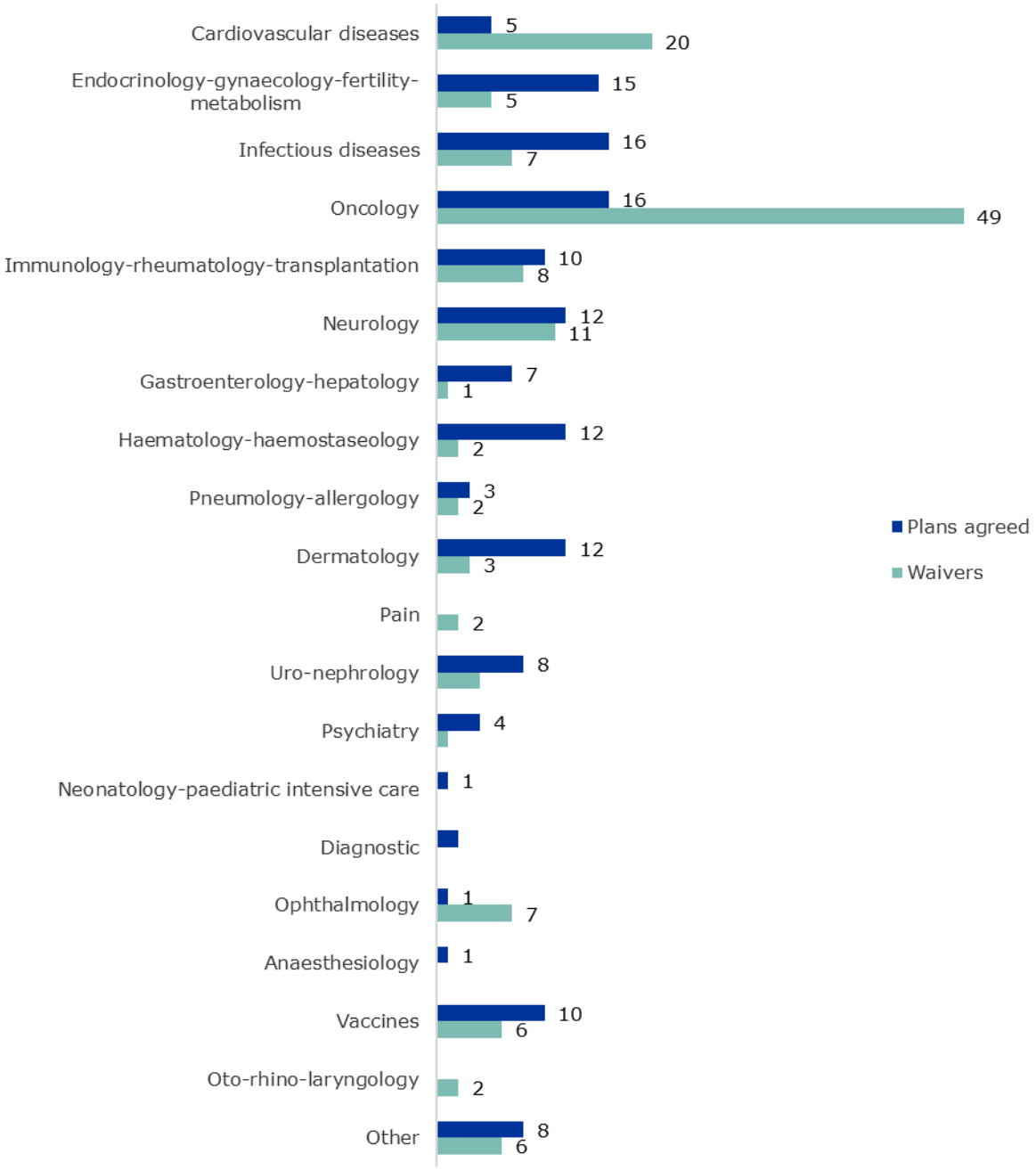
A PIP is a development plan aimed at ensuring that the necessary data are obtained through studies in children to support the authorisation of a medicine for children. Where studies in children are inappropriate or unnecessary, a waiver may be granted.



Total 2023: 570

Article 46 of the Paediatric Regulation requires marketing authorisation holders to submit studies on the use of already authorised medicines in children to regulatory authorities. This ensures that all paediatric studies are assessed by the relevant competent authorities. These studies are available to the public through the EU Clinical Trials Register.

Paediatric investigation plans agreed and waivers granted (2023)*

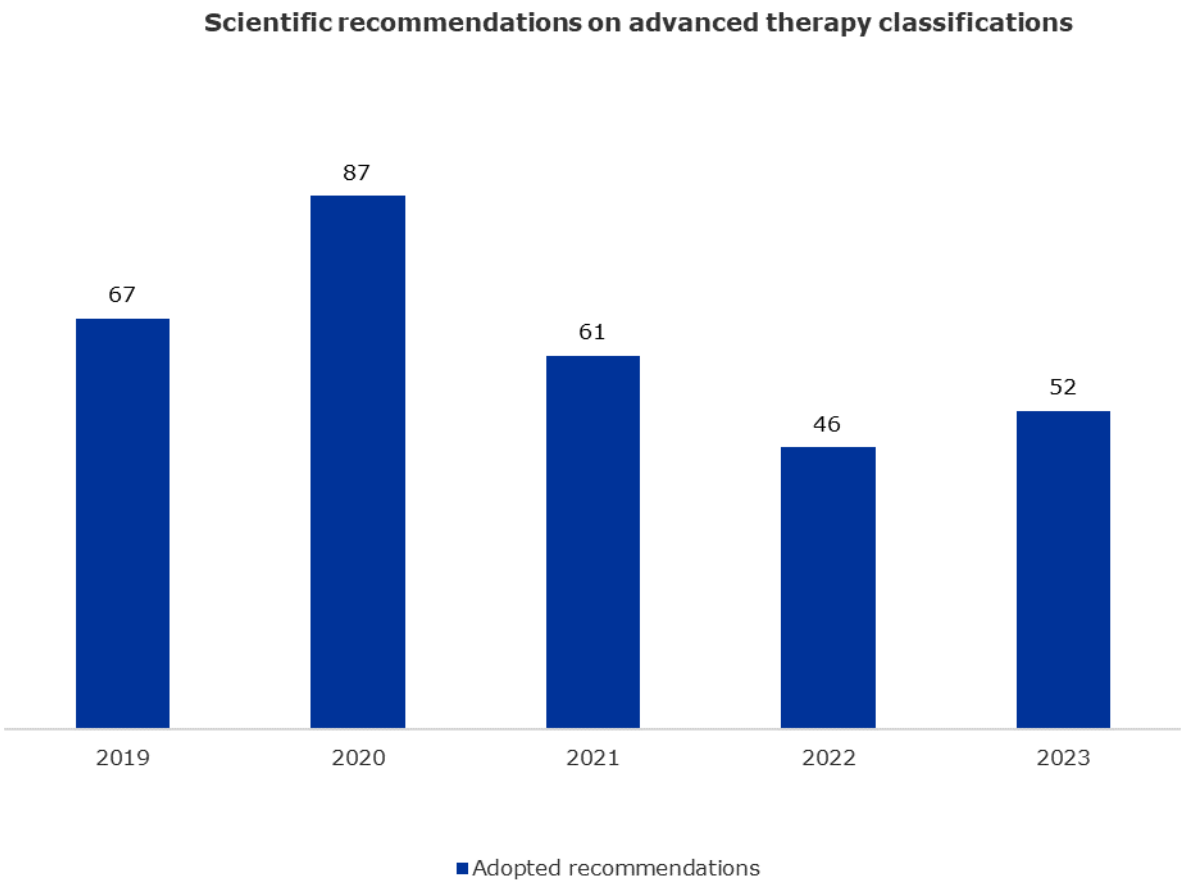


* Graph based on initial PIPs only. One opinion can cover several areas, therefore the total of areas is higher than the number of the opinions adopted.

Advanced-therapy medicinal products

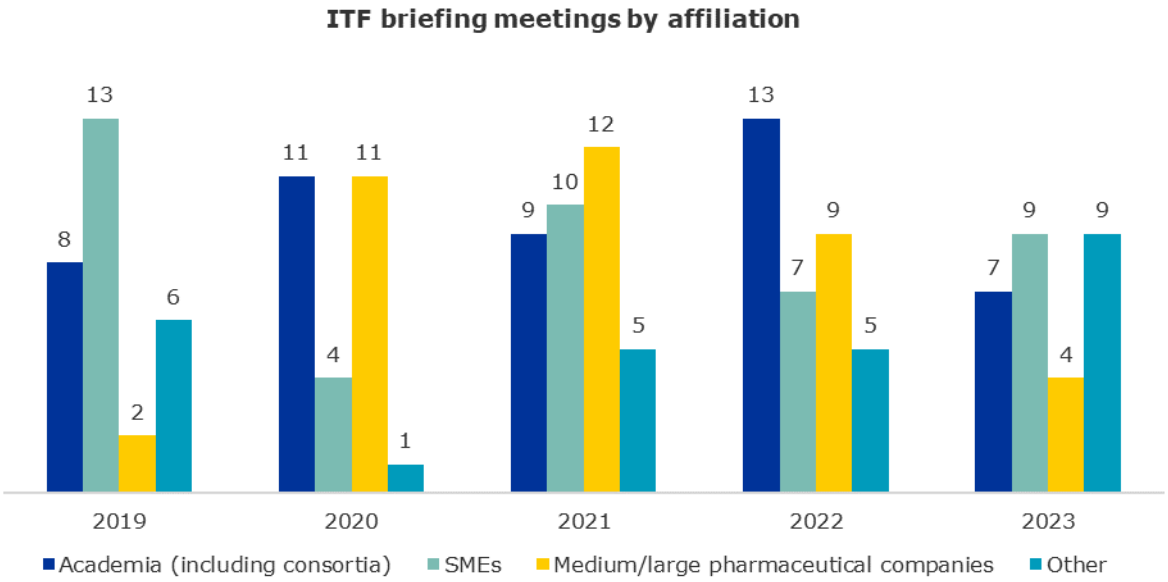
Advanced-therapy medicinal products (ATMPs) are medicines based on genes or cells that have the potential for ground-breaking new treatments. They are particularly important for severe, untreatable or chronic diseases for which conventional approaches have proven to be inadequate.

The Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety and efficacy of ATMPs. It prepares a draft opinion on each ATMP application before the CHMP adopts a final opinion for the medicine concerned. The CAT also reviews requests for the certification of quality and non-clinical data for SMEs developing ATMPs and provides scientific recommendations on the classification of a medicine as an ATMP.

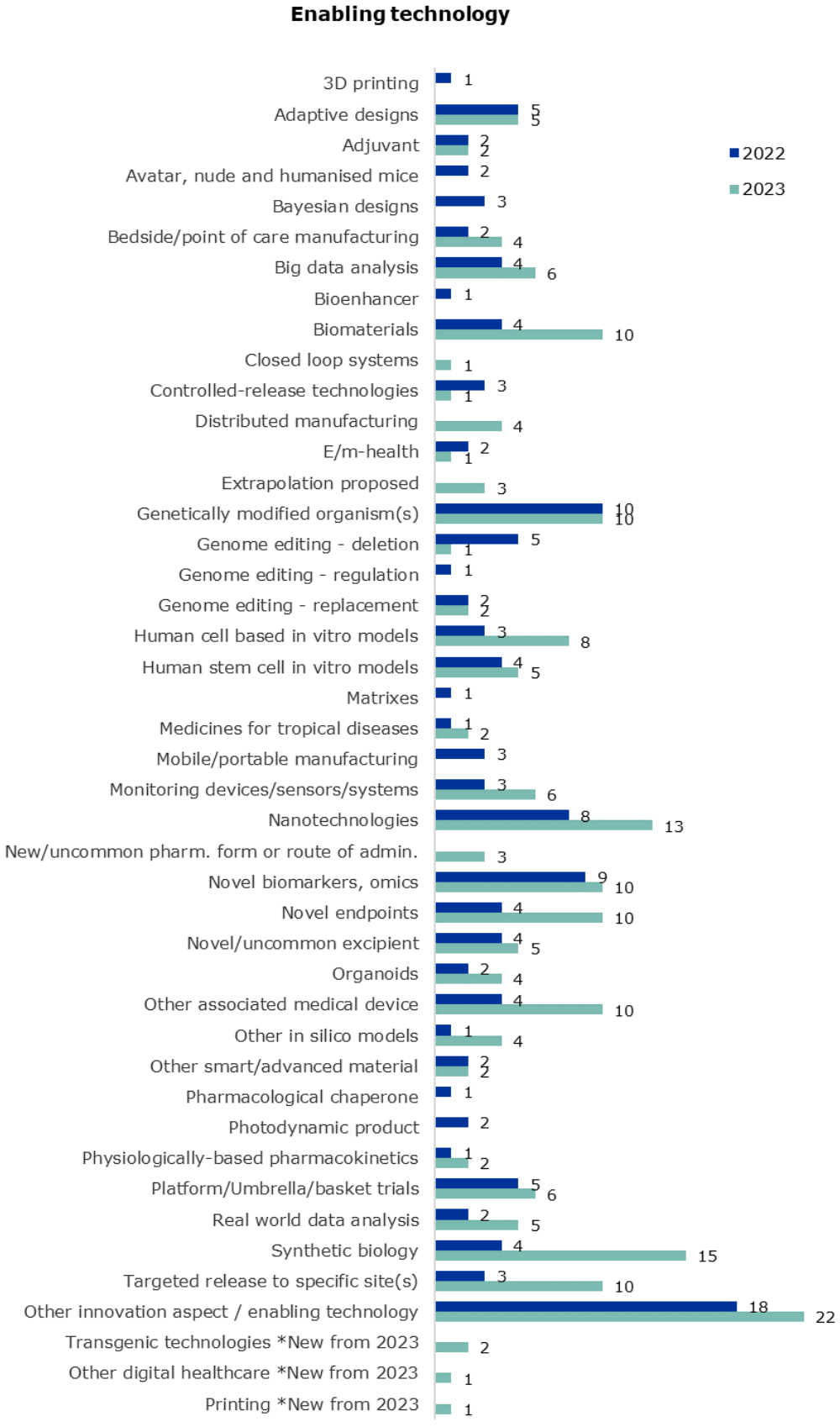


Innovation Task Force

The Innovation Task Force (ITF) is a multidisciplinary group that includes scientific, regulatory and legal competences. It provides a forum for early dialogue with applicants, in particular SMEs and academic sponsors, to proactively identify scientific, legal and regulatory issues linked to innovative therapies and technologies.


ITF briefing meetings by affiliation
13
8
2
6
11
4
11
1
9
10
12
5
13
7
9
5
7
9
4
9
2019
2020
2021
2022
2023
Academia (including consortia)
SMEs
Medium/large pharmaceutical companies
Other

Each request could be associated with up to three of the categories in the table:

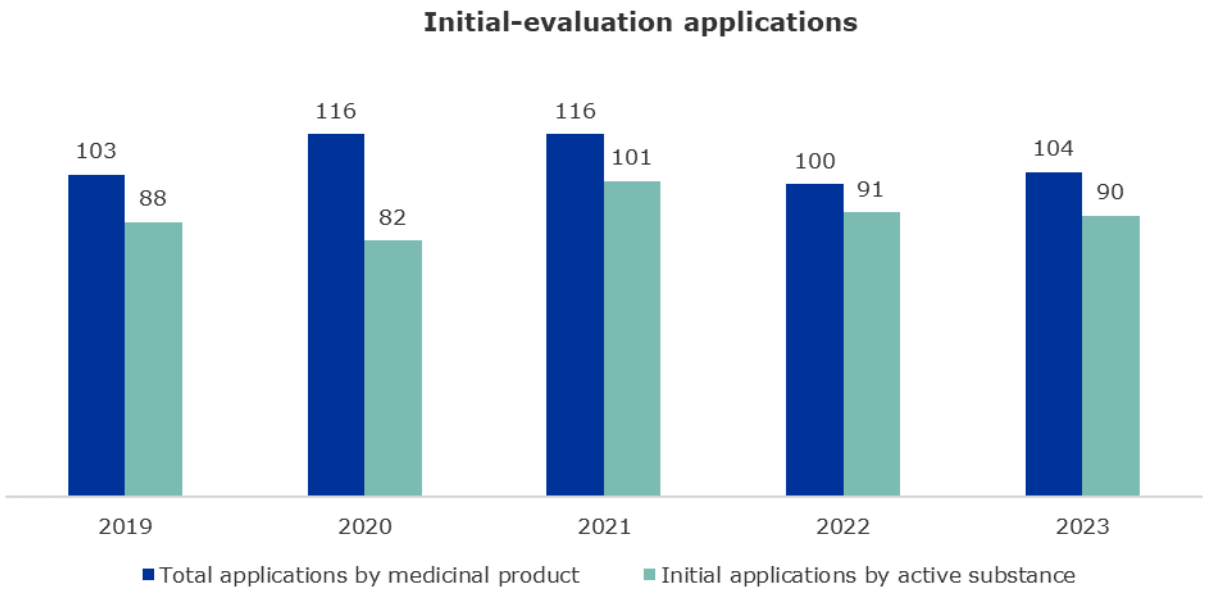


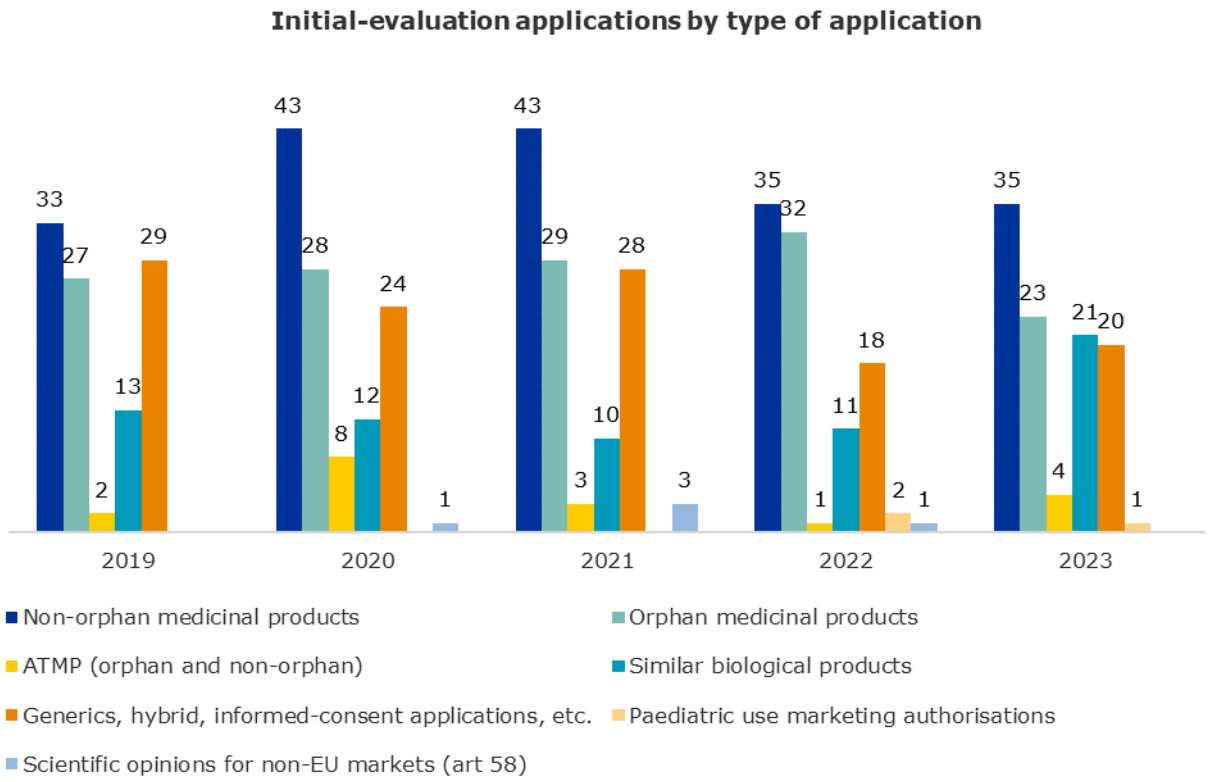
1.2. Recommendations for marketing authorisation

Applications for initial evaluation

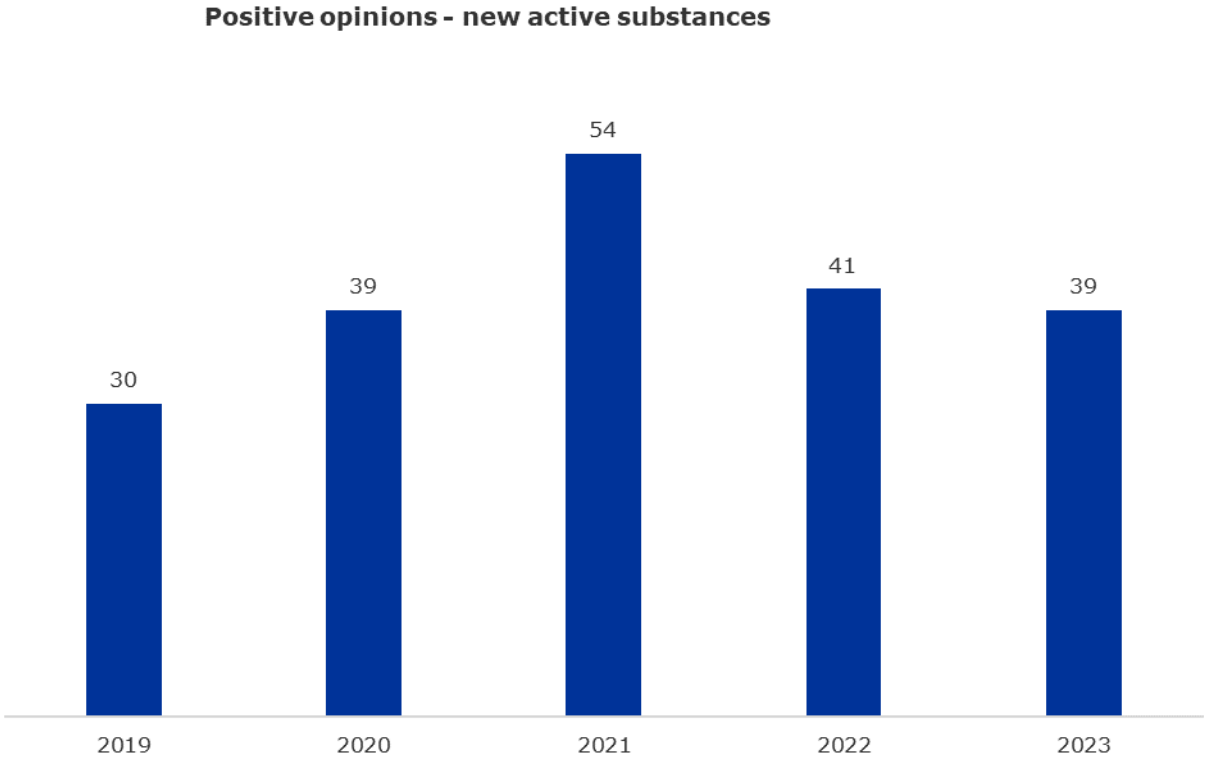
EMA's scientific committees carry out robust scientific evaluations of medicines and issue recommendations for the European Commission, which ultimately decides whether or not to authorise a medicine for marketing throughout the EU.

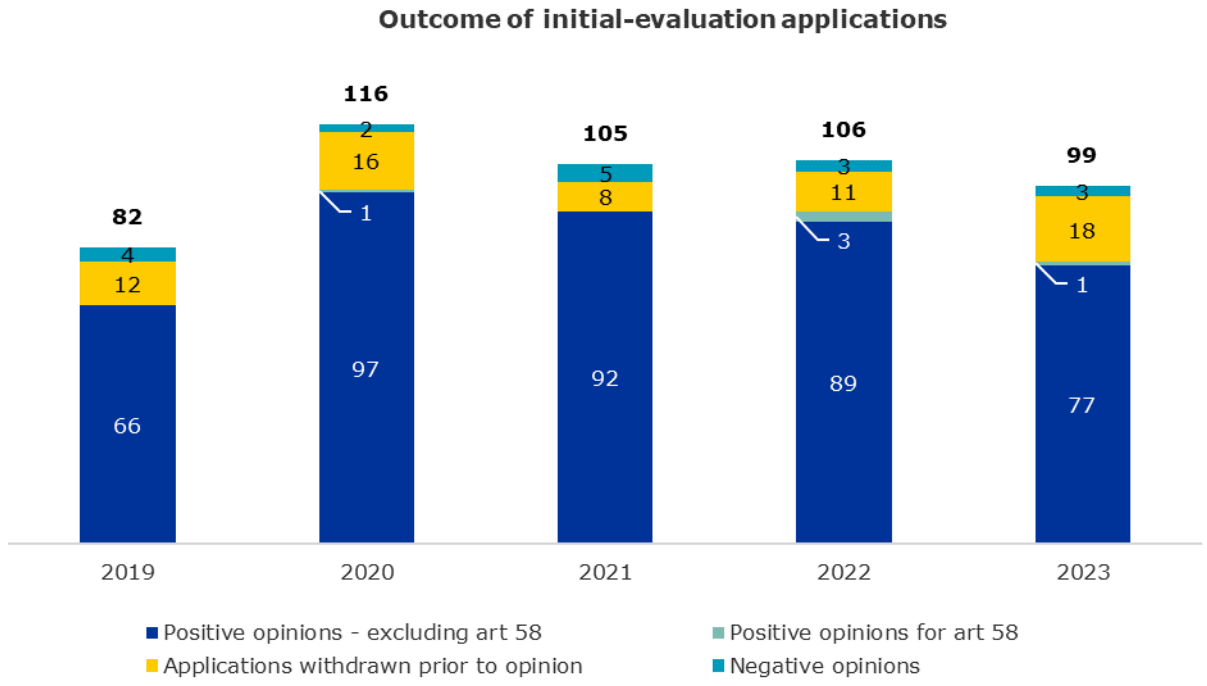
The initial evaluation covers all activities relating to the processing of marketing authorisation applications for new medicines which have never been assessed before, from the pre-submission discussion with future applicants, through to the evaluation by the CHMP and the granting of the marketing authorisation by the European Commission.




Initial-evaluation applications by type of application
33
27
2
13
29
43
28
8
12
24
1
43
29
3
10
28
3
35
32
1
11
18
2
1
35
23
4
21
20
1
2019
2020
2021
2022
2023
Non-orphan medicinal products
Orphan medicinal products
ATMP (orphan and non-orphan)
Similar biological products
Generics, hybrid, informed-consent applications, etc.
Paediatric use marketing authorisations
Scientific opinions for non-EU markets (art 58)

Outcome of initial evaluation





CMA and switch to standard marketing authorisation (excluding withdrawals)	2019	2020	2021	2022	2023
Positive opinions for CMAs	8	13	13	9	8
Opinions recommending switch of CMA to standard marketing authorisation	1	2	1	14	6
Opinions recommending revocation of MA	1	0	0	0	2

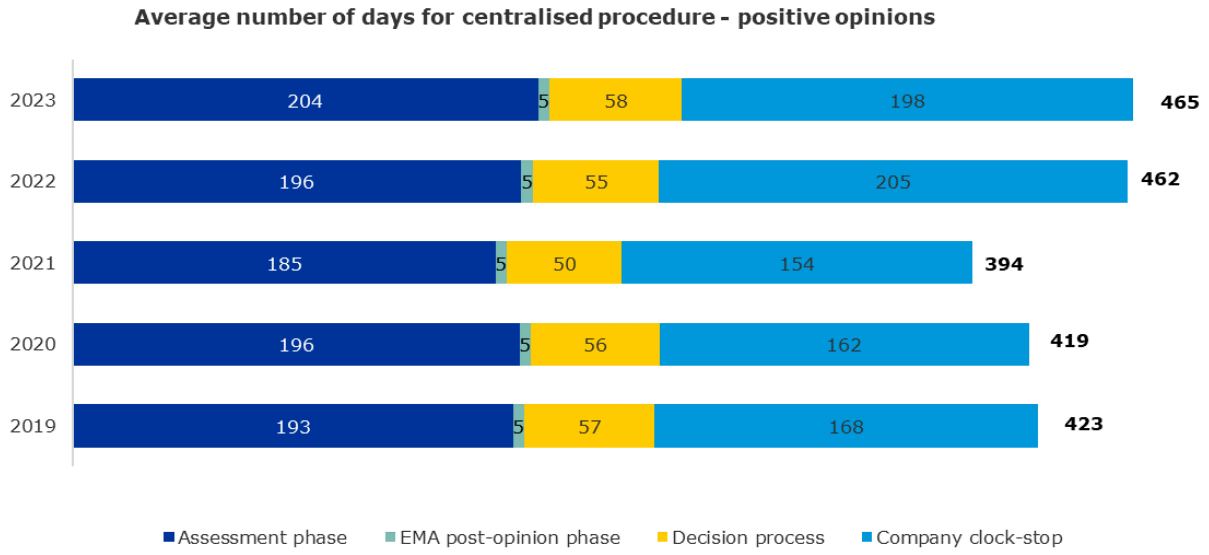
Accelerated assessment

This mechanism is reserved for medicines that can address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees.

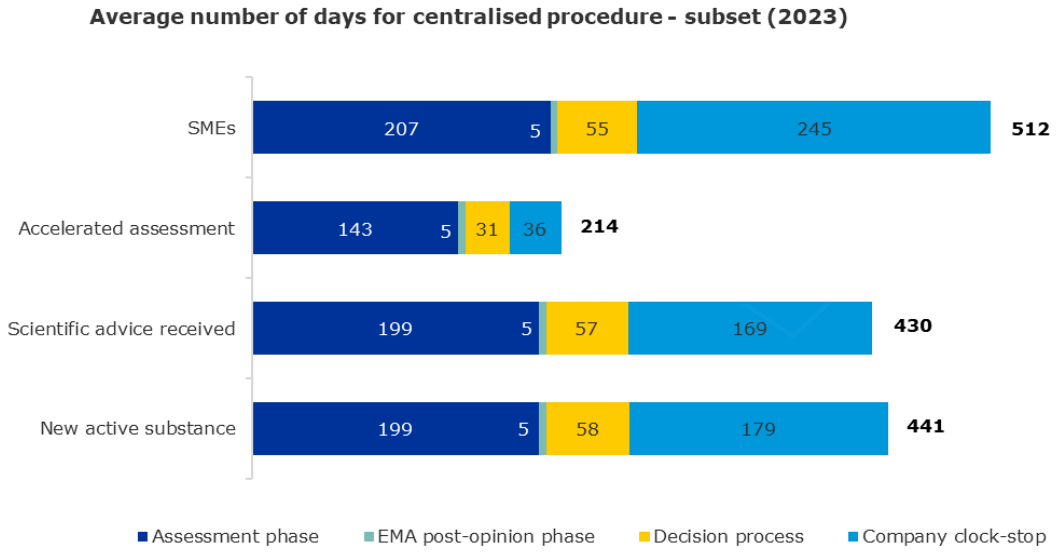
Average assessment time

EMA has a maximum of 210 active days to carry out its assessment. Within this time frame, the CHMP must issue a scientific opinion on whether the medicine under evaluation should be authorised. During the assessment, concerns with the application may be identified requiring further information or clarification from the company. In this case, the clock is stopped to give the company time to reply to the Agency. Once the reply is received, the counting of the days continues.

Once issued, the CHMP opinion is transmitted to the European Commission, which has the ultimate authority to grant a marketing authorisation and will take a decision within 67 days of receipt of the CHMP opinion.



Note: The average time for the decision process includes, in the case of orphan medicinal products, the time for the finalisation of the review of orphan designations carried out by EMA's COMP.



Post-authorisation activities

In 2023, EMA started the evaluation of:

- 3,864 type-IA variations;
- 3,332 type IB variations;
- 1,201 type-II variations;
- 94 extensions of marketing authorisations.

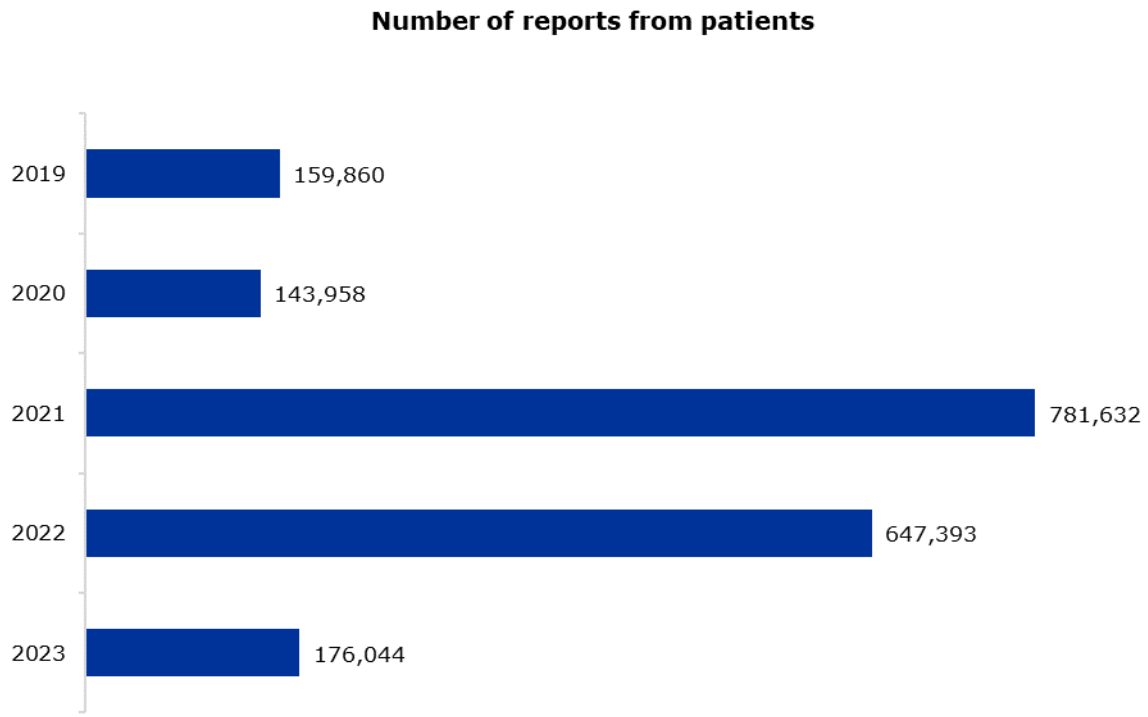
1.3. Safety monitoring of medicines

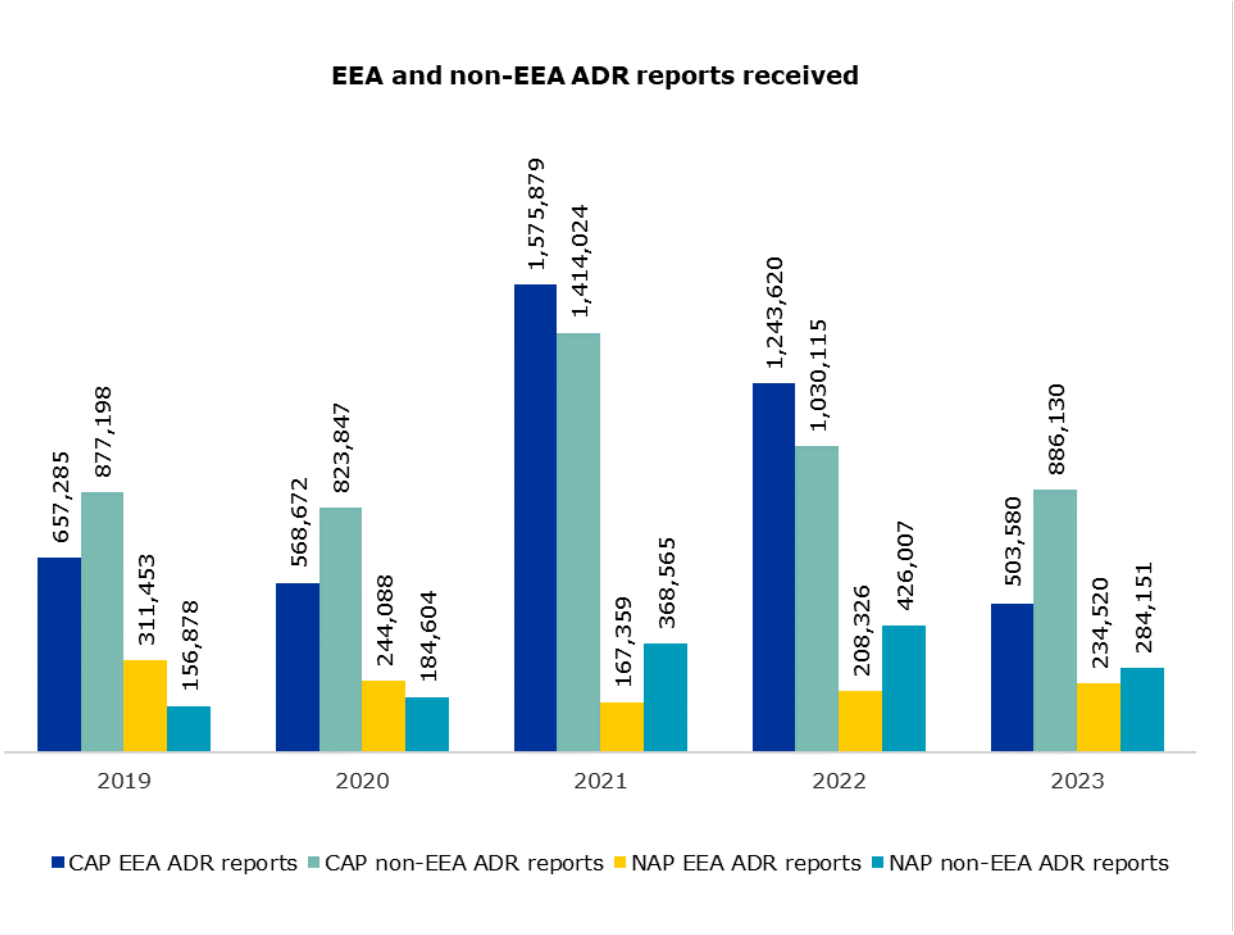
EMA and EU Member States are responsible for coordinating the EU's safety monitoring of medicines, also known as 'pharmacovigilance'. The regulatory authorities constantly monitor the safety of medicines and can take action on an indication that a medicine's safety profile or benefit-risk balance has changed since it was authorised. EMA's safety committee, the PRAC, plays a key role in overseeing the safety of medicines in the EU as it covers all aspects of safety monitoring and risk management.

The Agency's main responsibilities in relation to the safety-monitoring of medicines include coordination of the European pharmacovigilance system, setting standards and guidelines for pharmacovigilance, provision of information on the safe and effective use of medicines, detecting new safety issues for centrally authorised products (CAPs), managing assessment procedures, e.g. for periodic safety update reports (PSURs), and the operation and maintenance of the EudraVigilance system.

EudraVigilance

Both EMA and national competent authorities (NCAs) are legally required to continuously monitor the adverse drug reaction (ADR) data reported to EudraVigilance to determine whether new or changed risks have been identified and whether these risks have an impact on a medicine's overall benefit-risk balance.



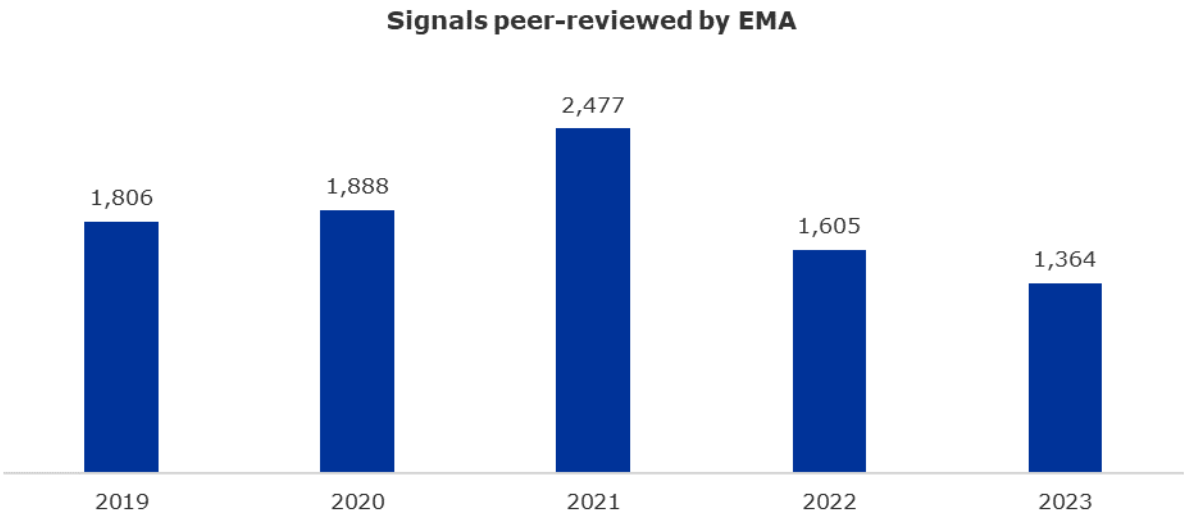


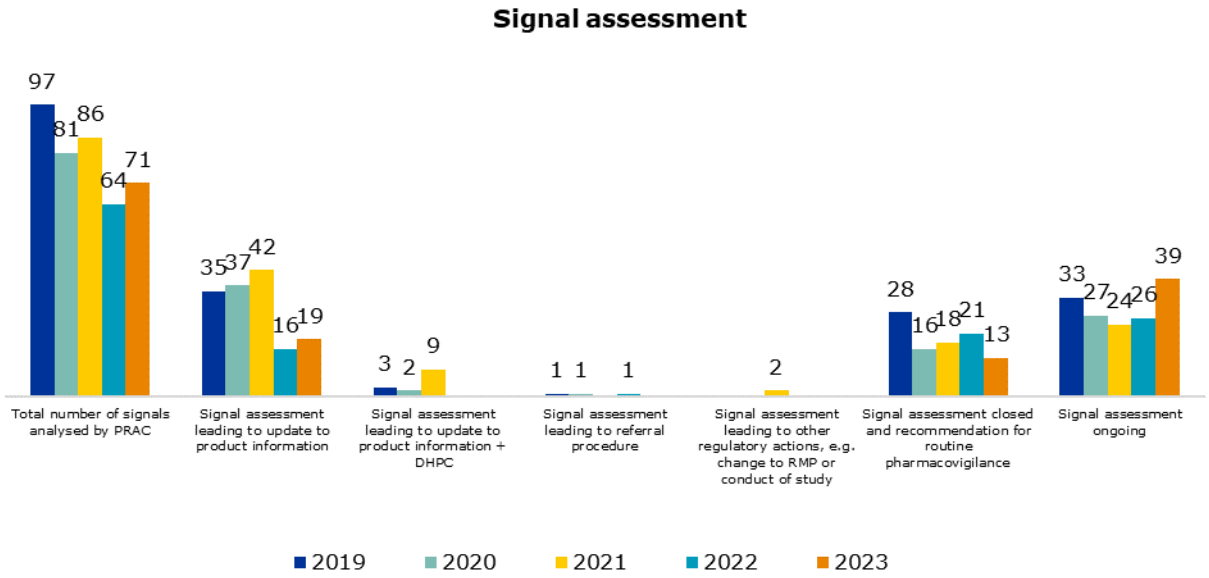
Note: Following the launch of the new EudraVigilance system in November 2017, figures in 2018, 2019, 2020, 2021, 2022 and 2023 include reports of nonserious, in addition to serious suspected adverse drug reactions.

Signal detection

A safety signal is information on a new or known adverse event that is potentially caused by a medicine and warrants further investigation. Signals are generated from several sources, such as spontaneous reports of suspected adverse reactions, clinical studies and the scientific literature. The evaluation of a safety signal is a routine pharmacovigilance activity to establish whether there is a causal relationship between a medicine and a reported adverse event.

In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary. This mainly comprises changes in the information on medicines available for patients (in the package leaflet) and prescribers (in the summary of product characteristics).





Signal assessment ongoing: Data from previous years (2019-2022) are all related to the situation at data cut by the end of each calendar year.

Outcome of signal assessment	2023
Signals peer reviewed by EMA	1,364
Signals assessed by PRAC (validated by EMA)	39
Signals assessed by PRAC (validated by Member States)	32
Signal assessment leading to update to product information	19
Signal assessment closed and recommendation for routine pharmacovigilance	13
Signal assessment ongoing	39

Periodic safety update reports (PSURs)

Marketing authorisation holders are required to submit a report on the evaluation of a medicine's benefit-risk balance to the regulatory authorities at regular, predefined intervals following the authorisation of a medicine. These reports summarise data on the benefits and risks of a medicine and take into consideration all studies carried out with it, both in authorised and unauthorised indications.

The Agency is responsible for procedures supporting the analysis of these reports for both CAPs and for nationally authorised medicines (NAPs) that are authorised in more than one Member State. These reports are called PSURs. When the assessment procedure involves more than one medicinal product with the same active substance, the procedures are referred to as periodic safety update single assessments or PSUSAs.

PSURs and PSUSAs finalised					
	2019	2020	2021	2022	2023
PSURs stand-alone (CAPs only) finalised	558	516	575	542	570
PSURs single assessment finalised	270	258	336	318	276
PSURs single assessment (CAPs with NAPs) finalised	48	49	49	46	37
PSURs single assessment (NAPs only) finalised	222	209	287	272	239
Total outcomes	828	774	911	860	846

PRAC outcomes of PSURs and PSUSAs					
	2019	**2020**	**2021**	**2022**	**2023**
Maintenance	655	630	748	720	718
NAPs only	166	161	226	216	196
CAPs/NAPs and CAPs only	489	469	522	504	522
CHMP Variation	173	144	163	140	128
NAPs only	56	48	61	56	43
CAPs/NAPs and CAPs only	117	96	102	84	85
Total outcomes	828	774	911	860	846

Post-authorisation safety studies and post-authorisation efficacy studies

A post-authorisation safety study (PASS) can be carried out after a medicine has been authorised to obtain further information on its safety, or to determine the effectiveness of risk-management measures. A PASS can be imposed on MAHs as part of their post-authorisation obligations. The PRAC is responsible for assessing the protocols of imposed PASS and their results. The PRAC also reviews protocols of large numbers of voluntarily submitted PASS in the context of RMP assessments.

In 2023, the PRAC assessed 40 imposed PASS protocols (14 PASS protocols and 26 PASS amendments) that were requested to obtain further information on a medicine's safety, which was in line with 2022. The Committee assessed 234 non imposed PASS protocols. In addition, the PRAC started to assess the results of seven imposed PASS.

Post authorisation safety studies					
	2019	**2020**	**2021**	**2022**	**2023**
Imposed PASS protocol procedures started	12	17	22	17	14
Imposed PASS protocol procedures finalised	13	13	23	16	14
Non-imposed PASS protocol procedures started	144	158	143	217	189
Non-imposed PASS protocol procedures finalised	180	167	226	233	234
PASS amendment - started	11 (started), 9 (finalised)	19 (started), 14 (finalised) + 9 follow up amendments (started) and 7 (finalised)	17 (started), 18 (finalised) + 15 follow up amendments (started) and 11 (finalised)	20 (started), 18 (finalised) + 12 follow up amendments (started) and 14 (finalised)	21 (8 PASS amendment + 13 PASS amendment follow up)
Imposed PASS result procedures started	3	4	11	2	7
Imposed PASS result procedures finalised	3	2	6	5	7
PASS scientific advice through SAWP	3	1	1	1	1

Post-authorisation efficacy studies (PAES) are also conducted after a medicine has been granted a marketing authorisation to collect data on aspects of the benefits in its approved indication that can only be explored once the medicine is marketed.

Post authorisation efficacy studies					
	2019	**2020**	**2021**	**2022**	**2023**
PAES (imposed)	9	8	8	10	13
PAES (non-imposed)	0	0	0	0	0

1.2.1. Withdrawals

Companies are required to report the cessation of the marketing of a medicine in any Member State for reasons affecting patient safety so that regulatory authorities can ensure that the same action is taken across all Member States. For CAPs, companies also need to notify EMA of withdrawals for commercial reasons. The Agency is responsible for coordinating these actions across the EU. These notifications are forwarded to all NCAs in the EEA. The list of withdrawn products is also published on the EMA website.

Other pharmacovigilance activities

Additional monitoring aims primarily to enhance ADR reporting for certain types of medicines. The list of medicines under additional monitoring is reviewed every month by the PRAC and is available on EMA's website and also published by the NCAs.

These medicines are identified by an inverted black triangle on their packaging. The EU incident management plan is coordinated by EMA and aims to ensure that concerned bodies in the EU take appropriate action whenever new events or information (known in this context as incidents) arise concerning human medicines. It covers medicines authorised centrally, nationally and through the decentralised and mutual-recognition procedures. The plan's operation involves representatives from EMA, the European Commission and regulatory authorities in the Member States.

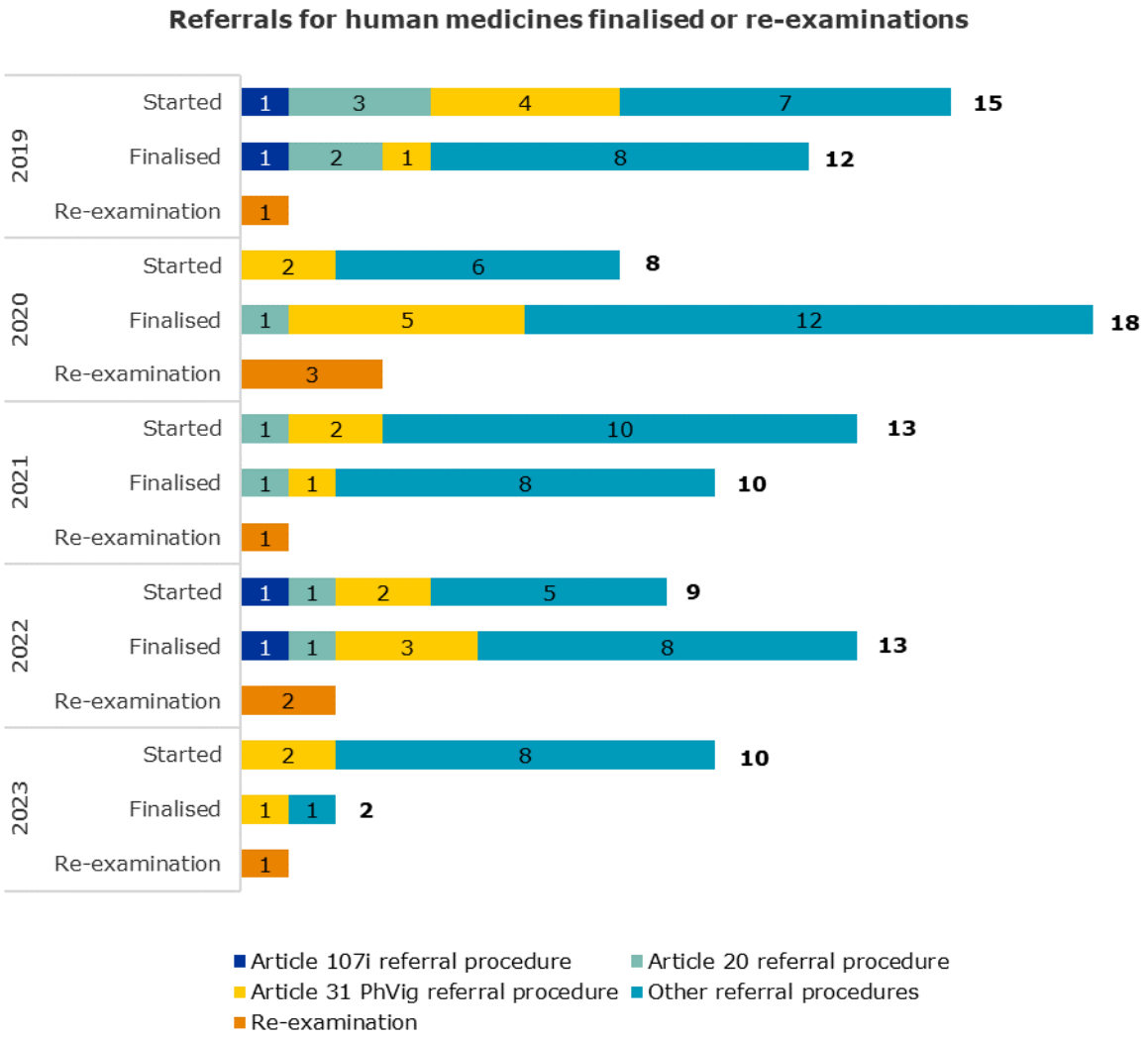
The European pharmacovigilance issues tracking tool (EPITT) is a database developed by EMA to promote the discussion of pharmacovigilance and risk-management issues between the Agency and Member States. It provides access to documents related to the safety of medicinal products/substances authorised in the EEA. EPITT helps medicines regulatory authorities in the EEA and EMA to track signals at EU level.

Scientific and medical literature is an important source of information to identify suspected adverse reactions with medicines authorised in the EU. EMA is responsible for monitoring a number of substances and selected medical literature to identify suspected adverse reactions with such medicines, and for entering the relevant information into the EudraVigilance database.

Other pharmacovigilance activities					
	2019	**2020**	**2021**	**2022**	**2023**
Cumulative number of products on the list of products to be subject to additional monitoring	342	343	372	365	351
Number of Incident management plans triggered	3	6	4	2	0
Number of non-urgent information or rapid alert notifications submitted through EPITT	43	15	20	30	24
Number of external requests for EV analyses	13	15	30	16	14
Number of MLM ICSRs created	9,676	9,550	9,193	8,278	9,698

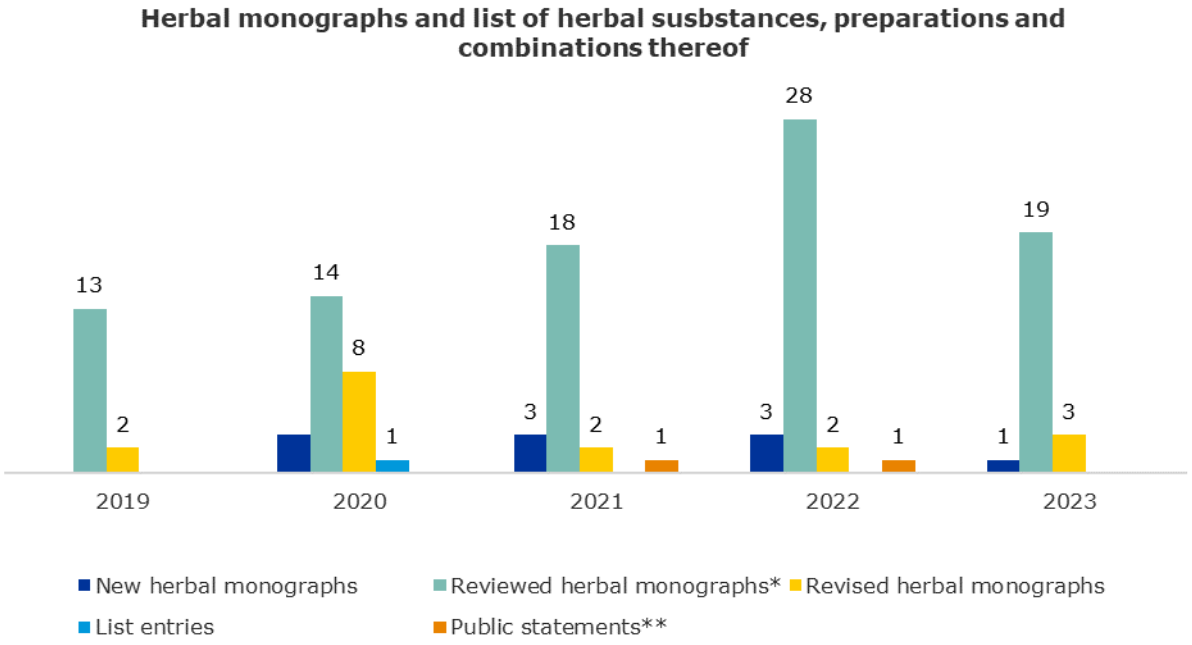
1.4. Referral procedures

Referral procedures are initiated to address concerns over the safety or benefit-risk balance of a medicine, as well as to deal with disagreement among Member States on the use of a medicine. In a referral, EMA is requested, on behalf of the EU, to conduct a scientific assessment of a particular medicine or class of medicines and issue a recommendation. Following the recommendation, the European Commission will issue a legally binding decision for the EU. Less often, in cases where only NAPs are concerned, the decision is taken by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). In cases where the CMDh position is agreed by majority, rather than by consensus of all CMDh members, the European Commission will issue a final decision applicable throughout the EU.



1.5. Herbal medicines

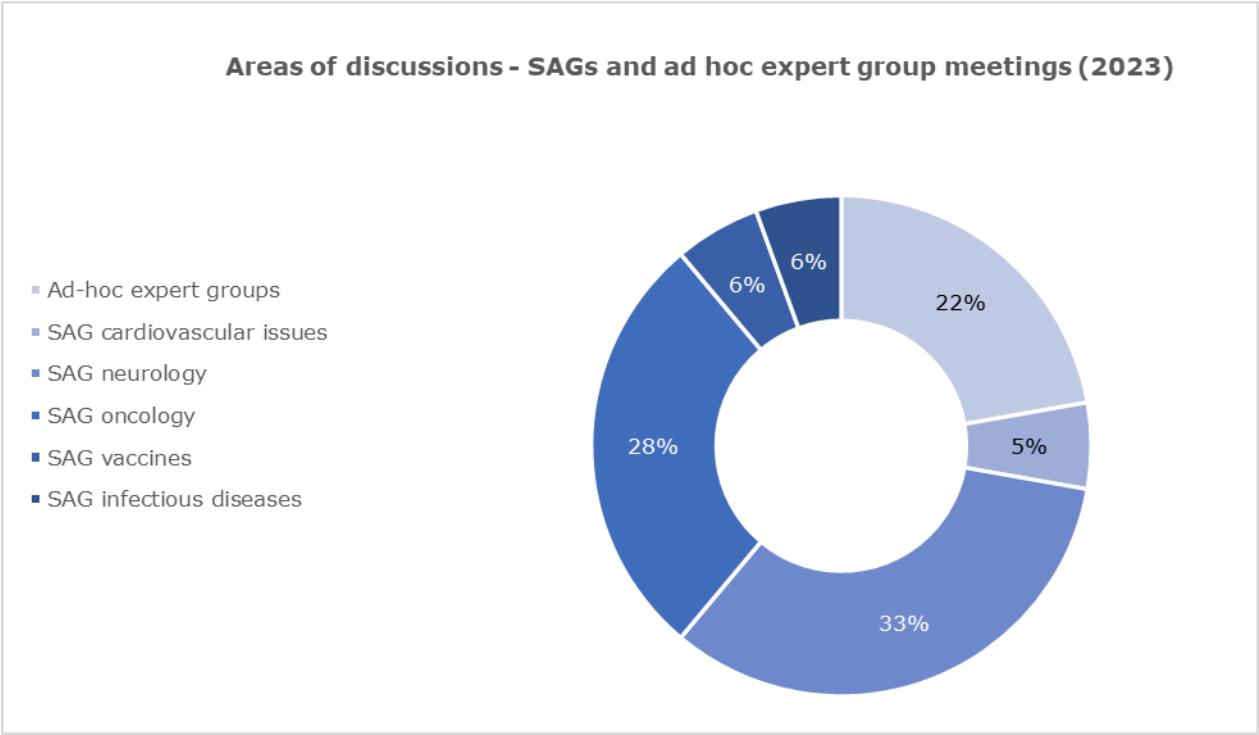
The Agency's Committee on Herbal Medicinal Products (HMPC) is responsible for preparing opinions on herbal medicines with the aim of promoting an increasingly harmonised process for licensing and information on herbal substances across the EU. The HMPC establishes EU monographs for traditional and well-established herbal medicines, as well as draft entries to the European Commission's list of herbal substances, preparations and combinations thereof for use in traditional medicines.



* When, after the review of new data, no change is required in the monograph, an addendum to the previous assessment report is prepared (otherwise start of revision procedure leading to a revised monograph). ** When the assessment does not lead to a monograph, a public statement is prepared.

1.6. Contribution of experts, patients and healthcare professionals to scientific assessments

EMA's scientific committees can consult additional experts, patients and healthcare professionals to enrich their scientific assessment of medicines. These external parties may be involved in scientific advisory groups (SAGs) or ad hoc expert groups.



Procedures with scientific advisory group or ad hoc expert group involvement (number of consultations)					
	2019	**2020**	**2021**	**2022**	**2023**
Marketing authorisation (new MAA, new MAA re-examination, Art 58)	15	18	11	10	9
Extension of indication (including line extensions)	3	7	2	7	1
Referral (including re-examination)	6	0	1	2	3
Guideline	1	0	0	0	0
Other topics (renewal, orphan designation, PSUR, signal, class review)	2	3	1	0	5
Total	**27**	**28**	**15**	**19**	**18**

Involvement of patients and healthcare professionals

Patients and healthcare professionals are involved in a wide range of EMA activities. They bring a valuable real-life perspective to scientific discussions on medicines, which is expected to lead to better outcomes of the regulatory process. Patients and healthcare professionals participate by:

- contributing as members of scientific committees and the Management Board;
- being consulted on disease-specific requests by the scientific committees and working parties;
- taking part in discussions on the development and authorisation of medicines;
- reviewing written information on medicines prepared by the Agency;
- being involved in the preparation of guidelines;
- taking part in the Agency's conferences and workshops.

Patient involvement in EMA activities					
	2019	**2020**	**2021**	**2022**	**2023**
Patient membership in MB, committees, working parties	57	57	56	57	60
EMA Management Board	2	2	2	2	2
Scientific committees	11	14	13	12	15
Patients' and Consumers' Working Party	44	41	41	43	43
Active patient experts nominated by EMA				80	163
Number of PCO eligible organisations				42	43

Healthcare-professional involvement in EMA activities					
	2019	**2020**	**2021**	**2022**	**2023**
HCP membership in MB, committees, working parties	58	62	57	56	56
EMA Management Board	2	2	2	2	2
Scientific committees	12	12	12	12	12
Healthcare Professionals' Working Party	44	48	43	42	42
Active HCP experts nominated by EMA				140	87
Number of HCP eligible organisations				39	40

1.7. Mutual-recognition and decentralised procedures

90% of the medicines entering the EU market are nationally authorised. These are mainly generics which reach the market through the mutual recognition procedure (MRP) and the decentralised procedure (DCP), the primary authorisation routes for generic applications within the EU. The CMDh, a separate body from EMA which represents the EU Member States plus Iceland, Liechtenstein and Norway, plays a key role, together with its working parties, in the authorisation and maintenance of these medicines. EMA provides secretarial support to the CMDh in accordance with the approved rules of procedure.

Detailed information about the work of the CMDh in 2023 in relation to pharmacovigilance and referrals can be found on the HMA website.

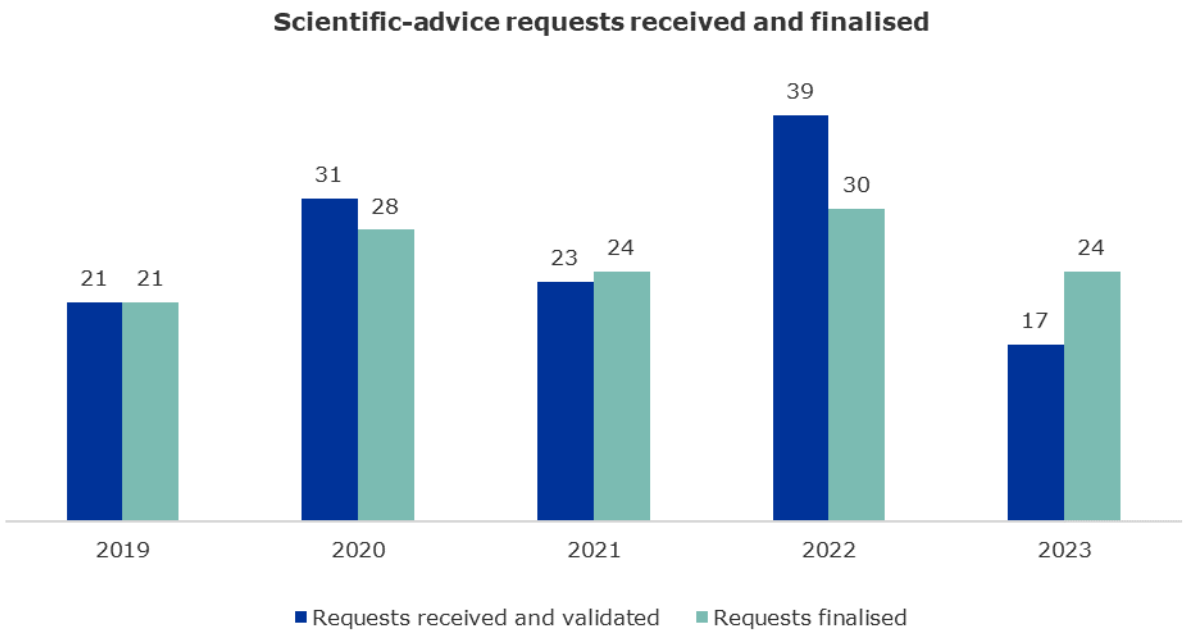
2. Veterinary medicines

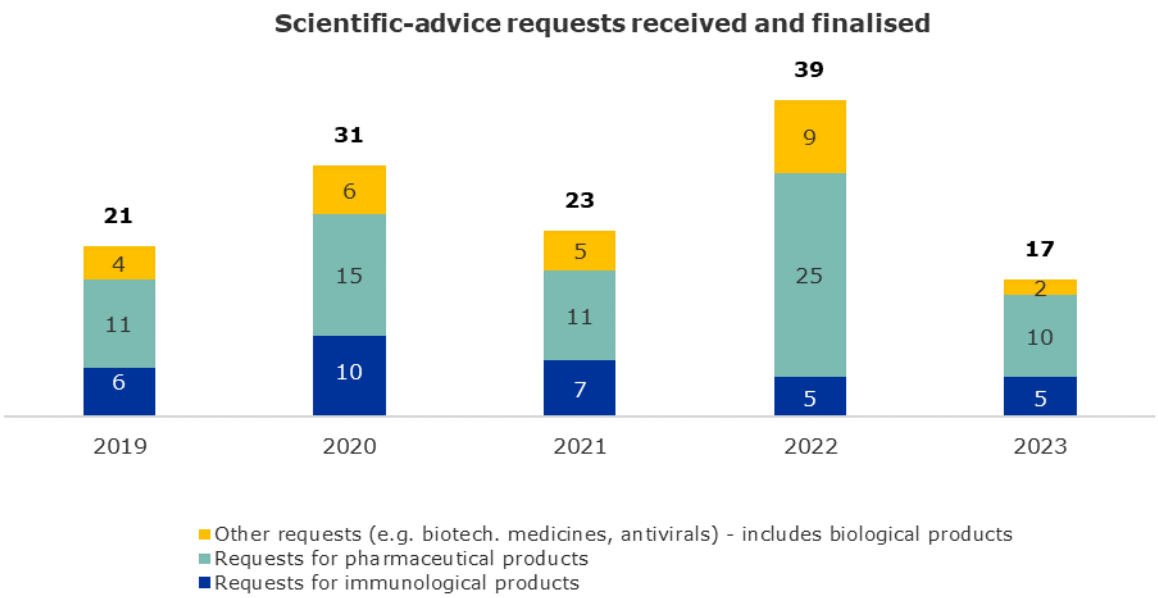
2.1. Activities supporting research and development

The Agency provides pre-authorisation support to medicine developers to boost innovation and research and enhance the availability of safe and effective veterinary medicines. This is achieved through activities and incentives offered to companies prior to submitting an application for marketing authorisation. These tools facilitate interaction and dialogue with the Agency from the very early stages of medicine development.

Scientific advice

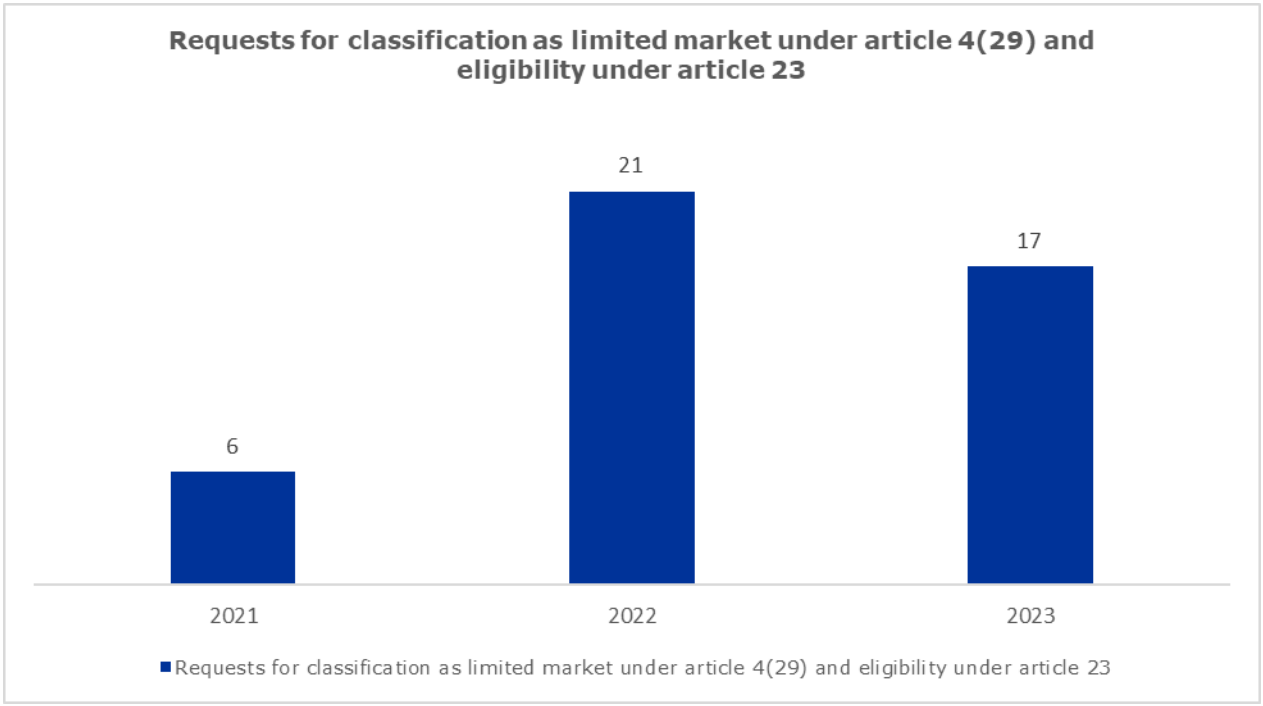
Scientific advice is provided on any aspect of research and development relating to the quality, safety or efficacy of medicines for veterinary use, and to the establishment of maximum residue limits. Scientific advice is a means of facilitating and improving the availability of new veterinary medicines.





Veterinary limited markets

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) introduced a specific authorisation route for medicines intended for veterinary limited markets in the EU. It enables the CVMP to recommend granting a marketing authorisation for such medicines based on less comprehensive data than normally required, where the benefit for animal or public health of placing the medicine on the market is greater than the inherent risk of a reduced data package on the medicine. Via the limited market classification request process, EMA provides an early advice to these applicants on whether their application can be considered under this framework. In 2023, EMA received 17 classification requests, and provided 18 recommendations.



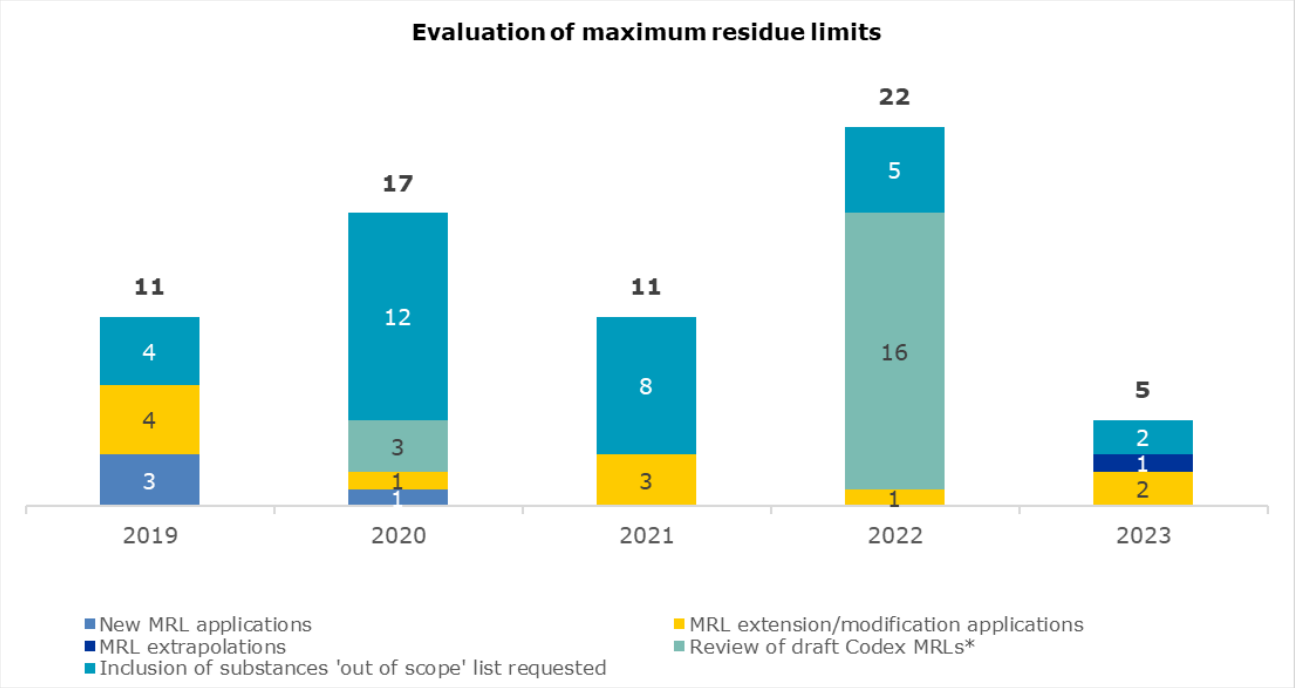
Innovation Task Force

The ITF is a multidisciplinary group that includes scientific, regulatory and legal expertise from across the EU. It provides a forum for early dialogue with applicants, in particular SMEs, to proactively identify scientific, legal and regulatory issues related to emerging therapies and technologies. In 2023, 10 meetings requests were received and 5 meetings were held with applicants.

2.2. Maximum residue limits

The use of veterinary medicines in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. The Agency assesses and recommends MRLs for pharmacologically active substances in veterinary medicinal products used to treat food producing animals. The objective is to ensure the safety of foodstuffs of animal origin, such as meat, fish, milk, eggs and honey. EMA has a parallel responsibility for recommending MRLs for pharmacologically active substances in biocidal products used in animal husbandry. MRLs are formally established by the European Commission on the basis of a recommendation from the CVMP.

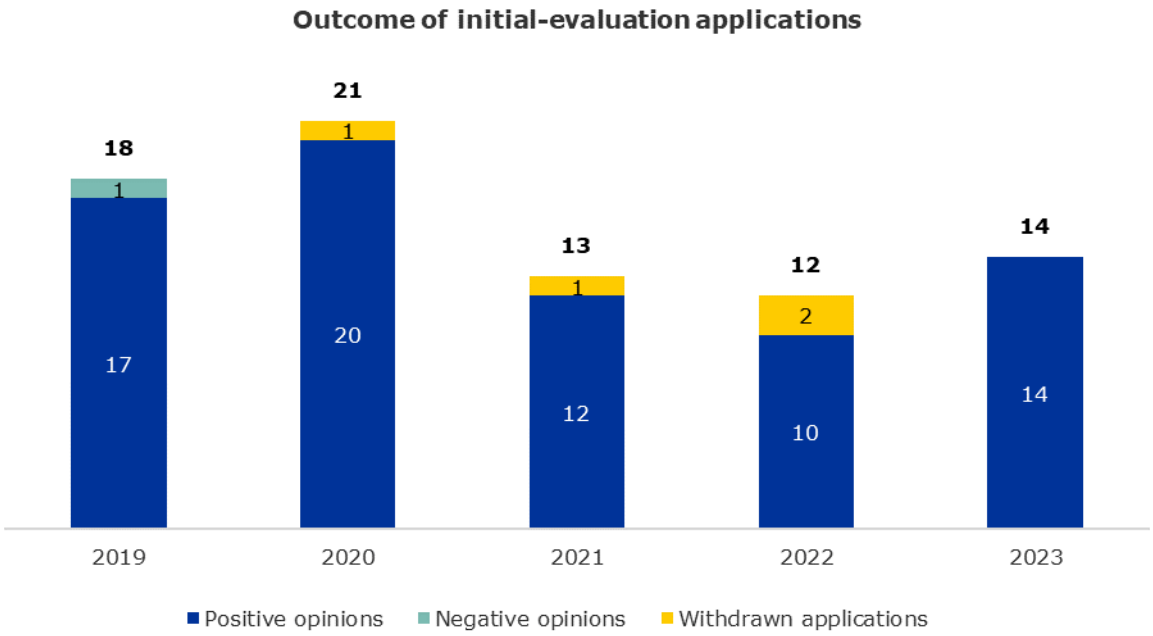
*From 2022, it also includes extrapolations.

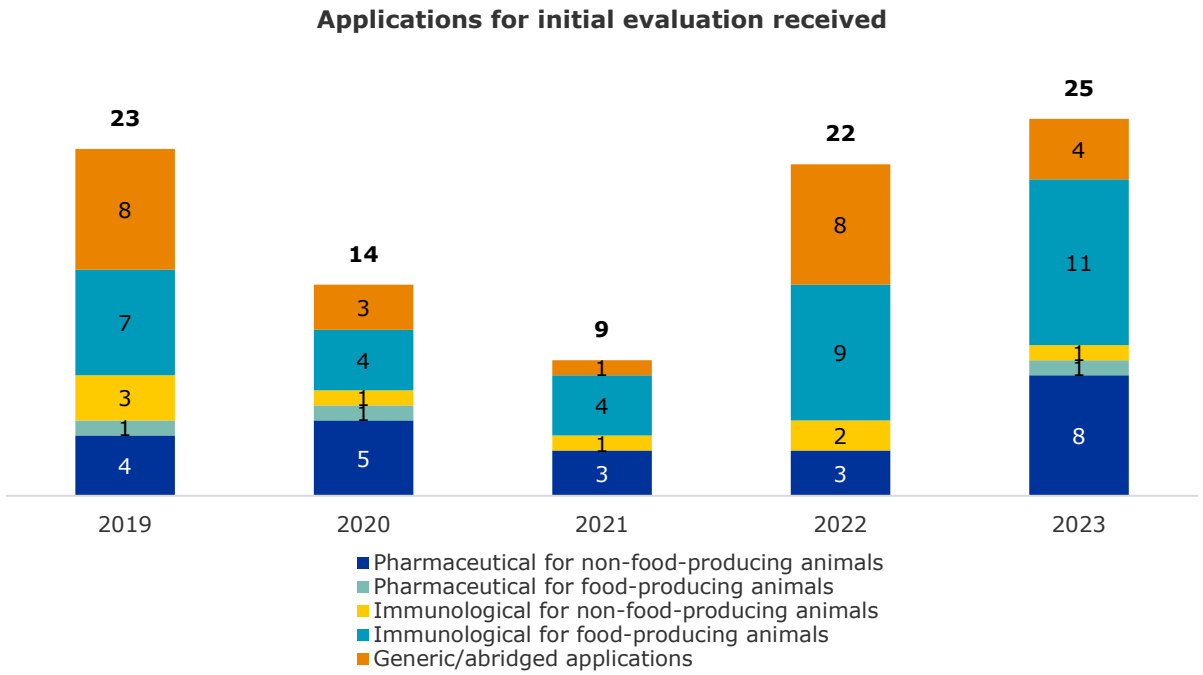


2.3. Recommendations for marketing authorisations

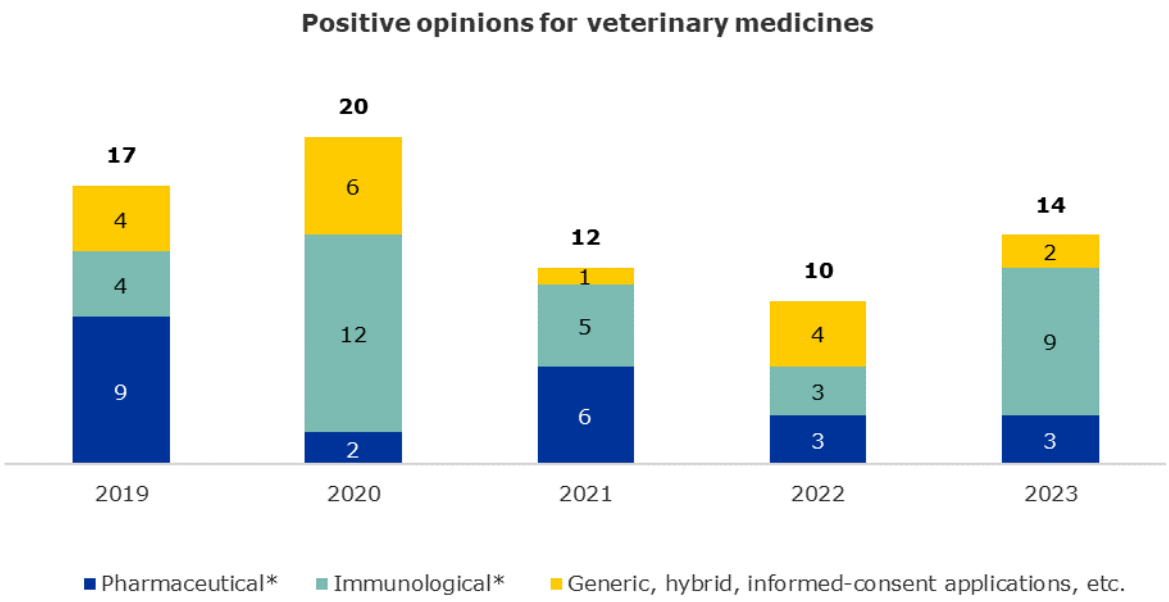
Applications for initial evaluation

The initial evaluation phase covers activities relating to the processing of marketing authorisations for veterinary medicines, ranging from pre-submission meetings with future applicants, through evaluation by the CVMP to the granting of marketing authorisation by the European Commission.

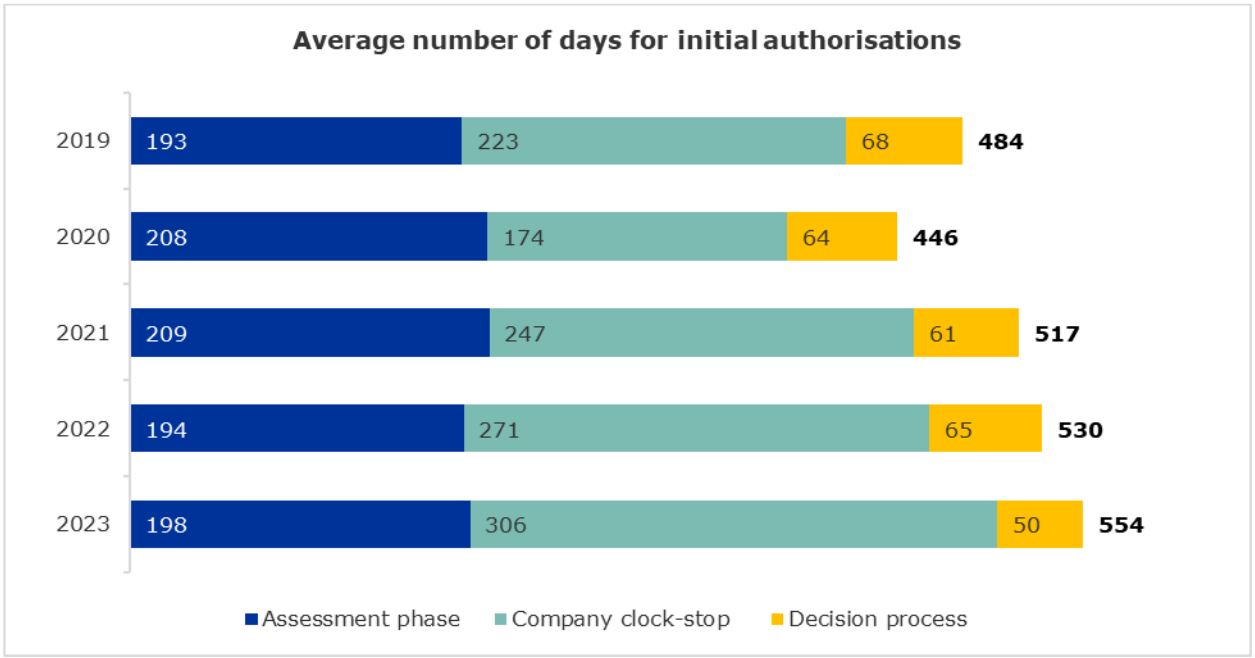

Outcome of initial-evaluation applications
18
1
17
21
1
20
13
1
12
12
2
10
14
14
2019
2020
2021
2022
2023
Positive opinions
Negative opinions
Withdrawn applications


Applications for initial evaluation received
23
8
7
3
1
4
14
3
4
1
1
5
9
1
4
1
3
22
8
9
2
3
25
4
11
1
1
8
2019
2020
2021
2022
2023
Pharmaceutical for non-food-producing animals
Pharmaceutical for food-producing animals
Immunological for non-food-producing animals
Immunological for food-producing animals
Generic/abridged applications

Recommendations for authorisation

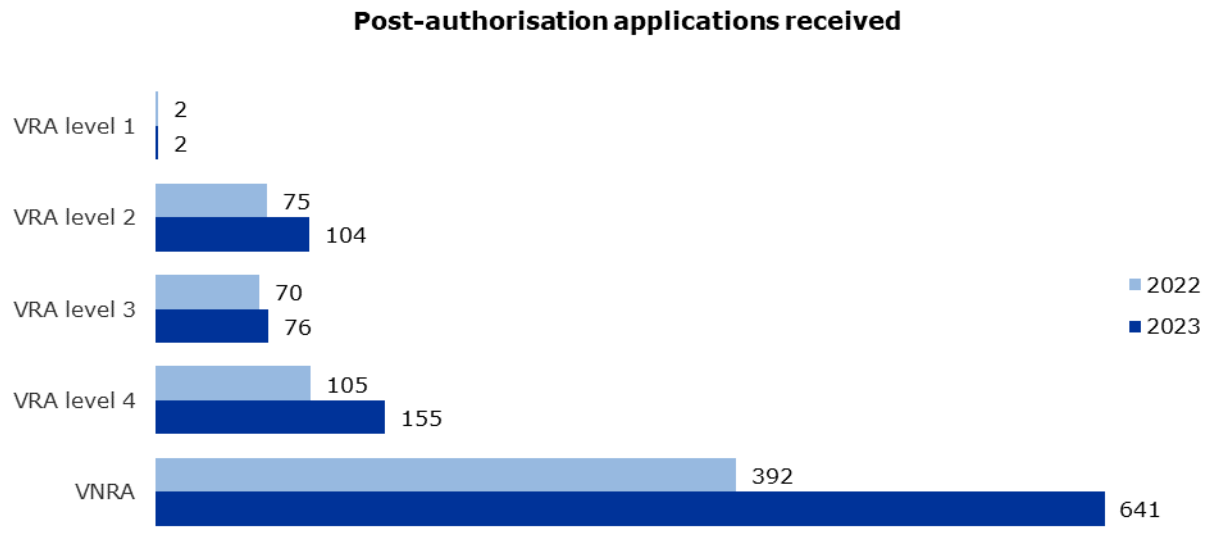


Medicines recommended for approval in 2023



Post-authorisation activities

Post-authorisation activities for veterinary medicinal products relate to variations and transfers of marketing authorisations.
Under the Veterinary Medicinal Products Regulation there are two types of variations (i.e. changes to the terms of a marketing authorisation): variations not requiring assessment (VNRA), which have minimal or no impact on the quality, safety or efficacy of the medicine, and variations requiring assessment (VRA), including different levels of complexity.

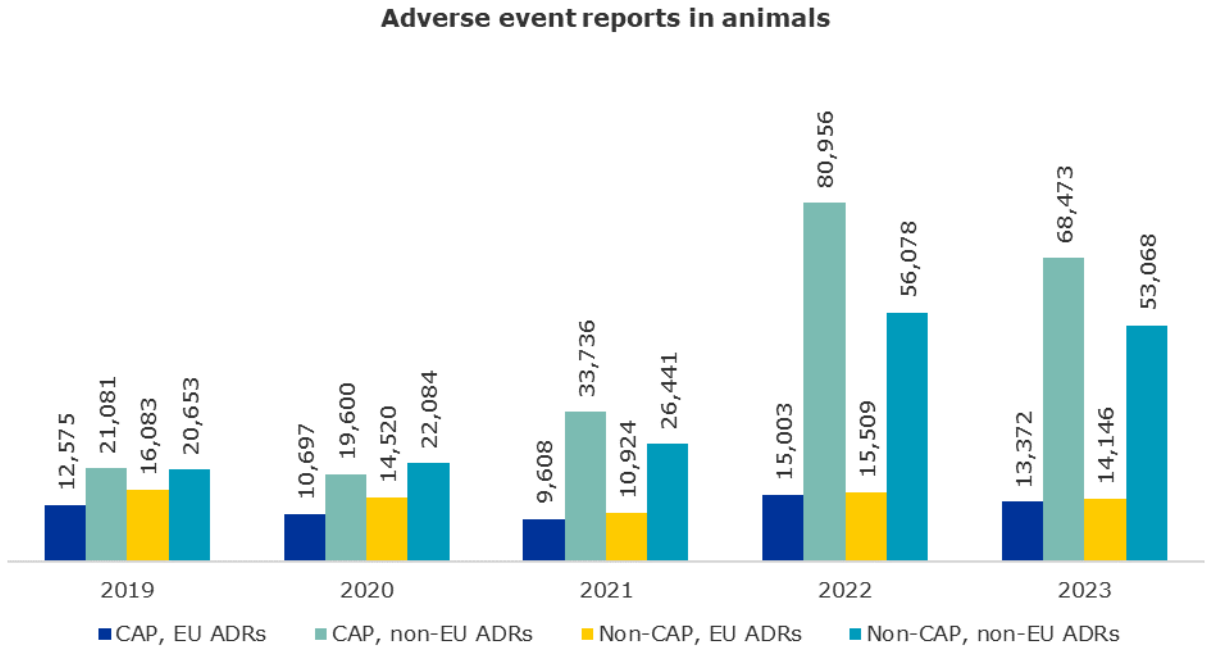


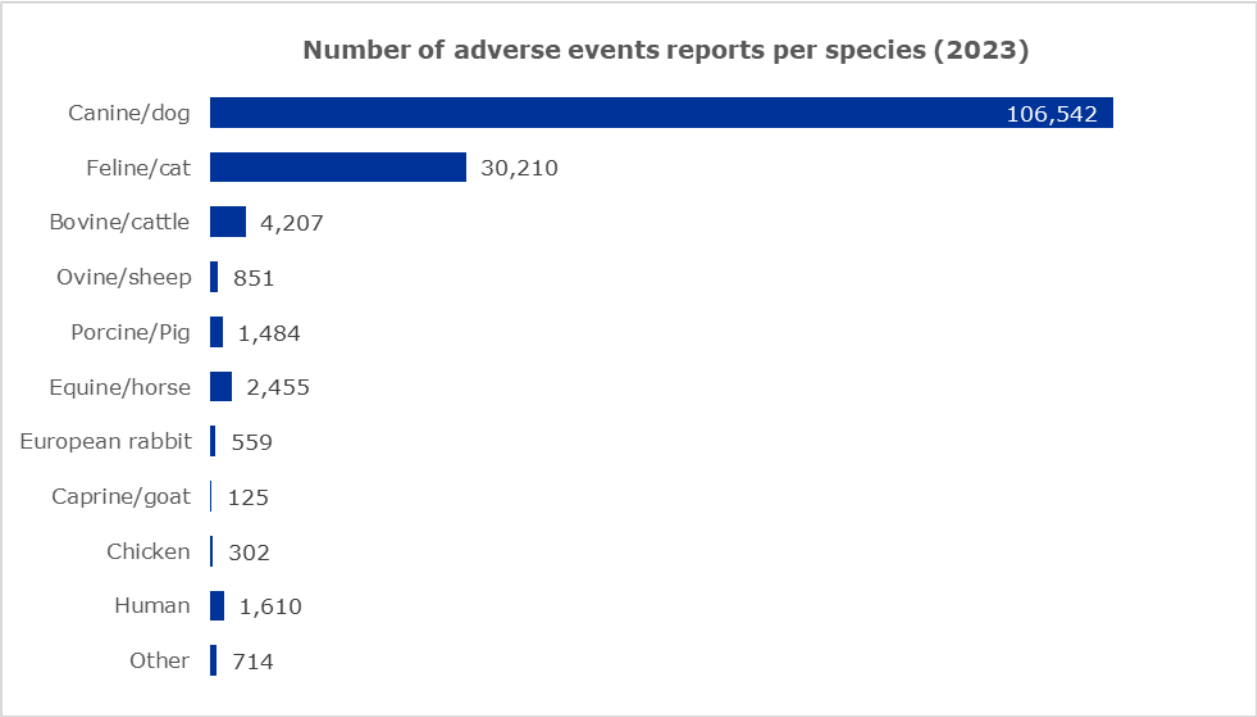
Safety monitoring of medicines

Pharmacovigilance covers activities related to the detection, reporting, assessment, understanding and prevention of adverse events (AEs) following the administration of veterinary medicines. It aims to ensure the monitoring of the safety of veterinary medicines and the effective management of risks throughout the EU.

EudraVigilance

The Veterinary Medicinal Products Regulation requires reporting of both serious and non-serious AE reports.

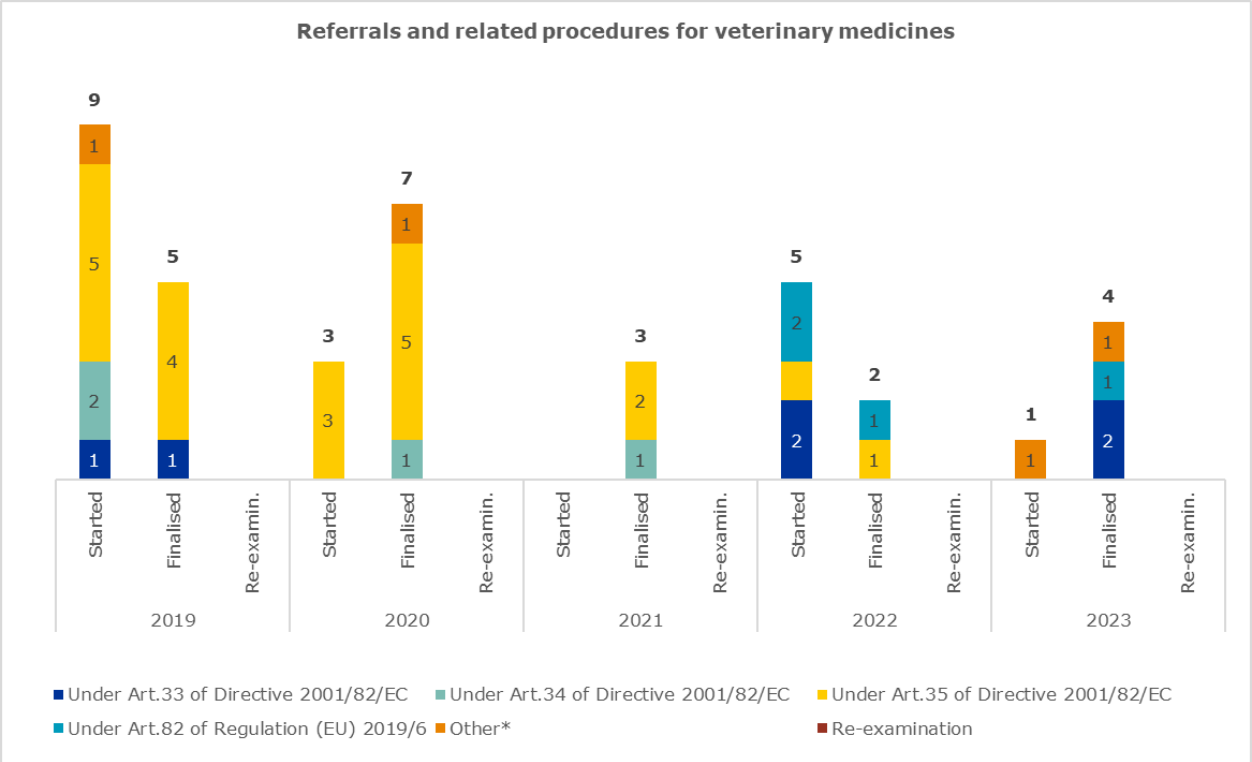




Total 2023: 149,059

2.4. Referral procedures

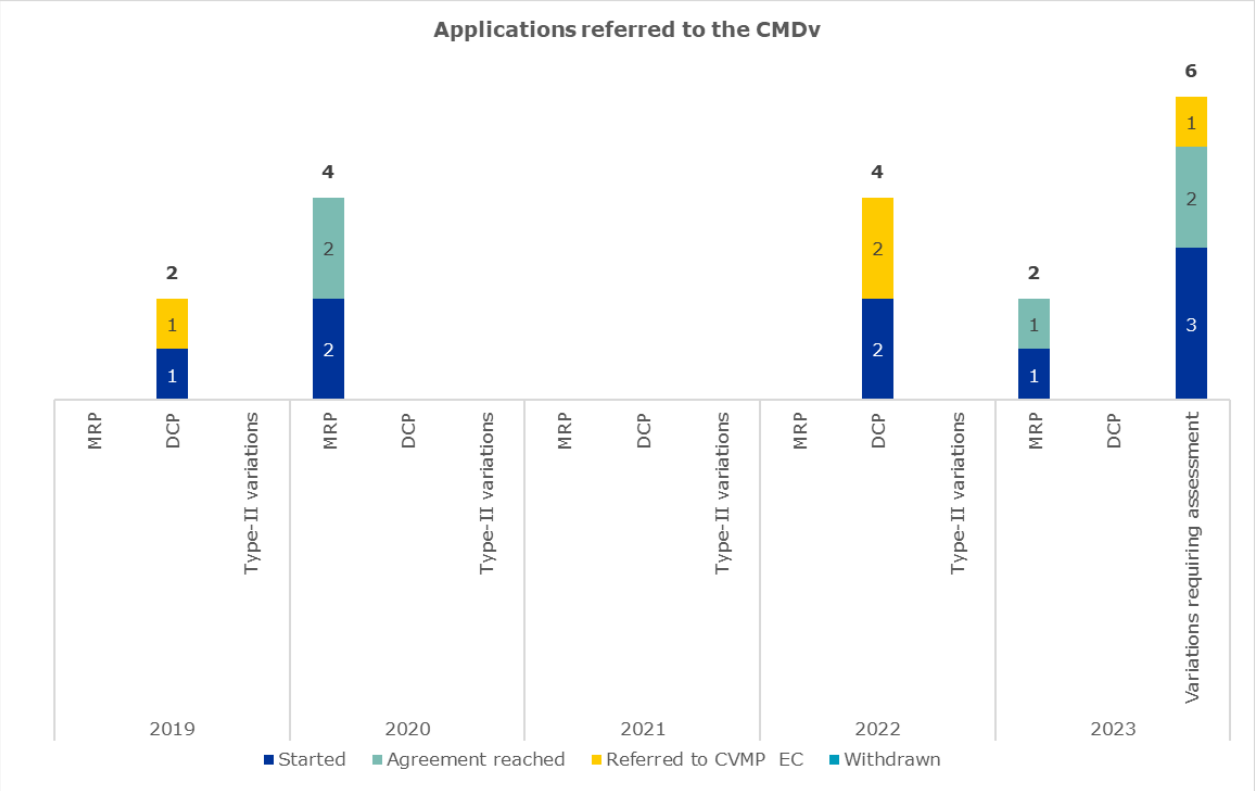
Referral procedures are used to address concerns over the quality, safety, efficacy or benefit-risk balance of a veterinary medicine, or disagreement among Member States on the use of a veterinary medicine. In a referral, the Agency is requested, on behalf of the EU, to conduct a scientific assessment of a particular veterinary medicine or class of veterinary medicines, and issues a cross-EU recommendation. The recommendation subsequently results in a legally binding decision throughout the EU issued by the European Commission.



*Including Art.13 of Regulation 1234/2008; Art.78 of Directive 2001/82/EC; Articles 30 or 45 of Regulation 726/2004 and Art.54(8), Art.130(4) and Art .141(1)(c) and (e) of Regulation (EU) 2019/6

2.5. Mutual-recognition and decentralised procedures

The Agency provides secretarial support to the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) and its working groups, in accordance with the approved rules of procedure. The work of the CMDv is essential for the effective authorisation and maintenance of veterinary medicines entering the EU market via the MRP and the DCP, which constitute the primary routes for veterinary medicines entering the EU market.



3. European medicines regulatory network

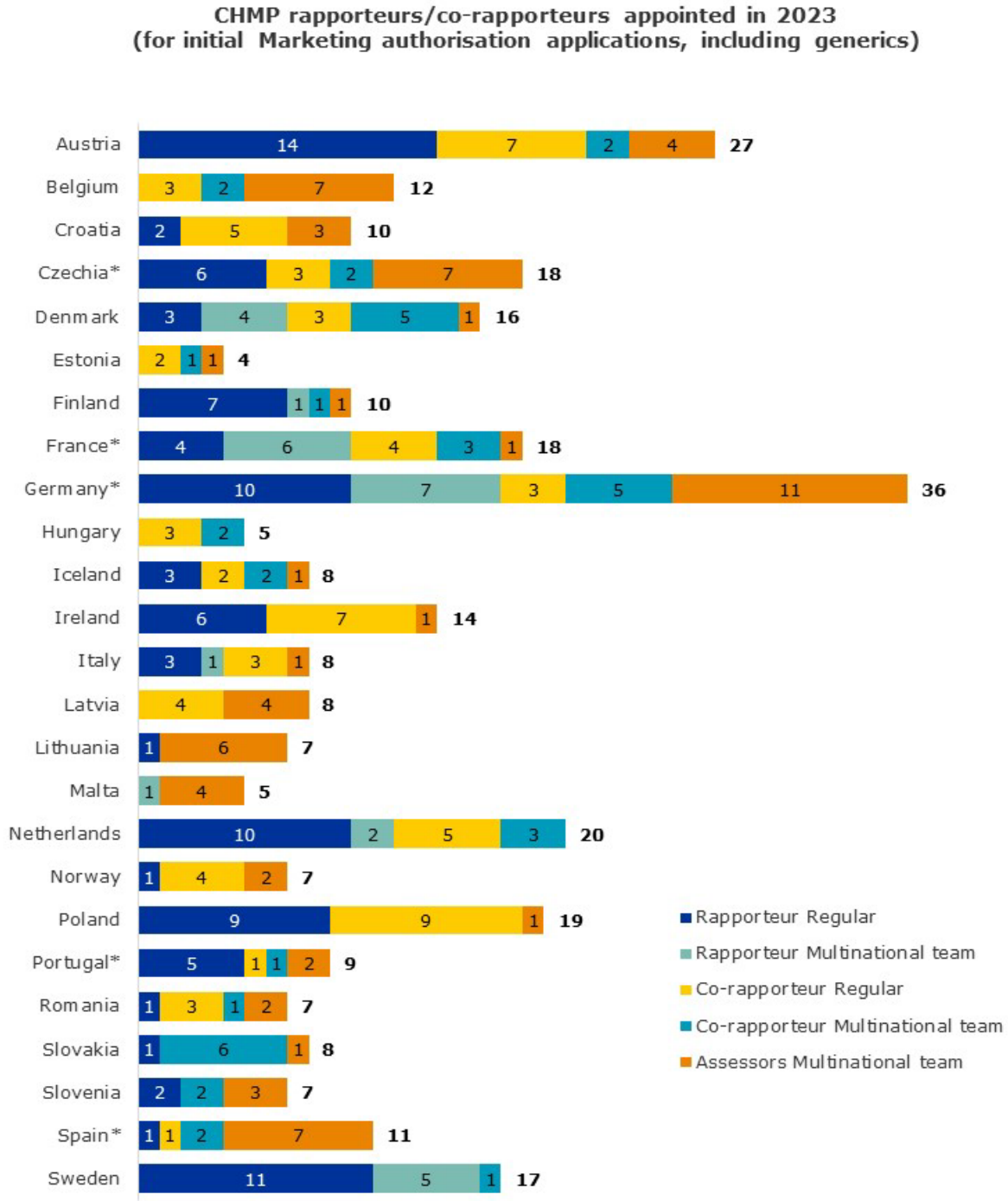
The European medicines regulatory network – a partnership between EMA, the European Commission and 50 medicines regulatory authorities in the EU and the EEA – is the basis of EMA's success. The network gives the Agency access to a pool of over 4,000 experts, who provide the best available scientific expertise for the regulation of medicines in the EU. Experts participate in the work of the Agency as members of its committees, working parties, Scientific Advisory Groups (SAGs) and a number of ad hoc advisory groups as well as members of the assessment teams carrying out the evaluation of medicines.

3.1. Rapporteurships and co-rapporteurships

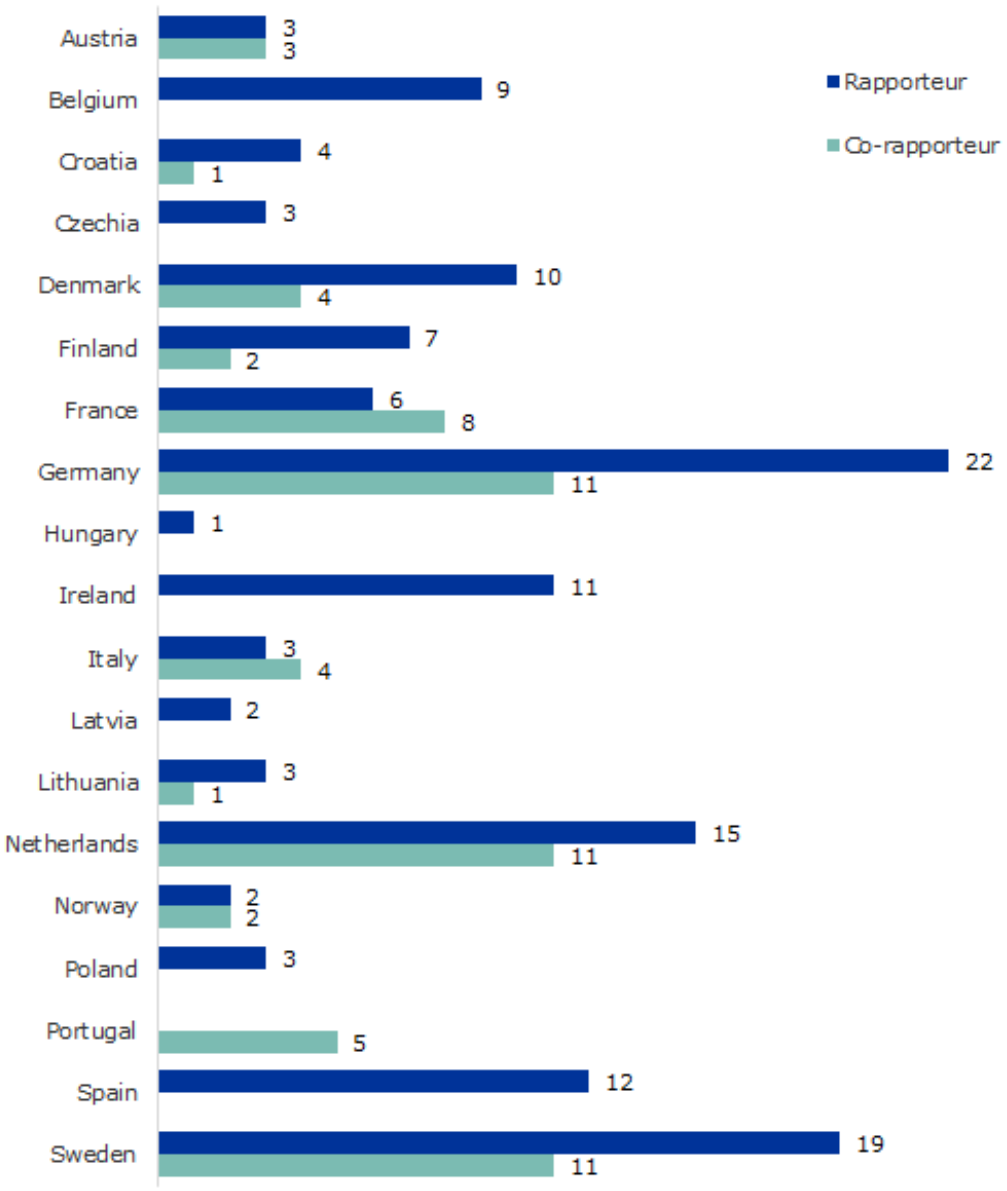
The assessment of a medicine by EMA's scientific committees is carried out by a rapporteur and a co-rapporteur, who prepare the assessment reports and lead the discussions in the committees. The appointment is made on the basis of the best possible expertise for the particular product. Rapporteurs work through assessment procedures and take the lead in evaluating any new information on the medicine that may become available.

CHMP rapporteurships/co-rapporteurships

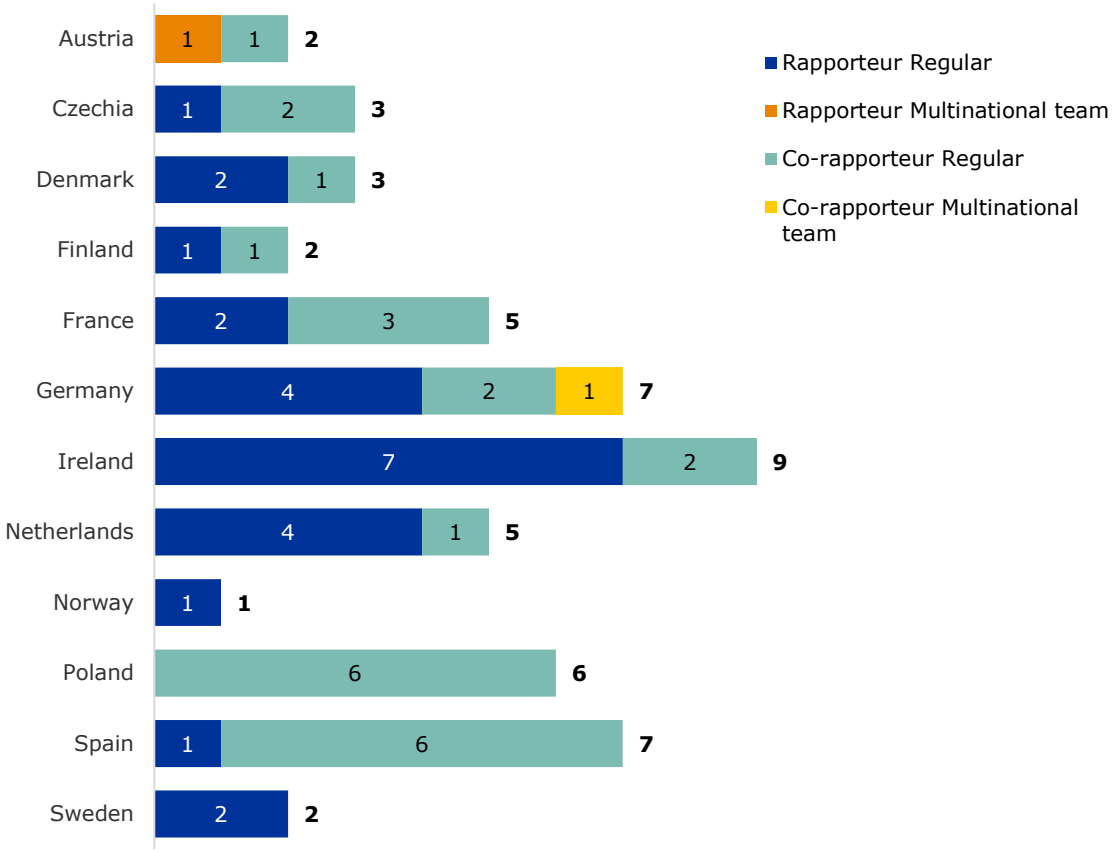
CHMP rapporteurs and co-rapporteurs are able to create multinational teams for the initial assessment of marketing authorisation applications. The table below presents the number of procedures for which each country in 2023 was appointed either as a regular rapporteur or co-rapporteur, as a rapporteur or co-rapporteur leading a multinational team, or as an assessor of part of a multinational team.

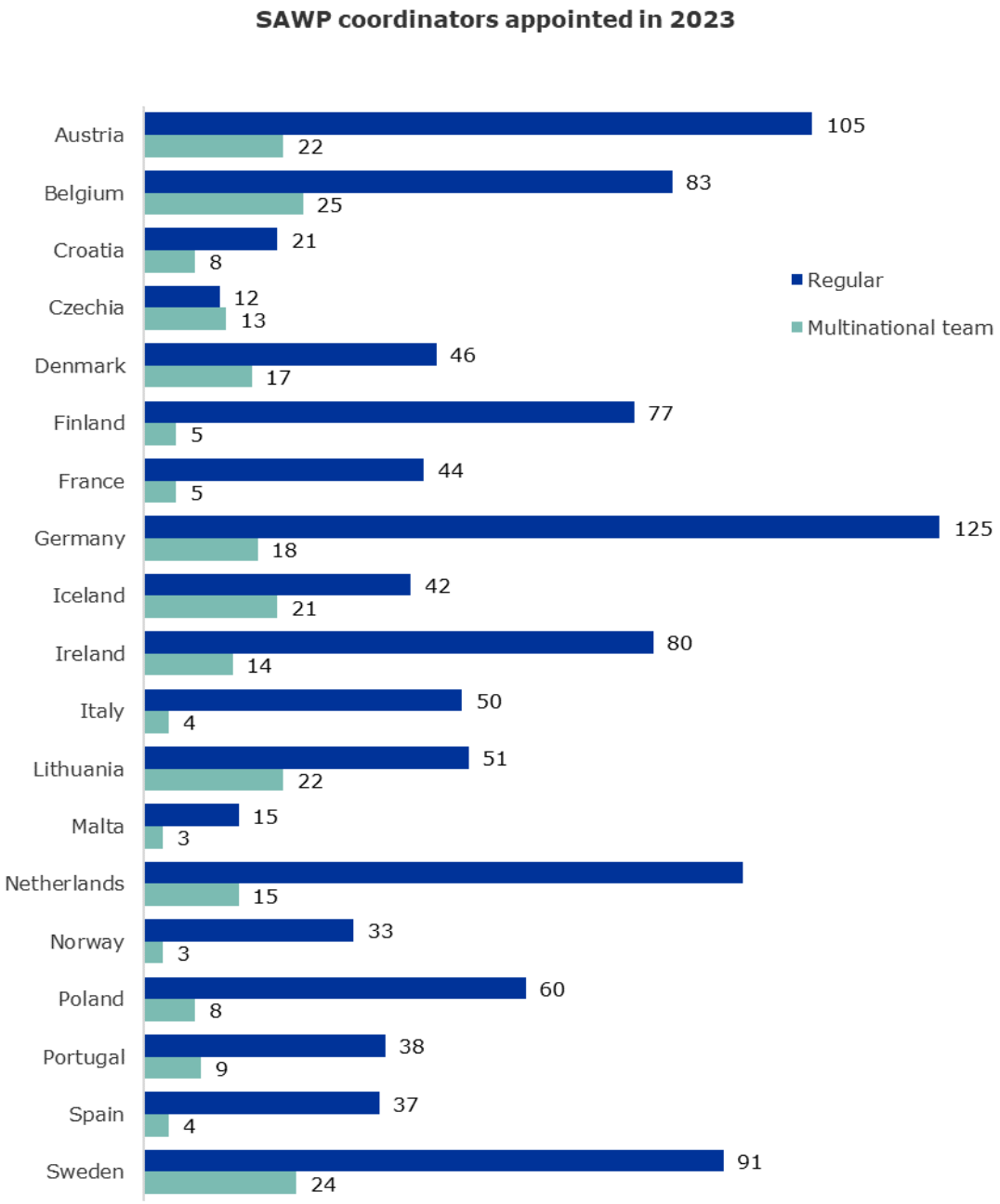

CHMP rapporteurs/co-rapporteurs appointed in 2023
(for initial Marketing authorisation applications, including generics)
Austria 14 7 2 4 27
Belgium 3 2 7 12
Croatia 2 5 3 10
Czechia* 6 3 2 7 18
Denmark 3 4 3 5 1 16
Estonia 2 1 1 4
Finland 7 1 1 1 10
France* 4 6 4 3 1 18
Germany* 10 7 3 5 11 36
Hungary 3 2 5
Iceland 3 2 2 1 8
Ireland 6 7 1 14
Italy 3 1 3 1 8
Latvia 4 4 8
Lithuania 1 6 7
Malta 1 4 5
Netherlands 10 2 5 3 20
Norway 1 4 2 7
Poland 9 9 1 19
Portugal* 5 1 1 2 9
Romania 1 3 1 2 7
Slovakia 1 6 1 8
Slovenia 2 2 3 7
Spain* 1 1 2 7 11
Sweden 11 5 1 17
Rapporteur Regular
Rapporteur Multinational team
Co-rapporteur Regular
Co-rapporteur Multinational team
Assessors Multinational team

PRAC rapporteurs/co-rapporteurs appointed in 2023 (for initial Marketing authorisation applications)



CVMP rapporteurs/co-rapporteurs appointed in 2023
(for initial Marketing authorisation applications, including generics)





3.2. EU network training centre

The EU Network Training Centre (EU NTC) is a joint initiative of EMA and the national competent authorities. It enables the entire European medicines regulatory network (EMRN) to access and build subject matter expertise through a shared learning ecosystem covering both, human and veterinary medicines. By providing a central resource and platform for scientific and regulatory training, the EU NTC supports the quality and efficiency of operations by addressing the training needs of the EMRN and making best use of available resources. The EU NTC provides tools to drive didactic quality and foster knowledge sharing. The table below highlights its key activities from when it was established in 2015 to 2023.

EU Network training centre									
	2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
New scientific, regulatory and network portfolio curricula developed	1	8	0	2	2	2	1	1	0
Number of training events advertised to the EU Network	105	140	100	60	40	46	77	76	79
Number of reimbursed training events to the EU Network	7	25	20 (14 by EU NTC)	8 (5 by EU NTC)	12	1	0	4	3
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	6	14	8	7	10	7	15	11	13
Number of users registered to the EU NTC Learning Management System		2,117	3,583	4,424	5,121	5,290	5,916	6,610	7,036
Number of NCA experts registered to the EU NTC Learning Management System		1,225	2,668	3,480	4,143	4,297	4,872	5,485	5,832

4. Inspections and compliance

EMA coordinates the verification of sponsor/manufacturing compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP), good pharmacovigilance practices (GVP) and certain aspects of the supervision of authorised medicinal products in the EU. The main verification tool is inspection, which can either be carried out routinely or upon a request of the CHMP or CVMP in the context of the assessment of marketing authorisation applications and/or matters referred to these committees in accordance with EU legislation.

The responsibility for carrying out inspections rests with EU NCAs, but EMA plays a coordinating role.

EMA also coordinates the preparation and maintenance of risk-based inspection programmes to verify compliance with the principles of GMP, GCP and pharmacovigilance at the EU level, in:

- a risk-based programme of GMP inspections based on the results of inspections by trusted authorities;
- a risk-based programme of routine GCP inspections of the clinical research organisations (CROs) most often used in the conduct of bioequivalence trials included in a marketing authorisation application in the mutual-recognition and decentralised procedures (in collaboration with NCAs/CMDh); • a risk-based programme of routine pharmacovigilance inspections in relation to CAPs (in collaboration with NCAs);
- a two-year programme of routine GCP inspections based on risk factors and a random element to ensure that a diverse range of applications, trials and sites and geographical locations are covered.

In the area of inspections, EMA ensures the best use of resources by promoting mutual reliance and work-sharing with other international authorities. For GMP inspections, there are several mutual recognition agreements in place.

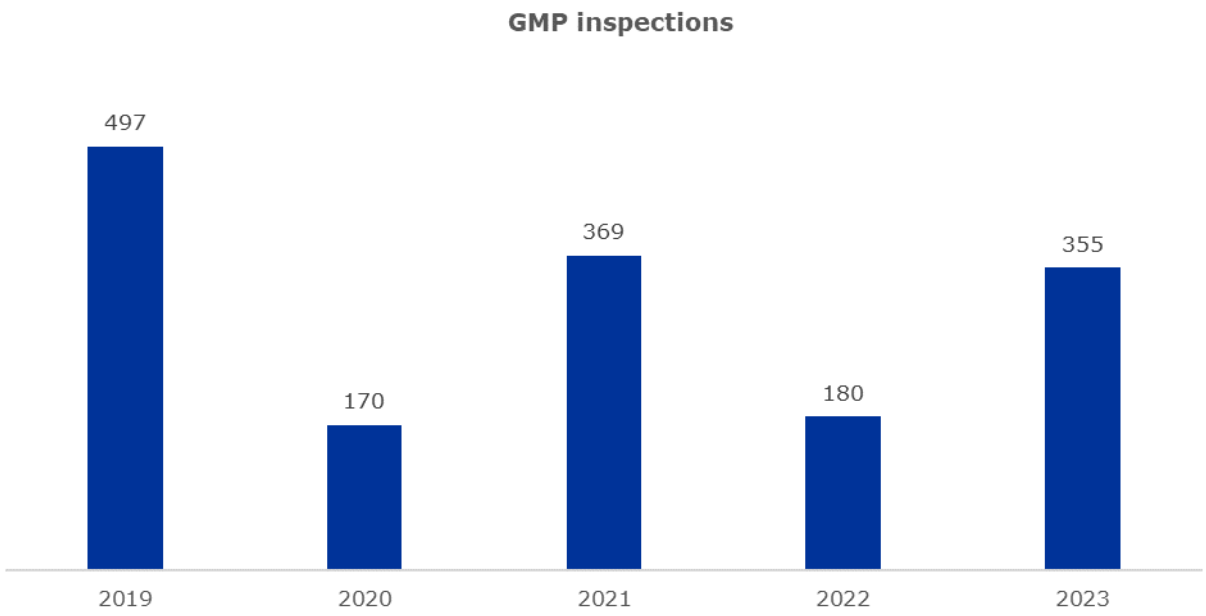
Through its inspectors' working groups, the Agency coordinates the development and setting of standards for GMP, GCP, GLP and GVP. This helps to harmonise standards within the EU and internationally, to strengthen global supply chains and improve access to authorised medicines. The delivery of training and capacity building on inspection-related activities for inspectors and assessors, including non-EU regulators, is one focus area for EMA. The Agency is the primary contact point for notification of suspected quality defects for CAPs and coordinates their investigation, evaluation and follow-up. It also operates a sampling-and-testing programme to supervise the quality of CAPs placed on the market and to check compliance of these products with their authorised specifications

4.1. Inspections

GMP, GCP, GLP and pharmacovigilance inspections requested by the CHMP or CVMP for medicines that are subject to centralised authorisation procedures take place worldwide. However, they represent just a small part of the total number of inspections performed by the EU/EEA inspectors, who also carry out inspections as part of their national programmes in the context of:

- the evaluation of marketing authorisation applications submitted to regulatory authorities across the EU;
- the oversight of manufacturers importing medicines into the EU;
- the oversight of the conduct of clinical trials in Europe;
- the oversight of compliance with pharmacovigilance obligations.

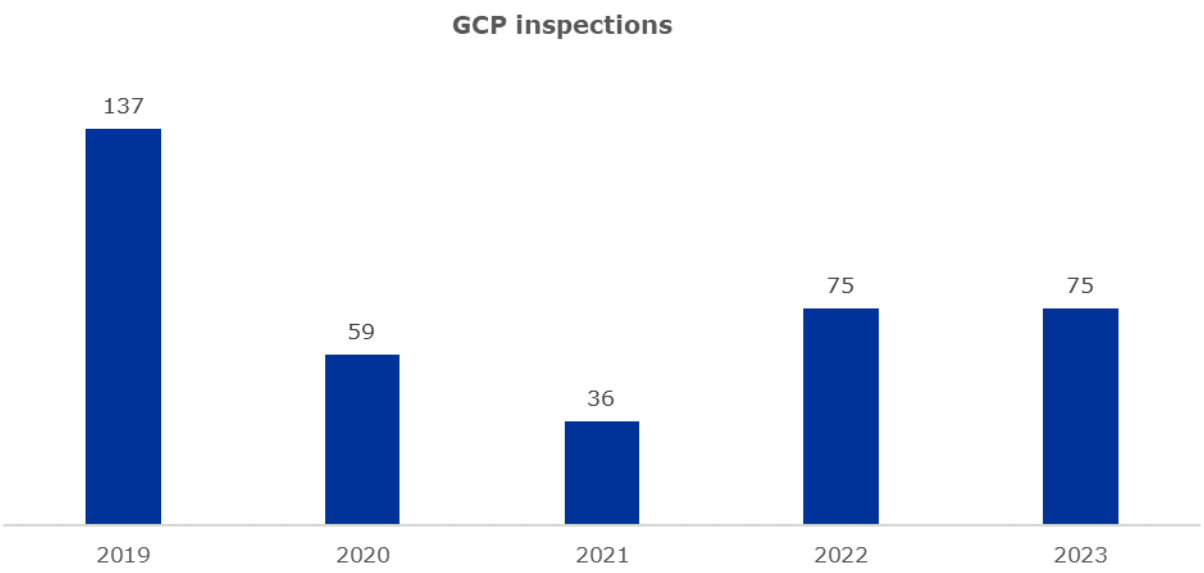
GMP inspections



GMP certificates and non-compliance statements issued by EEA authorities										
	2019		**2020**		**2021**		**2022**		**2023**	
	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement	GMP certificate	GMP non-compliance statement
EEA/EU	2,235	11	1,695	1	1,825	5	1,730	2	1,857	2
China	51	4	11	0	24	0	15	0	44	
India	105	1	64	0	29	0	81	2	101	4
USA	127	0	35	0	52	0	118	0	155	
Rest of the world	108	0	38	0	52	0	187	2	231	1
Total	**2,626**	**16**	**1,843**	**1**	**1,982**	**5**	**2,131**	**6**	**2,388**	**7**

Note: This table shows the number of GMP certificates and non-compliance statements issued by EEA authorities as an outcome of GMP inspections conducted between 2018 and 2023. It includes GMP inspections requested by the CHMP or the CVMP.

GCP inspections



Pharmacovigilance inspections

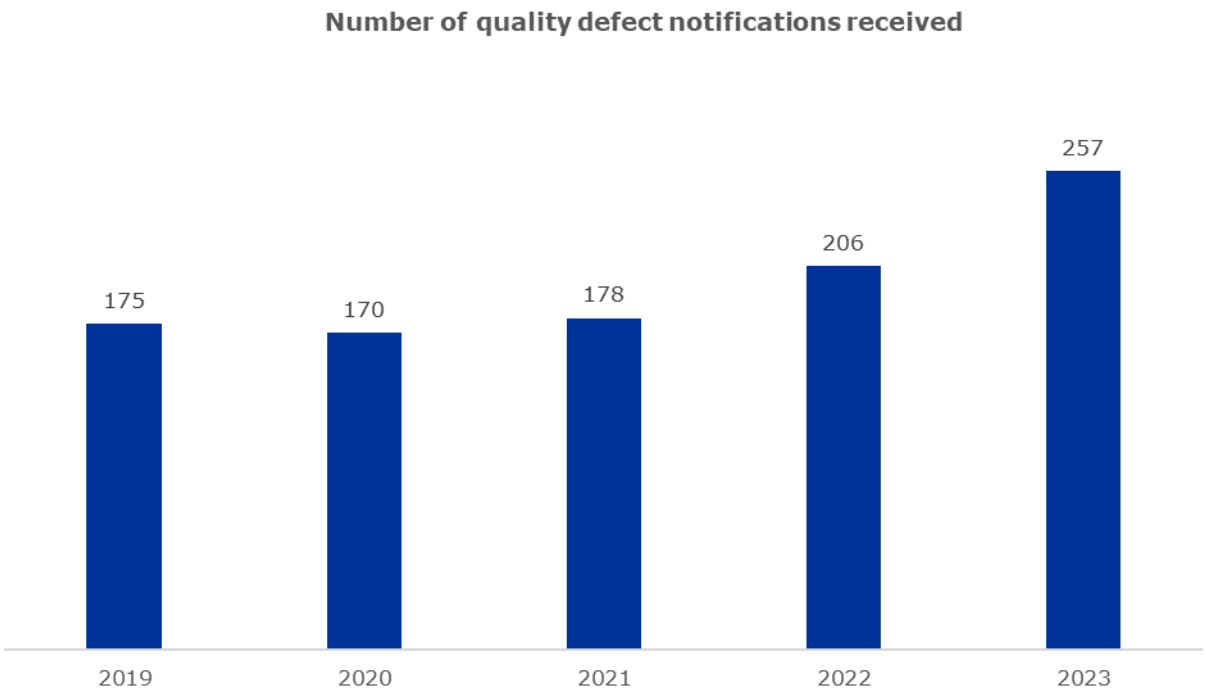
EMA, in cooperation with competent authorities in the Member States, maintains a risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders of CAPs and ensures its implementation. It also plays a key role in the coordination of pharmacovigilance inspections specifically triggered by the CHMP or CVMP and in inspection follow-up.

Number of pharmacovigilance inspections					
	2019	**2020**	**2021**	**2022**	**2023**
Pharmacovigilance	9	16	15	12	14

4.2. Market surveillance and quality defects

Manufacturers are required to inform authorities of quality defects in batches of a manufactured product. This can lead to a recall of batches from the market or the prevention of their release by the manufacturer. Where a defect is considered to be a risk to public or animal health, the marketing authorisation holder is requested to withdraw the affected batches of the CAP from the EU market and the supervisory authority issues a rapid alert. The alert is split into three classes, in line with the expected risk to public or animal health posed by the defective product:

- Class 1 recall: the defect presents a life-threatening or serious risk to health.
- Class 2 recall: the defect may cause mistreatment or harm to the patient or animal but is not life-threatening or serious.
- Class 3 recall: the defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification



Quality defects reported					
	2019	**2020**	**2021**	**2022**	**2023**
Quality defects confirmed cases			164	185	188
Recalls	15	15	10	11	9*
Class 1	3	3	1	2	0
Class 2	3	3	7	5	6
Class 3	9	9	2	4	2

* 1 recall not classified

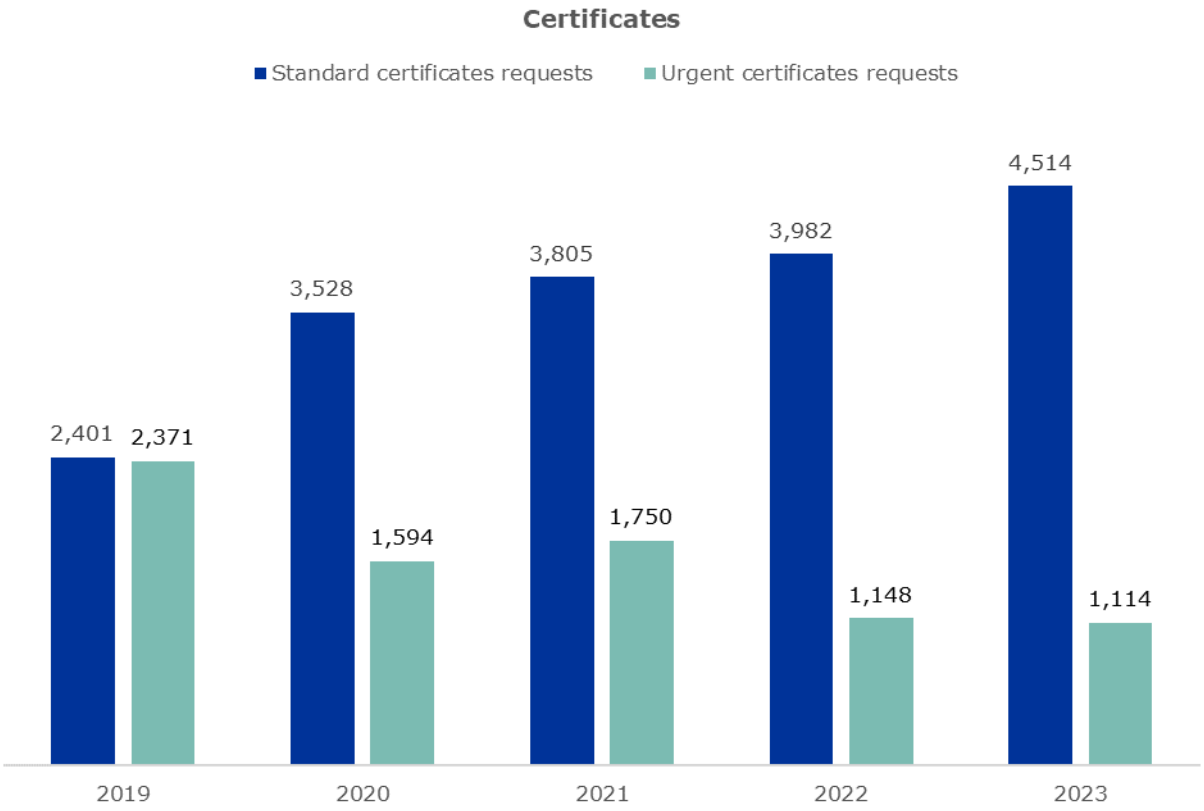
4.3. Parallel distribution

EMA checks that the parallel distribution of CAPs from one Member State to another by a company independent of the marketing authorisation holder is compliant with the rules.

Parallel distribution notifications received					
	2019	**2020**	**2021**	**2022**	**2023**
Initial notifications	2,468	3,172	2,555	1,816	2,092
Notifications of change	2,103		0	0	0
Notifications of bulk change	12	10	19	32	21
Annual updates	4,270	11,624	4,816	5,509	5,477
Total	**8,853**	**14,806**	**7,390**	**7,357**	**7,590**

4.4. Certificates

EMA also issues certificates to confirm the marketing authorisation status of medicines that have either been authorised or for which an application for marketing authorisation has been submitted to the Agency.


Certificates
Standard certificates requests
Urgent certificates requests
2,401
2,371
3,528
1,594
3,805
1,750
3,982
1,148
4,514
1,114
2019
2020
2021
2022
2023

5. Medical devices

For certain high-risk devices, EU legislation requires notified bodies to consult expert panels before issuing a CE certificate.

These high-risk medical devices include:

- Class III implantable devices and class IIb active devices that are intended to administer or remove medicinal products from the body;
- Class D in vitro diagnostic medical devices.

The expert panels can provide:

- opinions on the notified body's assessment of the manufacturer's clinical file of class III and class IIb medical devices, known as the clinical evaluation consultation procedure (CECP);
- views on the manufacturer's performance evaluation report of class D in vitro diagnostic medical devices, known as the performance evaluation consultation procedure (PECP).

CECP dossiers are first reviewed by the screening experts who decide whether or not an opinion should be provided on the clinical evaluation assessment report.

Figures on opinions by expert panels on high risk Medical Devices			
	2021	**2022**	**2023**
Number of finalised screened applications for CECP	9	29	48
Number of finalised scientific opinions for Clinical Evaluation Consultation Procedures CECP	3	7	1
Number of finalised Performance Evaluation Consultations PECP	15	1	2

6. Communication and stakeholders

The Agency has continued to seek proactive engagement with its stakeholders throughout 2023 to ensure that stakeholder views are integrated into EMA's strategic activities (such as the implementation of the legislation extending EMA's mandate or the ACT-EU initiative) and to enable knowledge sharing and learning from stakeholder experts on specific initiatives. In addition to bilateral interactions, promoting synergies through multi-stakeholder dialogue and cooperation has been a key part of efforts to address complex issues related to medicines, such as availability, crisis preparedness and innovation.

In addition, patient, consumer and health professional representatives continued to be involved in their individual capacity to support EMA's individual assessment of medicines.

6.1. External communication

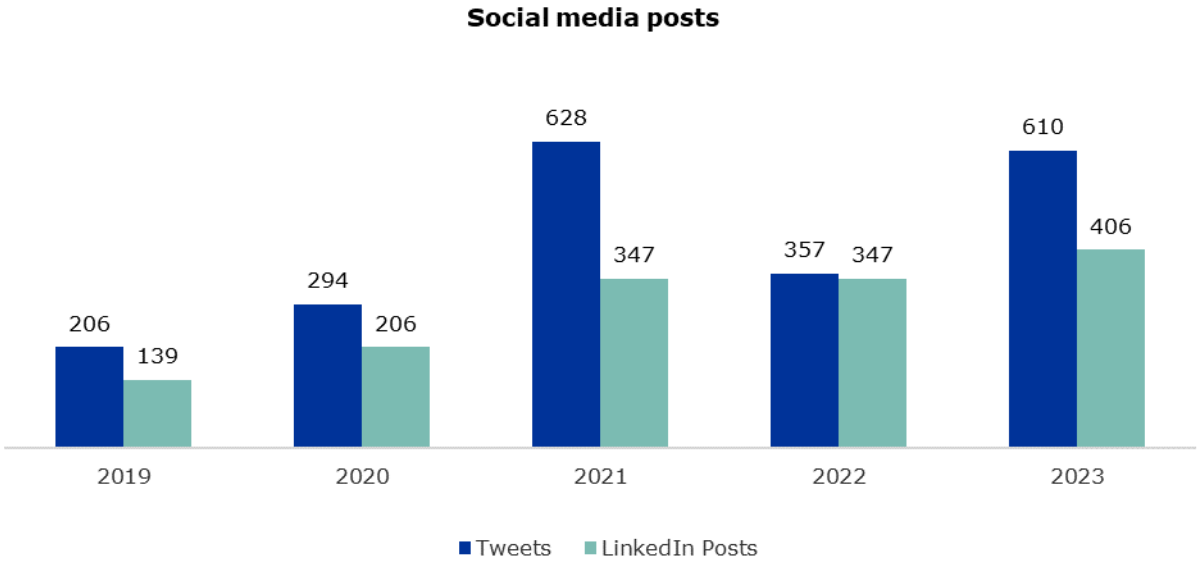
Provision of clear and accurate information on medicines patients, healthcare professionals, researchers, academia, industry and citizens is part of EMA's public health mandate. EMA's website is a comprehensive source of information and guidance on centrally authorised medicines and medicine regulation in the EU. In 2023, the Agency published and updated 5,105 webpages and published 6,611 documents. The website was relaunched by the end of 2023 with new and improved features and functionality.

In 2023, EMA published 124 news announcements informing audiences in the EU and beyond about important developments in relation to the assessment of medicines or significant milestones reached in new and existing initiatives.

Interaction with journalists continued: EMA replied to 1,242 queries from media organisation and organised 35 interviews as well as four press briefings. Two of these were part of the series of regular press briefings on COVID-19; one was co-organised with ECDC and covered the state of respiratory diseases at the beginning of autumn, including preventative and therapeutic medicines; one was on the potential of mRNA technology in areas such as cancer or rare diseases.

Activities on social media were extended, with a number of new creative approaches piloted to reach new audiences. By the end of 2023, EMA had shared 1,016 posts and 24 videos on our social media channels.

EMA's staff and experts continued publishing articles on scientific and regulatory topics in international journals.



Total 2023: 1,016

6.2. Requests for information and access to documents

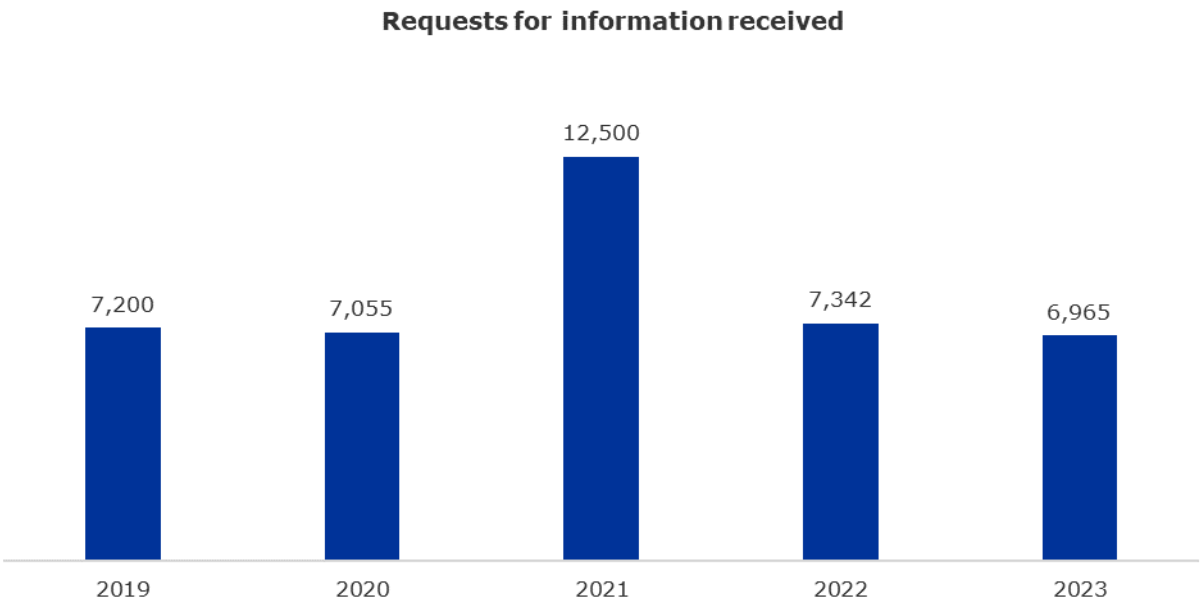
Transparency is an important feature of the European Medicines Agency's operations. Enquiries received are categorised according to the nature of the request.

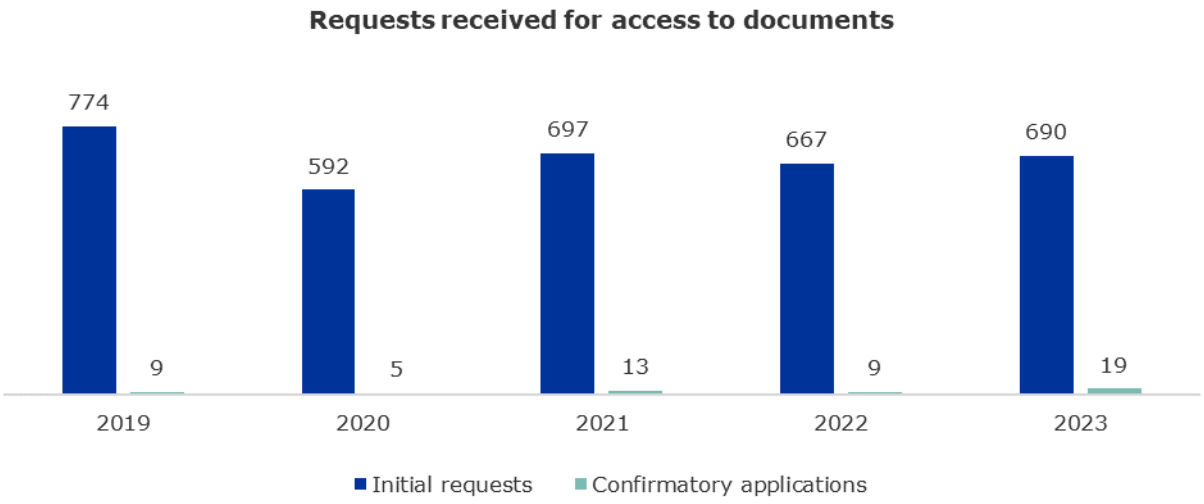
- Requests for information

  General requests submitted to EMA are processed in accordance with the Agency's Code of Good Administrative Behaviour and SOP0019.

- Access to Documents requests

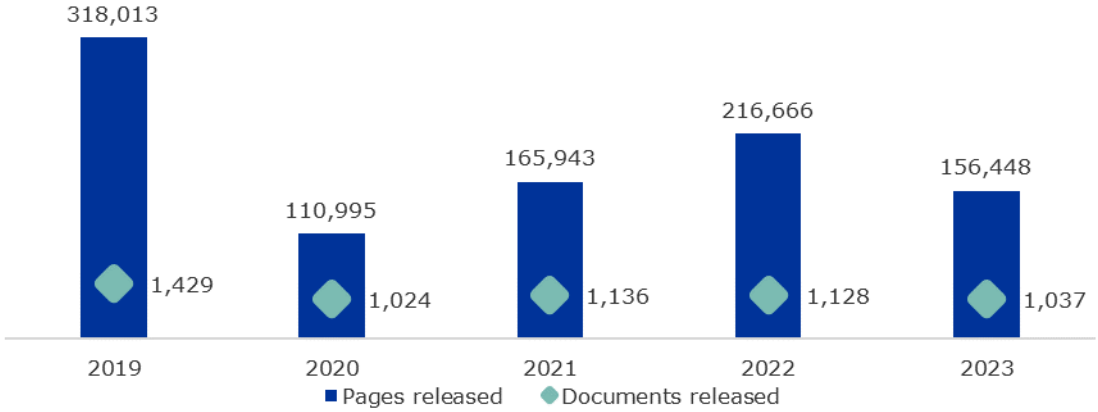
  EU citizens have the right to access documents held by EU institutions, bodies, offices and agencies. EMA grants this access according to the principles and conditions defined by Regulation (EC) No 1049/2001 and the Agency's policy on access to documents (Policy 0043).



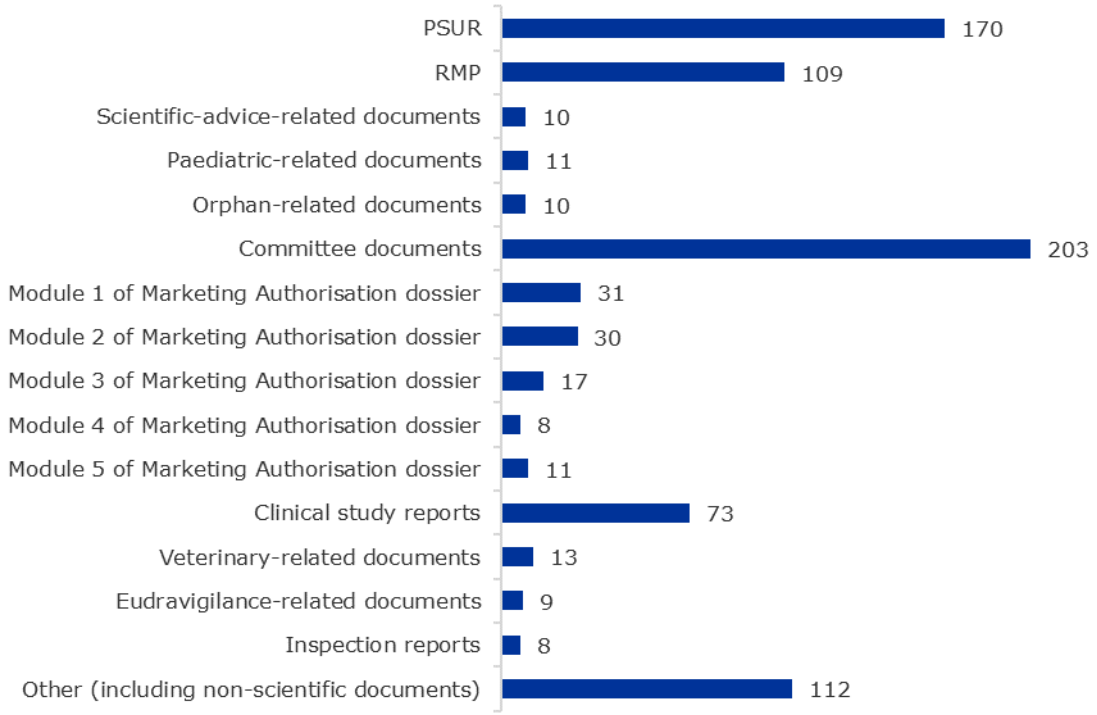


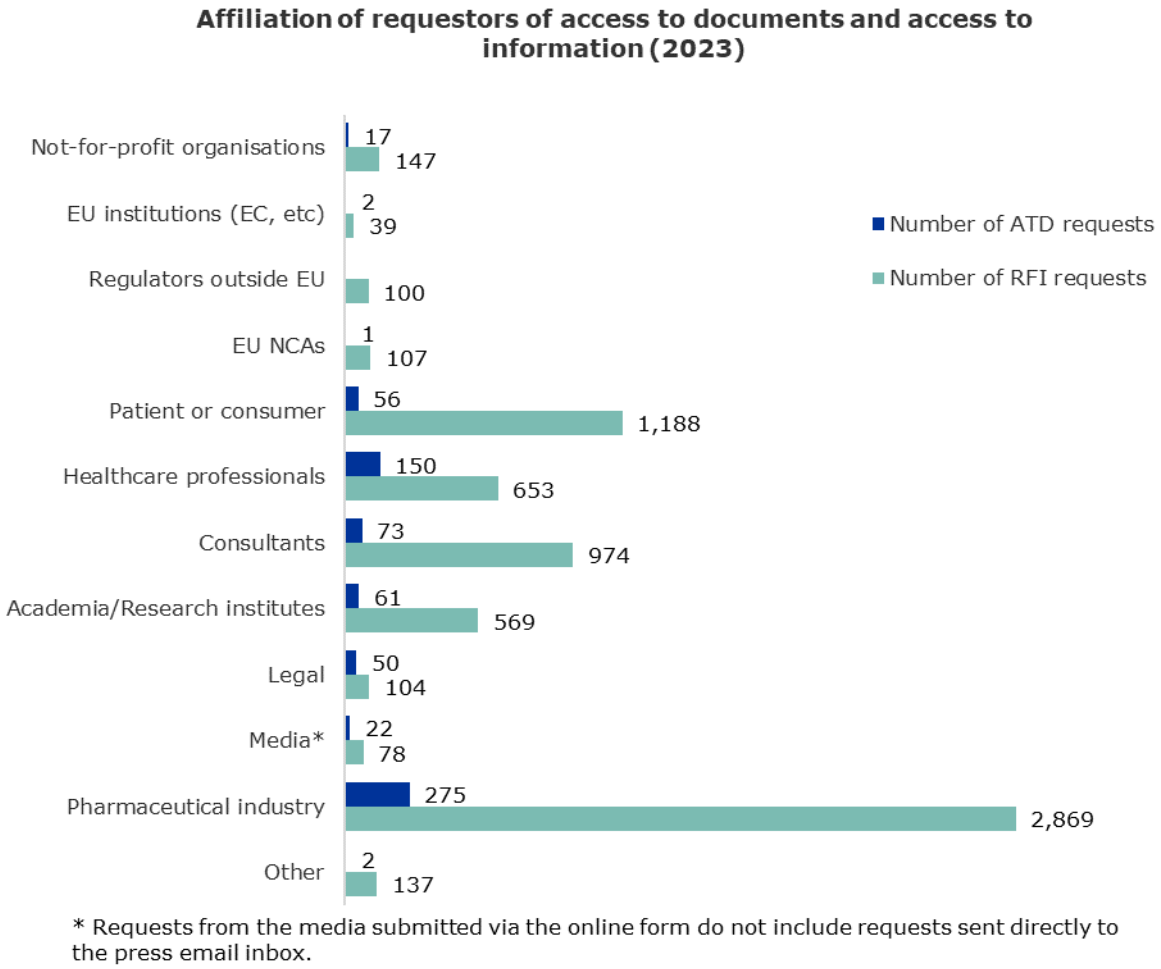
Total 2023: 709

Documents and pages released following access to documents requests



Access to documents by type of document (2023)

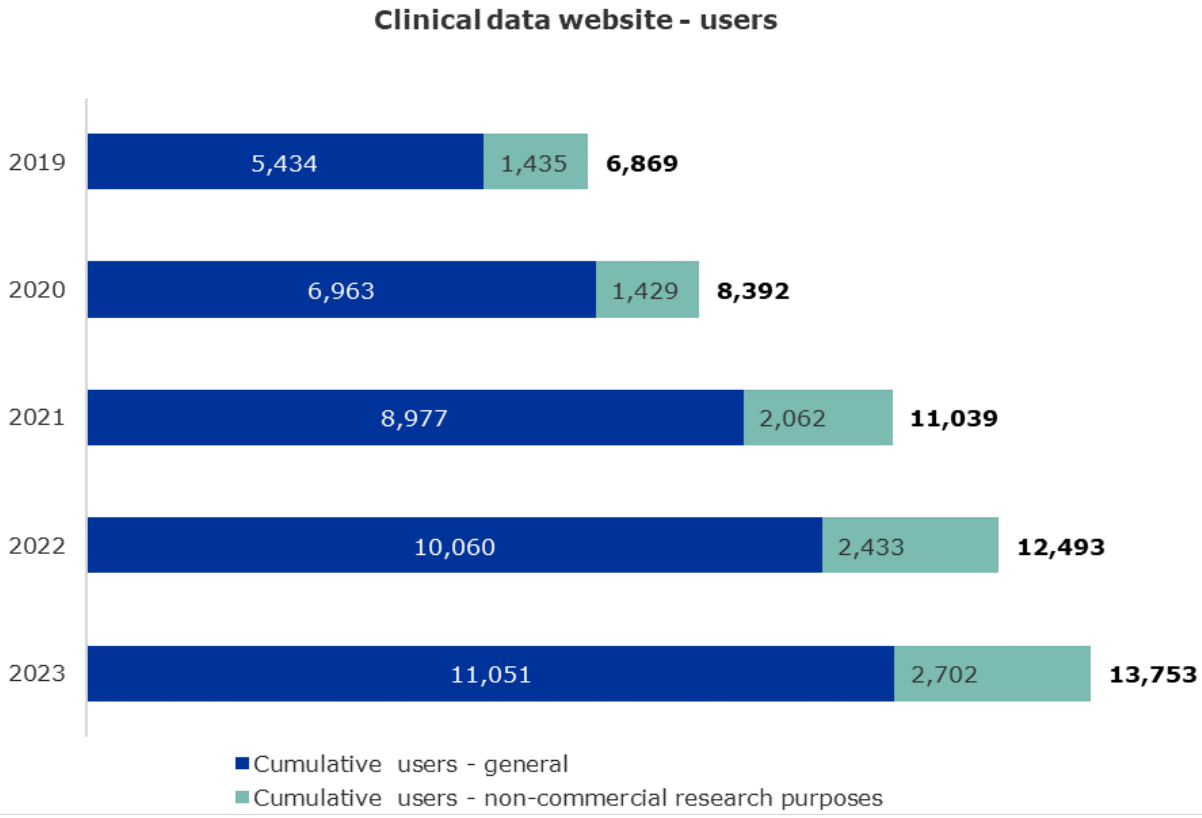


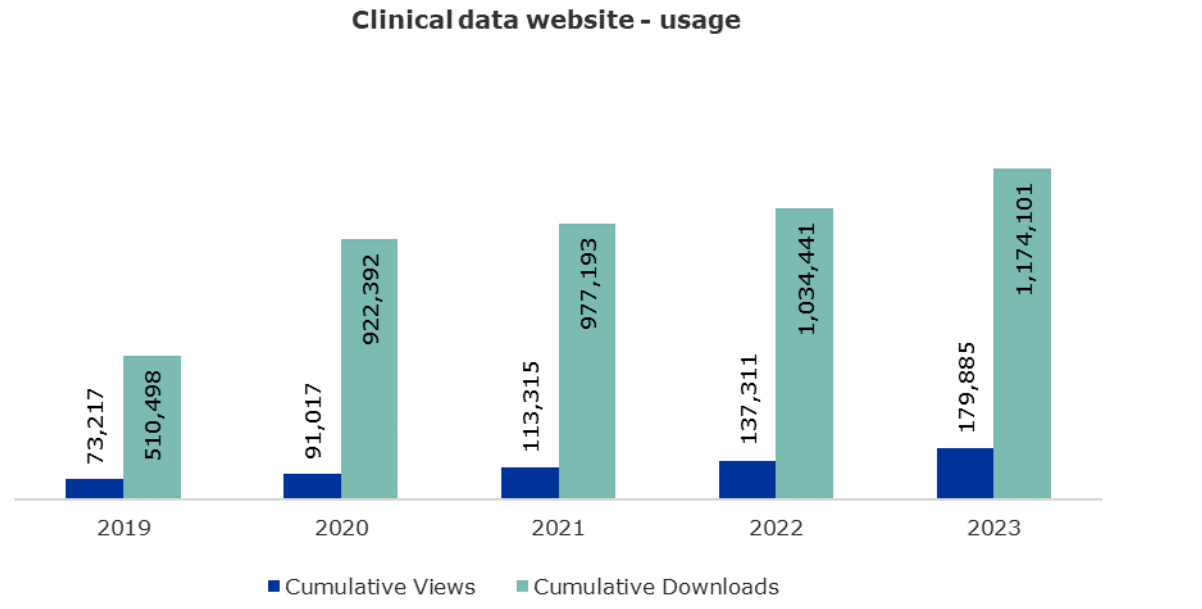


6.3. Publication of clinical data

In 2023 EMA restarted the publication of clinical data for non-COVID medicinal products for human use, under Policy 0070. Publication, which started in 2016, had been temporarily suspended at the end of 2018, first to ensure business continuity during the Agency's relocation to the Netherlands and after that, due to the Covid-19 pandemic.

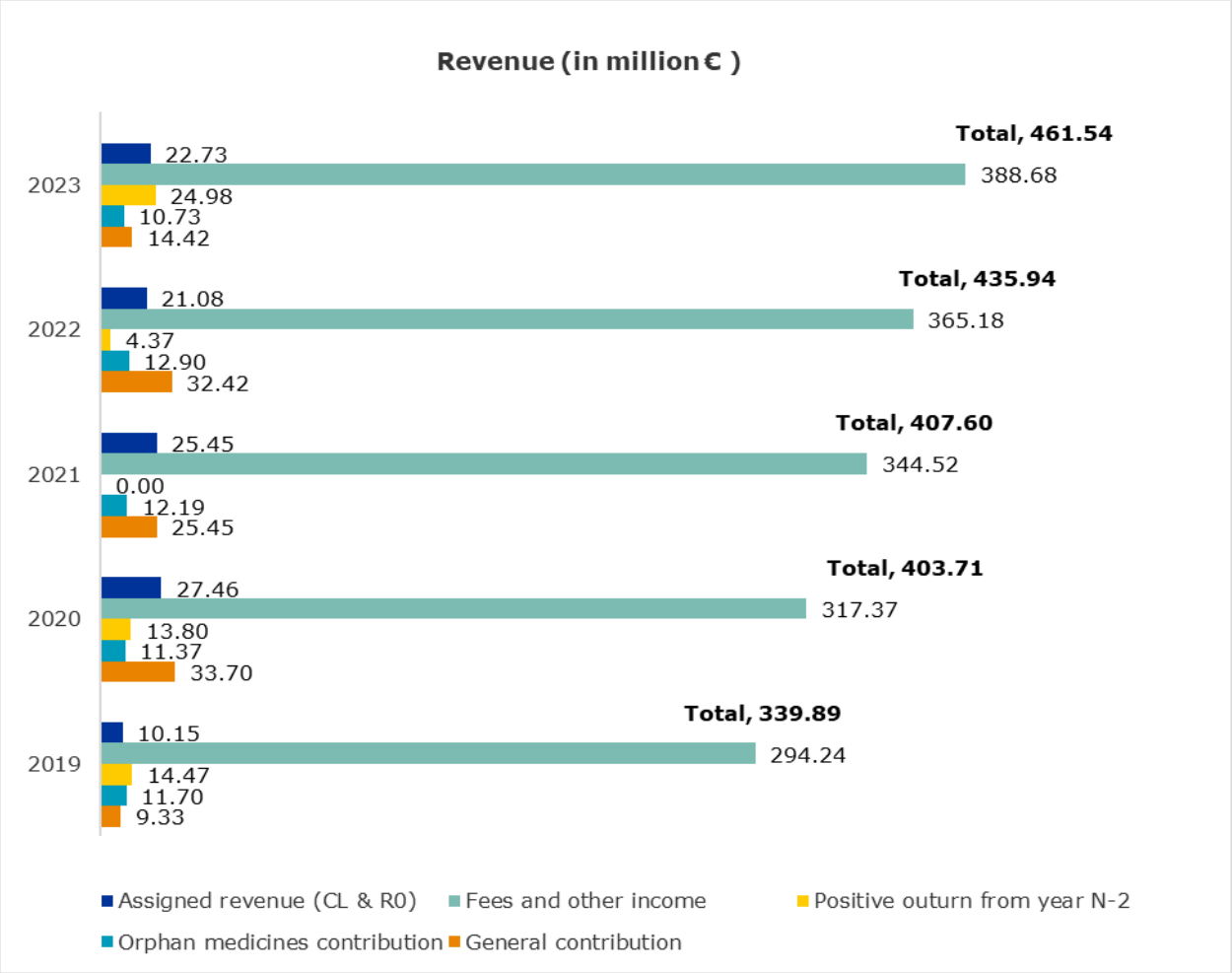
Since early 2024, EMA has been publishing clinical data packages of marketing authorisation applications for new active substances submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure on its CDP portal.


Clinical data website - users
2019
5,434
1,435
6,869
2020
6,963
1,429
8,392
2021
8,977
2,062
11,039
2022
10,060
2,433
12,493
2023
11,051
2,702
13,753
Cumulative users - general
Cumulative users - non-commercial research purposes


Clinical data website - usage
73,217
510,498
91,017
922,392
113,315
977,193
137,311
1,034,441
179,885
1,174,101
2019
2020
2021
2022
2023
Cumulative Views
Cumulative Downloads

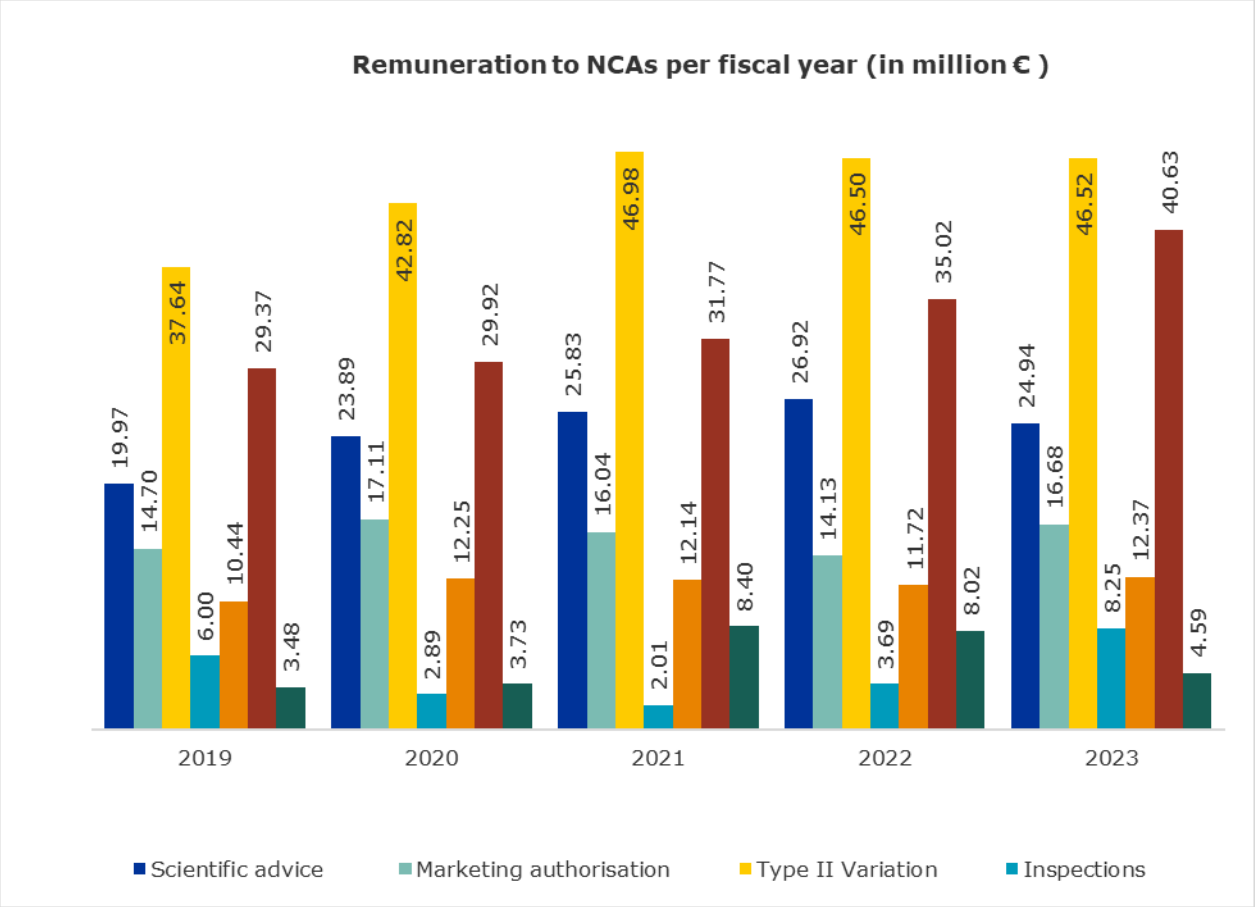
7. Administrative aspects

7.1. Budget – total revenue



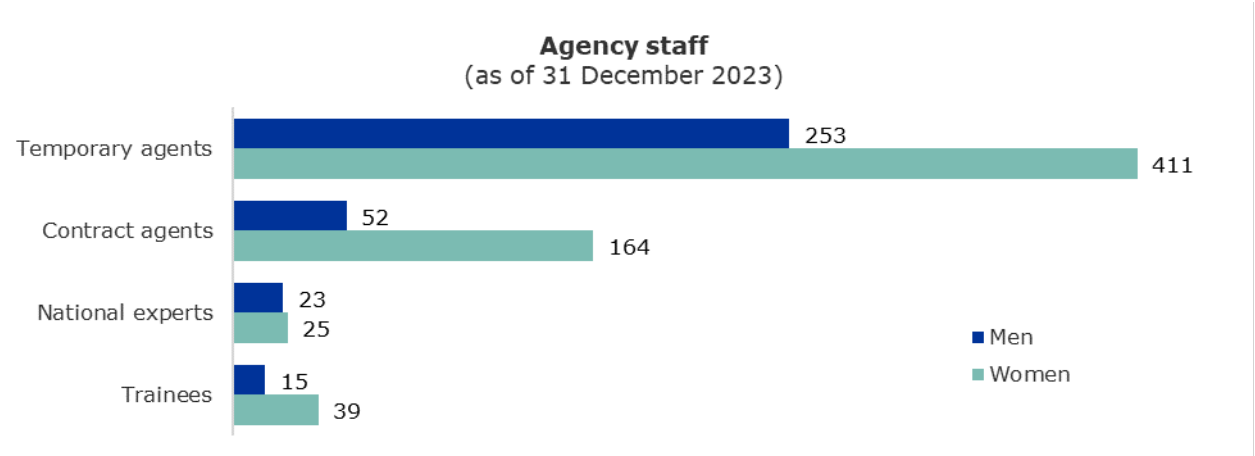
7.2. Remuneration to national competent authorities

NCAs in the EU Member States receive a share of EMA's revenue from fees for the assessments they carry out on behalf of the Agency.

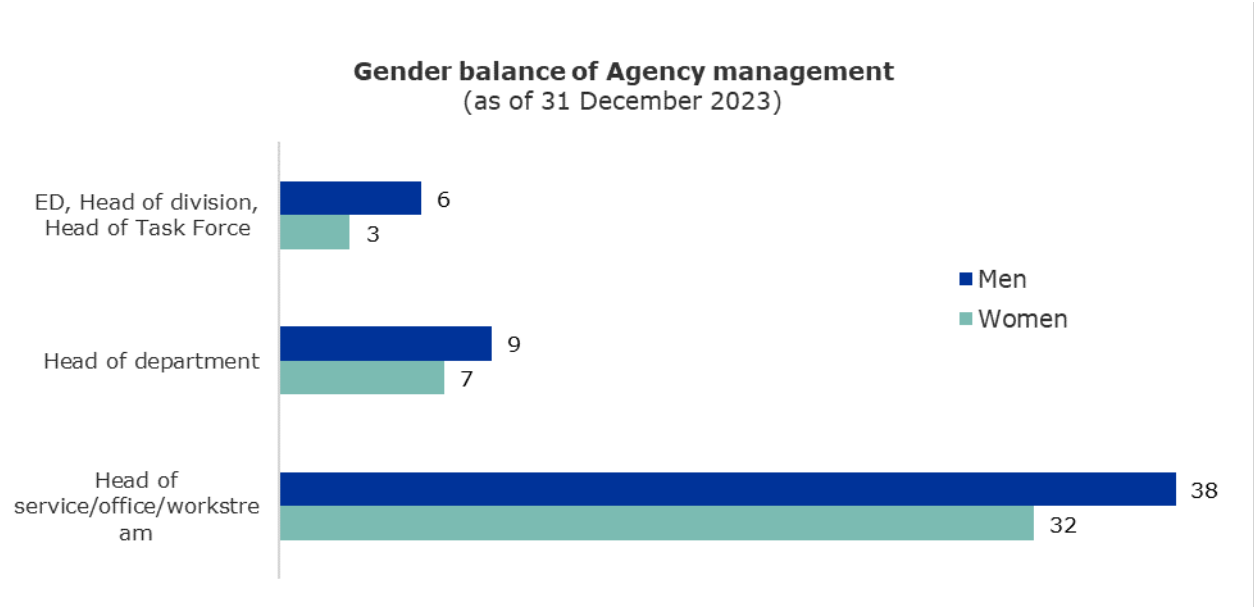


Total 2023: 153.97

7.3. Agency staff

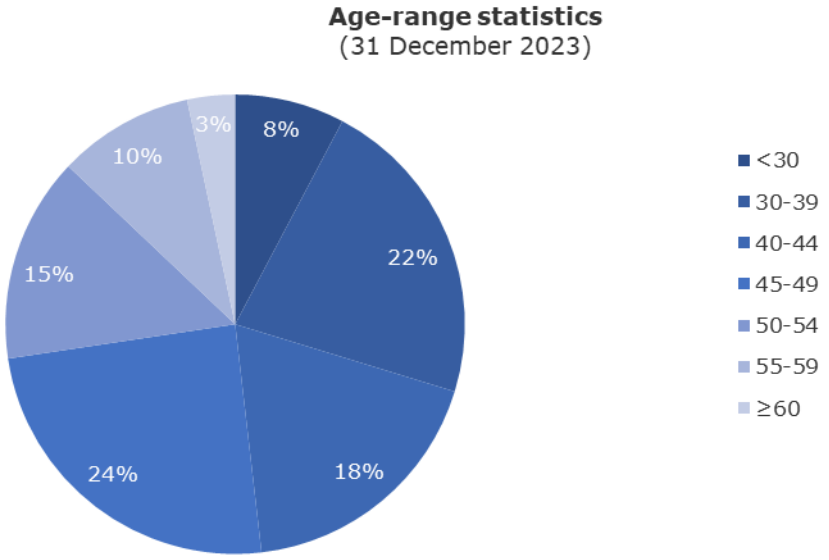


Total 2023: 982

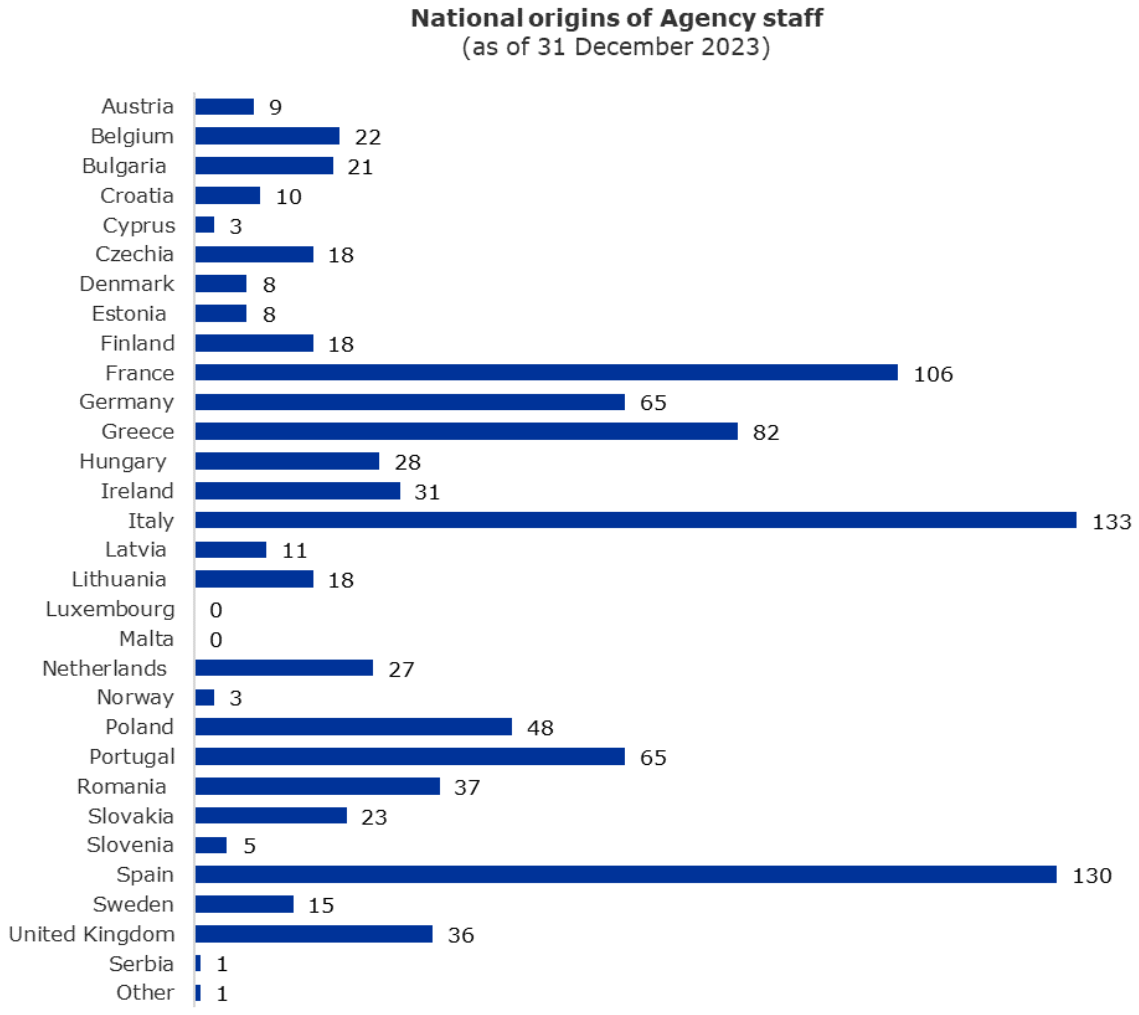


Total 2023: 95

Gender balance 2023												
Status	Category AD (administrators)				Category AST (assistants)				TA/CA - all grades			
	Men		Women		Men		Women		Men		Women	
Temporary agents	217		219		36		192		253		411	
Contract agents	34		80		18		84		52		164	
Total	251	46%	299	54%	54	16%	276	84%	305	35%	575	65%



[57]



[58]

[57] Includes TA, CA, SNE and trainees.
[58] Includes TA, CA, SNE and trainees.

Annex 2. Statistics on financial management

Budget outturn	2020	2021	2022	2023
Revenue actually received (+)	€ 376,246,022.54	€ 382,156,343.70	€ 414,862,609.76	€ 438,811,276.00
Payments made (-)	-€ 290,132,295.87	-€ 274,400,002.19	-€ 301,496,618.72	-€ 347,820,472.27
Carryover of appropriations (-)	-€ 75,300,936.06	-€ 91,090,698.54	-€ 106,828,218.21	-€ 96,226,655.69
Cancellation of appropriations carried over (+)	€ 2,423,908.71	€ 5,372,131.21	€ 4,455,177.77	€ 5,174,935.87
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 3.26	-€ 0.01
Exchange rate differences (+/-)	-€ 585,264.08	€ 2,944,406.68	-€ 533,910.72	€ 81,854.69
Adjustment for negative balance from previous year (-)	-€ 8,283,114.28	€ 0.00	€ 0.00	€ 0.00
TOTAL	**€ 4,368,320.96**	**€ 24,982,180.86**	**€ 10,459,043.14**	**€ 20,938.59**

The financial outturn, a surplus of approx. EUR 20,938.59, representing 0.005% (2.40% in 2022) of total revenue collected, i.e. EUR 461.5 million, cf. the draft budget outturn for all fund sources (C1, C11, R0 and CL), which is a good result considering that 88% of the revenue (C1 and C11) derives from fee paying services.

The Agency's adopted budget consists of non-differentiated appropriations only, so no distinction is made between commitment and payment appropriations.

Budget implementation 2023 is as follows:

- title I - Staff expenditure - final implementation was 99.5%, which is considered a good result
- title II - infrastructure and operating expenditure - final implementation was 98.8%, which is considered a good result
- title III - operational expenditure - final was 98.7%, which is considered a good result.

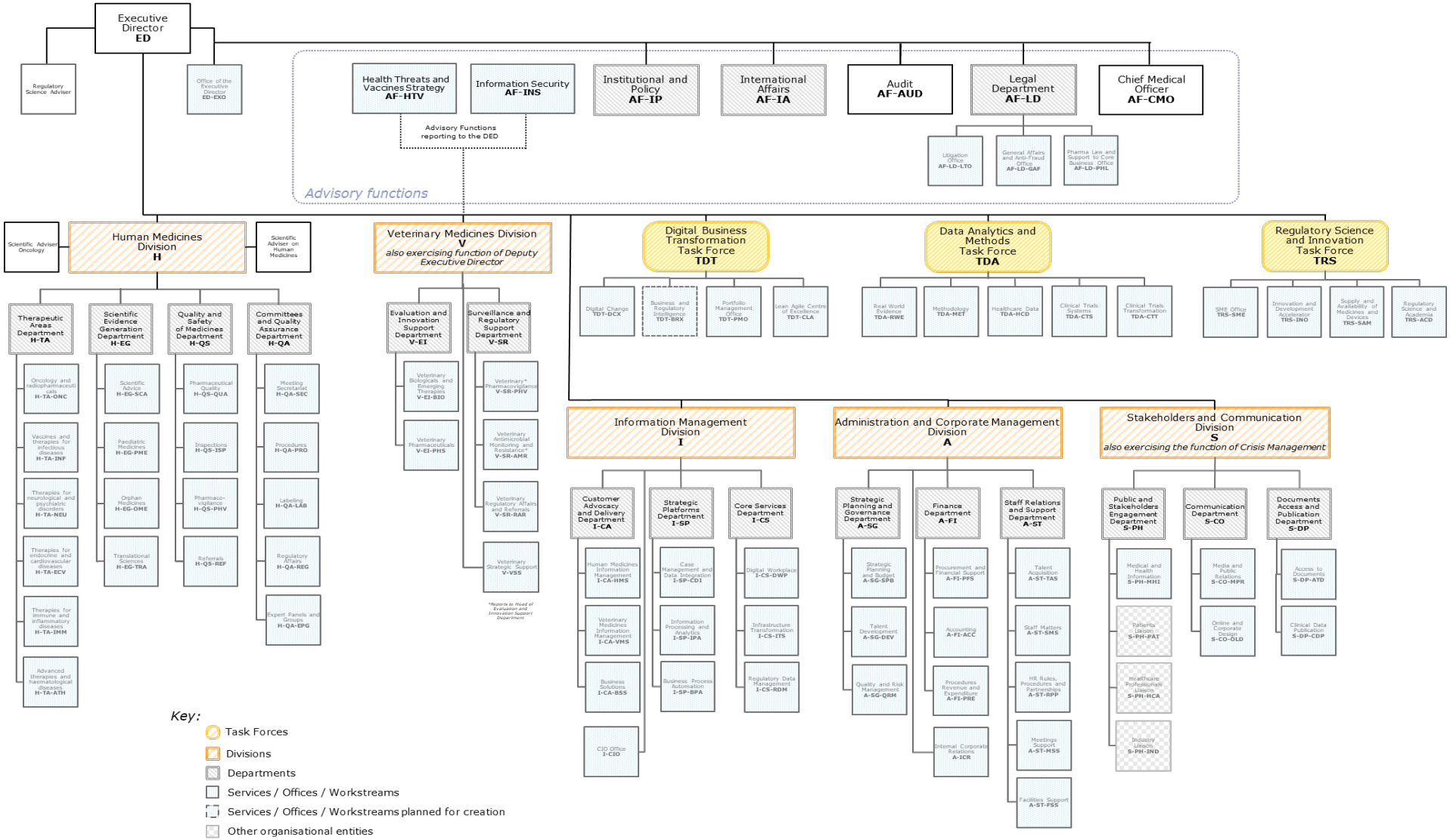
The ceilings/KPIs for the amounts carried forward from 2023 to 2024 (C1 to C8): title I (10%), title II (20%) and title III (30%), with the following percentages achieved for the automatic carry-forward:

- title I - Staff expenditure: 4.89% (4.34% in 2022)
- title II - infrastructure and operating expenditure: 24.86% (26.38% in 2022)
- title III - operational expenditure: 32.59% (40.06% in 2022).

The levels of carry forward in titles 2, building and equipment, and 3, operational expenditure have improved compared to 2022. The carry forward is mainly due to commitments and contracts being put in place in the second part of the year, for work and services related to IT consultancy, scientific studies and data management to be delivered mainly in 2024, which resulted in the relevant commitments being carried forward.

Annex 3. Organisation chart as of 31 December 2023

Organisation chart



Annex 4 Establishment plan and additional information on HR management

Function group and grade	2022				2023				2024	
	Authorised budget		Actually filled as of 31/12/2022		Authorised budget		Actually filled as of 31/12/2023		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16		0		0		0		0		0
AD 15		3		0		3		0		3
AD 14		10		9		12		3		12
AD 13		13		13		12		11		12
AD 12		50		50		57		52		61
AD 11		52		52		49		49		50
AD 10		50		50		53		53		57
AD 9		62		62		66		66		82
AD 8		77		77		87		87		78
AD 7		97		97		89		89		90
AD 6		60		60		67		67		55
AD 5		3		3		0		0		0
AD TOTAL	**0**	**477**		**473**	**0**	**495**		**477**		**500**
AST 11		2		2		2		2		3
AST 10		7		7		7		7		7
AST 9		10		10		10		10		10
AST 8		13		13		14		14		15
AST 7		19		19		25		25		29
AST 6		26		26		31		31		35
AST 5		43		43		43		43		49
AST 4		42		42		43		43		32
AST 3		23		23		12		12		11
AST 2		0		0		0		0		0
AST 1		0		0		0		0		0
AST TOTAL	**0**	**185**		**185**	**0**	**187**		**187**		**191**
AST/SC1										
AST/SC2										
AST/SC3										
AST/SC4										
AST/SC5										
AST/SC6										
AST/SC TOTAL	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
GRAND TOTAL	**0**	**662**	**0**	**658**	**0**	**682**	**0**	**664**	**0**	**691**

Grade filled refers to the number of staff occupying posts of a given grade, regardless of the staff member's actual grade

Contract agents	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024
Function Group IV	122	94	107	122	107	114	125
Function Group III	81	89	91	81	97	102	78
Function Group II	0	1	1	0	0	0	0
Function Group I	0	0	0	0	0	0	0
Additional CA[1]	20	8	8	0	0	0	0
TOTAL	**223**	**192**	**207**	**203**	**204**	**216**	**203**

1) Additional staff to cover Brexit-related additional work (FTE)

Seconded National Experts	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023
Total	30	25	30	45	42	47

Interims	Total FTEs in year 2023
Total	110

Information on the entry level for each type of post

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment	Indication whether the function is dedicated to administrative support or operations
Head of Division/Task Force (Level 2)	TA	AD12	Depending on function: operational or administrative
Head of Department (Level 3)	TA	AD09 (int.), AD10 (ext.)	Depending on function: operational or administrative
Head of Service/Office/Workstream (Level 4)	TA	AD06 (int.), AD08 (ext.)	Depending on function: operational or administrative
Adviser, Senior Expert	TA	AD13	Operational
Senior Specialist, Architect, Lead (e.g. scientific, information technology management, communication)	TA	AD08	Depending on function: operational or administrative
Specialist, Lead, Partner, Architect (e.g. scientific, information technology management, communication)	TA	AD06	Depending on function: operational or administrative
Senior Assistant, Technical adviser	TA	AST10	Depending on function: operational or administrative
Coordinator (e.g. scientific support, HR, communication, legal, facilities)	TA	AST03	Administrative / Operational
Executive Assistant (senior management support)	TA	AST03	Administrative
Officer (e.g. core and support functions)	CA	FGIV	Depending on function: operational or administrative

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment	Indication whether the function is dedicated to administrative support or operations
Analyst (information technology management)	CA	FGIV	Operational
Assistant (e.g. scientific support, HR, communication, department management support)	CA	FGIII	Administrative / Operational
Special functions			
Head of Audit	TA	AD09	Operational
Head of Accounting and Agency's Accounting Officer (Level 4)	TA	AD09	Operational
Data Protection Officer	TA	AD06	Administration

Results of the screening/benchmarking exercise as of December 2023

Job Type (sub) category	2022 (%)	2023 (%)
Administrative support and Coordination	14%	16%
Administrative Support	13%	14%
Coordination	2%	2%
Operational	79%	78%
Top level Operational Coordination	1%	1%
Programme management and Implementation	26%	29%
Evaluation & Impact assessment	34%	32%
General operational	18%	16%
Neutral	7%	6%
Finance/ Control	7%	6%
Linguistics	0%	0%
Total	100.00%	100.00%

HR implementing rules adopted in 2023

Implementing rule	Adopted	Effective date
Revised rules handling declared interests of staff and candidates before recruitment	1/03/2023	1/03/2023
Amendment to EMA decision on Type of post and post titles	13/12/2023	31/01/2024

Annex 5. Human and financial resources by activity

Activities	Full Time Equivalence (Temporary)	Full Time Equivalence (Contract Agents & Seconded National Experts)	Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	TOTAL
			€'000	€'000	€'000	€'000	€'000	
1 Evaluation activities for human medicines	**287**	**114**	**64,994**	**26,172**	**4,749**	**144,013**	**12,792**	**252,720**
1.1 Pre-authorisation activities	58	23	13,822	3,905	2,768	24,644	13	45,152
1.2 Initial evaluation activities	46	11	10,028	2,457	0	14,659	912	28,057
1.3 Post-authorisation activities	73	28	14,425	9,650	0	92,004	4,768	120,846
1.4 Referrals	6	2	1,042	314	0	43	177	1,576
1.5 Pharmacovigilance activities	46	22	10,396	4,493	1,061	12,370	4,071	32,391
1.6 Other specialized areas and activities	54	27	14,265	5,030	919	294	2,782	23,290
1.7 Medical Devices	5	1	1,016	322	0	0	69	1,407
2 Evaluation activities for veterinary medicines	**31**	**15**	**7,307**	**3,341**	**803**	**2,941**	**554**	**14,947**
2.1 Pre-authorisation activities	1	0	247	73	51	0	0	370
2.2 Initial evaluation activities	8	2	1,524	427	0	2,020	114	4,085
2.3 Post-authorisation activities	10	3	1,759	531	0	918	295	3,503
2.4 Arbitrations and referrals	1	1	198	72	0	0	138	408
2.5 Pharmacovigilance activities	5	3	1,321	1,259	383	3	7	2,973
2.6 Other specialized areas and activities	7	6	2,259	980	368	0	0	3,607
3 Horizontal activities and other areas	**206**	**95**	**50,302**	**55,757**	**9,544**	**7,014**	**4,951**	**127,567**
3.1 Committee coordination	38	19	9,146	2,476	4,201	0	0	15,822
3.2 Inspection and Compliance	25	19	6,014	2,851	1,118	7,014	4	17,001
3.3 Partners and Stakeholders	37	12	9,210	2,496	3,159	0	658	15,523
3.3a Transparency and access to documents	19	12	4,089	1,232	0	0	0	5,321
3.3b Information	39	19	9,334	5,561	1,065	0	2,058	18,018
3.4 International activities	15	1	3,657	805	1	0	0	4,464
3.5 Information Management (incl. EU Telematics)	34	12	8,852	40,336	0	0	2,231	51,419
4 Corporate Governance and Support activities	**139**	**38**	**32,940**	**12,502**	**224**	**0**	**2,833**	**48,500**
4.1 Governance, Quality Management and Internal Audit	24	7	5,697	1,392	224	0	512	7,825
4.2 Finance	28	10	7,181	5,352	0	0	75	12,609
4.3 Information technology	28	6	7,917	2,127	0	0	2,212	12,256
4.4 Human resources	46	12	10,023	3,029	0	0	33	13,086
4.5 Infrastructure services	12	3	2,122	601	0	0	0	2,724
Total	**664**	**263**	**155,543**	**97,773**	**15,319**	**153,968**	**21,131**	**443,734**

Annex 6. Contribution, grant and service level agreements. Financial Framework Partnership Agreements

	General information					Financial and HR impacts			
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**N-1**		**N**	
Grant agreements										
STARS	17/07/2019 (EMA's accession)	€ 6,000.00	31/12/2022	DG RTD	Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice	Amount	CA € 0	PA € 0	CA € 1,659	PA € 1,659
						Number of CA	0		0	
						Number of SNEs	0		0	
ConcePTION	26/04/2019	€ 85,000.00	31/03/2024	IMI 2 Joint Undertaking	Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding:	Amount	CA € 0	PA € 0	CA € 0	PA € 0
						Number of CA	0		0	
						Number of SNEs	0		0	
SISAQOL	30/10/2020	€ 78,756.25	31/12/2024	IMI 2 Joint Undertaking	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life endpoints	Amount	CA € 0	PA € 0	CA € 0	PA € 0
						Number of CA	0		0	
						Number of SNEs	0		0	
PREMIER	29/06/2020	€ 47,000.00	31/08/2026	IMI 2 Joint Undertaking	Prioritisation and Risk Evaluation of Medicines in the Environment	Amount	CA € 0	PA € 0	CA € 0	PA € 0
						Number of CA	0		0	
						Number of SNEs	0		0	
Total grant agreements						**Amount**	**CA** **€ 0**	**PA** **€ 0**	**CA** **€ 1,659**	**PA** **€ 1,659**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Contribution agreements										
IPA II IPA/2019/413-383	19/12/2019	€ 254,919.00	31/12/2023	DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	CA € 0	PA € 0	CA € 253,719	PA € 253,719
						Number of CA	0		0	
						Number of SNEs	0		0	
ePI 2021/SI2.869573&SI2.869590	13/04/2022	€ 1,500,000.00	31/12/2023	DG SANTE	Development of electronic product information (ePI) for EU medicines	Amount	CA € 1,399,778	PA € 1,399,778	CA € 1,495,988	PA € 1,495,988
						Number of CA	0		0	
						Number of SNEs	0		0	
NDICI Africa 2023/448-919	20/12/2023	€ 10,000,000.00	01/12/2027	DG INTPA	Local manufacturing and access to vaccines, medicines and health technologies in Africa	Amount	CA € 0	PA € 0	CA € 0	PA € 0
						Number of CA	0		0	
						Number of SNEs	0		0	
IPA III 700001692	11/12/2023	€ 600,000.00	31/12/2026	DG NEAR	EU4 Alignment on medicines regulation in the Western Balkans and Turkiye	Amount	CA € 0	PA € 0	CA € 0	PA € 0
						Number of CA	0		0	
						Number of SNEs	0		0	
Total contribution agreements						**Amount**	**CA** **€ 1,399,778**	**PA** **€ 1,399,778**	**CA** **€ 1,749,707**	**PA** **€ 1,749,707**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Service-level agreements										
1. …						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
2. …						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
…						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
Total service-level agreements: 0						Amount	**CA** **€ 0**	**PA** **€ 0**	**CA** **€ 0**	**PA** **€ 0**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
TOTAL						**Amount**	**CA** **€ 1,399,778**	**PA** **€ 1,399,778**	**CA** **€ 1,751,366**	**PA** **€ 1,751,366**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	

Annex 7. Environment management

Aspect	Environmental objectives	Environmental targets	Actions to achieve environmental objectives	Reporting
Direct	Energy efficiency: "EMA drives energy efficiency in line with good practices"	100% renewable energy for electricity achieved Actions targeted to directly support the objective	Replacement scheme of electronic equipment such as laptops and small electricity for further energy efficiency, when technically and financially justifiable	Over the last year, the EMA improvement actions focused on decreasing ventilation hours on office floors by 1,5 hours and reducing restaurant ventilation by 2 hours without impacting on comfort. Also, through the public procurement procedures, efficient energy management is ensured by selecting equipment with energy efficient labels; for example, the MFDs (printers) with EPEAT and Energy Star labels, kitchen equipment with at least EU label and classification A, etc. Some floors have reduced numbers of printers and the new contract include 23 devices compared with 45 previously, expected to reduce energy consumption due to a lower number of machines on stand-by.
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor consumption of materials used (paper, plastic) to reduce or maintain levels during the pandemic	Promote reduced use of single-use materials along a circularity approach Promote paper-less workflows and digitisation	During 2023 all single-use items such as paper cups and food boxes for take-out were removed from the EMA restaurant. The total number of printed copies continues to be at low levels despite the return to the offices in 2023, see performance indicator table for more details.
	Water – not relevant due to the water efficiency at the EMA building	N/A	N/A	Water consumption continues to be monitored as part of the EMA environmental management activities. Some increase is related to higher occupancy of the EMA building and many staff cycling to the offices and therefore using the shower facilities provided.
	Waste: "EMA drives waste reduction in line with good practices"	Monitor the generation of waste to reduce the non-recyclable waste and hazardous waste	Monitor total waste per FTE and year and manage waste along a circularity approach	Despite increased on-site working the volume of total waste as well as the individual waste streams are well maintained. Following the removal of single-use cups and food boxes and the continues reduction of printing the volumes of recyclable paper waste continues to go down.
	Biodiversity – not relevant due to no further land being taken into use	N/A	N/A	EMA did not perform any actions regarding biodiversity at its premises.
	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] Air emissions [t]	Monitor travel by staff and delegates to align with internal interim mission rules, for a balanced approach between face to face and virtual meetings Enable agile working for employees, thus reducing transport needs by providing support to remote and home working	EMA has received the new draft mission rules expected to come into effect by the end of 2024. Meanwhile the Agency continues to use the temporary rules from June 2022 for staff missions as well as maintain a hybrid approach to committee meetings with every other meeting virtual. To further manage the continuous improvements EMA implements green criteria in its public procurement procedures when available. Each procurement includes a wide range of green criteria that are a result of consultations with the EP Green Public Procurement Helpdesk.
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2022-2025	Actions as included in the SPD 2022-2025	Actions and outcome of reviewing Environmental Risk Assessments as part of marketing authorisations are presented in the operational sections of this AAR.

Performance indicator	2020	2021	2022	2023
Electricity, kW	1.131.079	1.736.230	2.144.909	2.228.183
Renewable electricity, % (carbon neutral)	100%	100%	100%	100%
Water, M3	3.955	3.660	5.958	7.566
Office paper consumption, n sheets	906.046	613.747	554.486	672.426
Waste total, kg	69.035	41.998	54.717	64.267
- paper, kg	13.165	5.070	5.476	6.164
- plastic, kg	1.044	763	451	1.199
- glass, kg	1.554	1.257	3.204	3.922
- food, kg	26.875	13.848	13.691	14.756
- confidential (paper), kg	1.690	1.719	1.988	2.050
- non-recyclable, kg	24.707	19.341	29.907	36.176
Purchased heat and steam	4.694	4.549	4.387	3.978
Purchased cooling	568	567	752	3.031
TCO2e from building	236	177,7	203,01	219
TCO2e from travel	525,7	0,8	791,6	1.682,9
TCO2e total	809,1	178,5	979,9	1.901,9

The EMA building has a net lettable area of 33,100 Sqm and 1300 work-stations.

Further environment performance reporting will be presented in the EMA Environmental Statement 2023, as part of EMA registration to the EU Eco-management and Audit Scheme (EMAS), Regulation (EC) No 1221/2009 as amended, and in line with the Sectoral Reference Document on best environmental management practices, sector environmental performance indicators and benchmarks of excellence for the public administration sector, Commission Decision (EU) 2019/61.

Annex 8. Draft annual accounts

Following a positive opinion by the European Court of Auditors, the Agency's annual accounts for the financial year 2022 were successfully adopted by the Management Board in June 2023 and sent to the Budget authority (European Parliament and Council) by 1 July 2023.

During the assessment of the Annual Activity Report, EMA management board has been involved in the review of 2023 provisional annual accounts.

At the time of writing, the Court of Auditors had not yet provided the Agency with their observations on the provisional accounts 2023 and therefore, the Agency's final accounts 2023 has not been issued yet.

The Agency's annual accounts are published yearly on the Agency's website Financial management and budgetary reporting | European Medicines Agency (europa.eu) on or around the 1st July.

Annex 9. 2023 report on staff engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

Individual decisions of senior EMA staff leaving the agency, are published on the Art 16/CoI webpage:

Handling competing interests | European Medicines Agency (europa.eu)

Engaging in an occupational activity within two years of leaving the service - restrictions applied to applications in 2023:

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
1	Scientific Officer	3 years	29/03/2023	18/04/2023	During a period of six months to be counted as of the date they leave the Agency, they should refrain from individually liaising with any member of staff of EMA with respect to the specific products and/or areas they may have dealt with during their last three years of service. The distance clause is without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders.	19/04/2023
2	Seconded National Expert	1 years 10 months	28/06/2023	14/07/2023	During a period of six months to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during their last three years of service. This distance clause is without prejudice to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings	18/07/2023

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
					offered by the Agency to the different stakeholders.	
3	Seconded National Expert	6 years	6/06/2023	1/09/2023	During a period of six months to be counted as of the date they leave the service, they should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas they may have dealt with during their last three years of service. The distance clause is without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders.	4/09/2023
4	Scientific officer	2 years 9 months	31/08/2023	22/09/2023	Holds that during a period of six months to be counted as of the date they leave the service, they should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity they may have dealt with in the performance of their responsibilities at the Agency during the last three years of service. The distance clause is without prejudice to the possibility to liaise or attend meetings through the standard channels available to all members of the public, including standard procedural services and meetings offered by the Agency to the different stakeholders	25/09/2023

Annex 10. Administrative appropriations – Building policy

#	Building name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	Non-office space	Total	Rent (€/year)	Duration of the contract	Type	Break-out clause Y/N	Conditions attached to breakout clause	
1	EMA premises Amsterdam	Domenico Scarlattilaan 6 Amsterdam, 1083 HS	22,574	10,837	33,411	10,938,000 (for 2023; yearly indexation)	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (NL government Agency)	Y (condition to terminate)	The Lease can be terminated - At any time by mutual consent of the parties - At any moment by the Lessee/EMA with a notice period of 6 months if a decision is made to transfer EMA headquarters to another EU location - By either party after a consecutive period of 6 months of force majeure events which make the performance of the aggrieved Party impossible.	EUR 18 million inducement of which EUR 15 million were for enhancements to fitting out the premises and EUR 3 million are for rent reductions over the term of the lease.
2	Former EMA premises, London	30 Churchill Place, Canary Wharf, London E14 5EU	17,946	12,394	30,340	Sub-let	25 years from 1 July 2014 to 30 June 2039	Lease agreement with Canary Wharf Mgt	N	n/a	None

#	Building name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	Non-office space	Total	Rent (€/year)	Duration of the contract	Type	Break-out clause Y/N	Conditions attached to breakout clause	
Total			**40,520**	**23,231**	**63,751**	**10,721,100**					

Financial Regulation, Article 110 (GFR Article 266 (2)) Evolution of surface area and locations and building projects in planning phase

The Agency does not have any further building projects in planning phase.

Financial Regulation, Article 110 (GFR Article 266 (3)) Building projects submitted to the European Parliament and the Council

In December 2023 the Agency submitted a pre-information note for developments with regards to its previous headquarters in London, UK and anticipates submitting a building notification to the European Parliament and the Council in Q1/2024.

Annex 11. Annual report 2023

Please see the Agency's Annual report 2023, publicly available on the EMA corporate website.

Annex 12. Pharmacovigilance Fee Regulation- Key Performance Indicators and performance information for the calendar year 2023

Context

The Pharmacovigilance Fee regulation (Regulation (EU) No 658/2014) was adopted on 15 May 2014. The first procedural fees were charged as of 26 August 2014 and the first annual fees in July 2015.

The aim of the regulation is to enable the Agency to charge fees for the pharmacovigilance tasks introduced by the pharmacovigilance legislation i.e. Union pharmacovigilance procedures (PSURs, PASS, pharmacovigilance referrals), literature monitoring and improved use of information technology tools. Financing the activities contributes to "achieving an internal market as regards medicinal products, taking as a basis a high level of protection of health" and inseparable from this is the aim "to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products."

Article 15 of the regulation, dealing with transparency and monitoring, states that the Executive Director of the Agency shall provide the Commission and the Management Board once per year with the performance information set out in part V of the annex to the regulation based on a set of performance indicators adopted by the Agency.

Section 2 of this report presents these key performance indicators for the calendar year 2023, and section 3 presents the more detailed performance information required by the regulation.

Part 1: Key Performance Indicators

KPI 1: procedures started within the year for which a fee has been charged

Pharmacovigilance activities financed by PhV fees	2023 actual
Number of PSURs and PSUSAs procedures started	852
Number of imposed PASS protocol procedures started	2
Number of imposed PASS report procedures started	7
Number of pharmacovigilance referral procedures started	2
Number of pharmacovigilance annual fee chargeable units invoiced	144,661

KPI 2: percentage of marketing authorisation holders eligible for fee exemption or fee reductions within a given year for procedures carried out at Union level

Pharmacovigilance activities financed by PhV fees	* 2023 estimated	2023 actual	2023 percentage
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **CAPs only**:		615	
· Micro sized enterprises	2.25%	2	0.33%
· Small and medium sized enterprises	7.50%	36	5.85%
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **NAPs or CAPs/NAPs**:		278	
· Micro sized enterprises	2.50%	35	12.59%
· Small and medium sized enterprises	7.50%	162	58.27%
MAHs invoiced for **Imposed PASS protocol** procedures started for **CAPs only**:		2	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%
MAHs invoiced for **Imposed PASS protocol** procedures started for **NAPs or CAPs/NAPs**:		0	
· Micro sized enterprises	2.50%	0	
· Small and medium sized enterprises	7.50%	0	
MAHs invoiced for **Imposed PASS report** procedures started for **CAPs only**:		5	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	1	20.00%
MAHs invoiced for **Imposed PASS report** procedures started for **NAPs or CAPs/NAPs**:		182	
· Micro sized enterprises	2.5	1	0.55%

· Small and medium sized enterprises	7.50%	8	4.40%
MAHs invoiced for Pharmacovigilance **referral** procedures started for **CAPs only:**		0	
· Micro sized enterprises	2.25%	0	
· Small and medium sized enterprises	0.75%	0	
MAHs invoiced for Pharmacovigilance **referral** procedures started for **NAPs or CAPs/NAPs:**		132	
· Micro sized enterprises	2.50%	0	0.00%
· Small and medium sized enterprises	7.50%	7	5.30%

* Estimates based on the impact assessment

KPI 3: percentage of chargeable units eligible for fee exemption or fee reductions within a given year for annual fees for information technology systems and literature monitoring

Pharmacovigilance activities financed by PhV fees	* 2023 estimated	2023 actual	2023 percentage
Eligible for pharmacovigilance **annual fee** chargeable units invoiced		144,661	
· Micro sized enterprises	2.5%	1,111	0.77%
· Small and medium sized enterprises	7.5%	8,289	5.73%
· Generics (non-SME)	36.0%	63,494	43.89%
· Authorised homeopathic, authorised herbal, and well-established use product	0%	24,889	17.21%

Target: the estimated percentages

* Estimates based on the impact assessment

KPI 4: percentage of fees which has been recovered for the procedures invoiced within a given year and committed/paid to NCAs

Pharmacovigilance activities financed by PhV fees	[59] Invoiced in 2023	Cash collected in 2023	[60] Percentage	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	17,880	17,593	98% (98% in 2022)	12,014
Income recovered for imposed PASS protocol procedures started	50	50	100% (100% in 2022)	21
Income recovered for imposed PASS report procedures started	189	189	100% (100% in 2022)	68
Income recovered for pharmacovigilance referral procedures started	400	399	100% (100% in 2022)	267
Income recovered for pharmacovigilance annual fee chargeable units invoiced	9,228	9,164	99% (99% in 2022)	n/a

[59] The figures in this table differ from the ones in tables 4,5,6 and 9 because they also include adjustments and corrections related to 2023 and processed in 2024, whereas the amounts shown in the tables below show only the value of the invoices related to the applications started between January and December 2023. In addition, some of the applications received at the end of the year were processed in the financial system in January 2024.

[60] Invoices are issued with 30 days credit which means that the payment of the invoices issued in November and December 2023 were paid for in 2024. The final 2023 cash recovery rate as of April 2024 is 99.8% for PSURs and PSUSAs and 99.6% for Annual fee.

Part 2: Performance information criteria defined in Part V of the Annex to the Regulation

Fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use - Regulation (EU) No 658/2014: Performance Information

Reporting period: 1st January - 31st December 2023

Table	Performance Information (Part V of the Annex)
1	Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Article 4 to 7.
2	Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.
3	Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Article 4 to 7.
4	Performance information relating to periodic update safety reports (PSURs)
5	Performance information relating to post-authorisation safety studies (PASS)
6	Performance information relating to referrals initiated as result of the evaluation of pharmacovigilance data
7	Information on marketing authorisation holders that have claimed a small and medium-sized enterprise or micro enterprise status
8	Information on marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees
9	Performance information relating to the annual fees
10	Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
11	Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

Note: the Agency has made every effort to complete the detailed reporting requirements of the following tables but in a small number of cases some data has not been available for the full calendar year 2023 pending the development of additional IT reporting functionality, in which cases the relevant fields are left blank.

1) Number of FTEs involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees.	Full Time Equivalence (FTEs)
Periodic safety update reports	**10**
Post-authorisation safety studies	**2**
Referrals initiated as a result of the evaluation of pharmacovigilance data	**3**
TOTAL	**15**

	2023		
2) Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.	**Units**	**Units**	**Cost €'000**
Identifying and managing duplicates	Number of duplicate couples assessed	109,689 (147,875 in 2022)	2,214
	Number of 'master' reports generated based on duplicated data	105,033 (41,728 in 2022)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded	77,598 (147,054 in 2022)	
	Number of adverse reaction reports recoded:	66,461 (13,619 in 2022)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review	160 (32 in 2022)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected	163,013 (131,436 in 2022)	

[61]Monitoring of substance groups and selected medical literature	Number of literature references screened and reviewed	581,041 (487,635 in 2022)	1,700
	Number of individual case safety reports (ICSRs) entered into Eudravigilance database and made available to National Competent Authorities and Marketing Authorisation Holders.	9,698 (8,278 in 2022)	

3) Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees.	**Staff costs '000**	**Non-staff costs '000**
Cost for assessment of periodic safety update reports	1,575	12,704
Cost for assessment of post-authorisation safety studies	357	246
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	562	513
Annual cost for information technology systems and literature monitoring		10,572
Overall pharmacovigilance costs	**26,529**	

[61] The European Medicines Agency (EMA) is responsible for monitoring 409 substance groups (309 chemical & 100 herbal) and selected medical literature to identify suspected adverse reactions with medicines authorised in the European Union, and for entering the relevant information into the EudraVigilance database.

4) Performance information relating to the assessment of periodic safety update reports (PSURs)											
Number of procedures started	Number of reports received	Number of MAHs expected to submit	Number of MAHs who submitted	Number of CUs[2]	Number of joint submissions[3]	Number of MAHs who submitted joint report[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
852	n/a	1,498	n/a	38,381	267	4,533	137	4	32	0	16,933,715

5) Performance information relating to the assessment of draft protocols and of final reports of post-authorisation safety studies (PASS)											
Number of procedures started	Number of protocols and reports submitted[1]	Number of (parent) MAHs[2]	Total number of MAHs[2]	Number of joint submissions[3]	Number of (parent) MAHs in case of joint submission[4]	Total number of MAHs in case of joint submission[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
2	n/a	2	2	0	0		0	0	0	0	38,700
7	n/a	133	183	148	130	180	8	0	1	0	126,820

6) Performance information relating to referrals initiated as a result of the evaluation of pharmacovigilance data							
Number of procedures started	Number of MAHs	Number of CUs	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
2	152	414	8	1	0	0	400,402

7 (a) Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	202	4
Fee for assessment of post-authorisation safety studies	9	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	8	1
Annual fee for information technology systems and literature monitoring	390	0

7 (b) Number of marketing authorisation holders that have claimed micro enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	37	0
Fee for assessment of post-authorisation safety studies	1	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	0	0
Annual fee for information technology systems and literature monitoring	156	0

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2023
Generic application (Article 10(1) of Directive No 2001/83/EC)	1,791
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,742
Authorised homeopathic medicinal product	82
Authorised herbal medicinal product	222

9) Performance information on annual fees											
Number of marketing authorisation holders invoiced for annual fees	Number of CUs	SME status claimed?	SME status denied?	Micro status claimed?	Micro status denied?	Number of CUs: Generic Application	Number of CUs: Well-established Use Application	Number of CUs: Authorised Homeopathic	Number of CUs: Authorised herbal	Total Amount Invoiced (€)	Average Amount Invoiced (€)
3,407	144,661	390	0	156	0	68,463	24,116	2,766	1,676	9,240,780	63.88

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	**PASS**	**Referral**
Austria	43	0	0
Belgium	29	1	0
Czech Republic	26	0	1
Germany (BfArM)	73	2	0
Germany (PEI)	51	0	0
Denmark	53	0	0
Estonia	5	0	1
Spain	29	2	0
Finland	27	0	0
France	48	0	1
Greece	4	0	0
Croatia	33	0	0
Hungary	18	0	0
Ireland	34	0	0
Iceland	1	0	0
Italy	34	1	1
Lithuania	9	0	0
Latvia	14	0	0
Malta	6	0	0
Netherlands	118	2	0
Norway	12	0	0
Poland	43	0	0
Portugal	43	1	0
Romania	2	0	0
Sweden	78	0	0
Slovenia	8	0	0
Slovakia	11	0	0
Total	**852**	**9**	**4**

11) Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.							
	PSUR and PSUSA			PASS		Referrals	
NCAs	No. of procs.	Total hours	Average per proc.	No. of procs.	Total hours	No. of procs.	Total hours
Austria	46	2,510	55				
Belgium	31	4,080	132	1	72		
Croatia	17	918	54				
Czech Republic	10	633				1	470
Denmark	58	8,715	150				
Estonia	5	278	56			1	217
Finland	32	2,513	79				
France	35	3,927	112				
Germany-BfArM	66	7,425	113	2	702		
Germany-PEI	29	4,505	155				
Hungary	5	746	149				
Ireland	27	1,894	70				
Italy	25	1,780	71	1	52	1	306
Lithuania	1	222	222				
Malta	1	441	441				
Netherlands	93	4,008	43	1	278		
Norway	14	849	61				
Portugal	43	1,902	44	1	90		
Romania	1	74	74				
Slovakia	8	899	112				
Slovenia	3	187	62				
Spain	8	774	97	1	58		
Sweden	61	3,490	57				
Grand Total	**619**	**52,770**	**85**	**7**	**1,252**	**3**	**993**

The data in the above table was provided by each NCA in line with the reporting requirements of the relevant cooperation agreement and include only finalised procedures. On-going procedure will be reported in the next reporting period.

The data in the table above is based on the information provided by the end of April. It was noted that not all NCAs were in a position to provide data for 2023.

Annex 1

Performance information required as per Part V of the regulation

The following information shall relate to each calendar year:

Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of hours outsourced to third parties with specification of the activities concerned and cost incurred.
Overall pharmacovigilance cost and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of procedures relating to the assessment of periodic safety update reports, as well as number of marketing authorisation holders and number of chargeable units per procedure; number of reports submitted per procedure and number of marketing authorisation holders that have submitted a joint periodic safety update report.
Number of procedures relating to the assessment of draft protocols and of final reports of poste-authorisation safety studies; number of marketing authorisation holders having submitted a draft protocol; number of marketing authorisation holders having submitted a final study report; number of marketing authorisation holders that have submitted a joint study.
Number of procedures relating to the referrals initiated as a result of the evaluation of pharmacovigilance data as well as number of marketing authorisation holders and number of chargeable units involved per marketing authorisation holder and per procedure.
Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure; number of marketing authorisation holders whose claim has been denied. Number of marketing authorisation holders that have claimed a micro enterprise status; number of marketing authorisation holders whose claim for fee exemption has been denied.
Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees; number of chargeable units per marketing authorisation holder concerned.
Number of invoices sent out and annual fees charged in respect of the annual fee and average and overall amount invoiced to marketing authorisation holders. Number of marketing authorisation holders that have claimed a small and medium-sized enterprise or a micro enterprise status for each application of the annual fee; number of marketing authorisation holders whose claim has been denied.
Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

Terms and abbreviations

Term/ abbreviation	Definition
ACE	Analytics Centre of Excellence
ACPC	Advisory Committee on Procurement and Contracts
ACT EU	Accelerating Clinical Trials in the EU
AD	administrator category post
ADR	adverse drug reaction
ADRA	Antimicrobials Dose Review and Adjustment group
AE	Adverse event
AER	Adverse event report
Agency	European Medicines Agency
AI	Artificial intelligence
AM	antimicrobial
AMA	African Medicines Agency
AMEG	Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization programme
ANIMUSE	global database on animal antimicrobial use
API	Active pharmaceutical ingredient
AST	Assistant category post
ASU	Antimicrobial sales and use
ATAm	Alternative to Antimicrobials
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUDA-NEPAD/AMRH	African Union Development Agency/African Medicines Regulatory Harmonization
AVS	Assisted Validation System
AWP	Annual Work Programme
BDSG	Big data steering group
BEMA	Benchmarking of European medicines agencies
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
BI	Business Intelligence
BMJ	British Medical Journal
BoT	breach of trust
BPM	Business Pipeline Meeting
BURT	Batch Update Review Tool
BWP	Biologics Working Party
CA	Contract agent
CAMD	Competent Authorities for Medical Devices
CAP	Centrally authorised product
CAPA	corrective and preventive actions
CAT	Committee for Advanced Therapies
CCI	commercially confidential information

Term/ abbreviation	Definition
CDISC	Clinical Data Interchange Standards Consortium
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CDSCO	Central Drugs Standard Control Organisation
CE	Conformité Européenne
CECP	clinical evaluation consultation procedure
CHMP	Committee for Medicinal Products for Human Use
CMA	conditional marketing authorisation
CMA/MA	conditional marketing authorisation/marketing authorisation
CMC	Chemistry, Manufacturing and Controls
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDS	Critical Medical Devices Shortages System
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CO_2	Carbon dioxide
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CRM	Customer Relationship Management
CRP	Collaborative Registration Procedure
CT	Clinical trial
CTD	common technical document
CTIS	Clinical trial information system
CTR	Clinical Trials Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Scientific committees of the Agency
DADI	Digital Application Dataset Integration
DAP	Data Analytics Platform
DARWIN EU	Data Analytics and Real World Interrogation Network
DCP	Decentralised procedure
DG	Directorate-General of the European Commission
DG ENV	Commission Directorate-General for Environment
DG INTPA	European Commission Directorate-General for International Partnerships
DG NEAR	European Commission Directorate-General for Neighbourhood and Enlargement Negotiations
DG SANTE	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DoI	Declaration of interests
DPC	Data Protection Coordinators
DPIA	Data Protection Impact Assessments
DPO	Data Protection Officer
DPR	Data protection Regulation for EU institutions and bodies

Term/ abbreviation	Definition
DQF	Data Quality Framework
DREAM	Document Records Electronic Archive Management) system
EAAD	European Antibiotic Awareness Day
EAB	EMA's Enterprise Architecture Board
EC	European Commission
EC SUMMA	Financial Platform of the European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission priority
eCTD	Electronic common technical document
ED	Executive Director
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EIW	European Immunisation Week
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMRN	European medicines regulatory network
EMS	Environmental Management System
END	Seconded national expert (Experts nationaux détachés)
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
ENS	Early Notification System
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
ERA	Environmental risk assessment
ERAWP	Environmental Risk Assessment Working Party
ESEC	European Specialised Expert Community
ESIP	European Social Insurance Platform
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	Emergency Task Force
EU	European Union
EU NTC	EU Network training centre
EU PAS register	European Union electronic register of Post-Auhorisation Studies
EUAN	EU Agencies Network
EUDPR	European Union Data Protection Regulation
EU-IN	EU-Innovation Network
EU-M4all	Medicines for use outside the EU
EUnetHTA	European network for health technology assessment
EUNTC	EU Network Training Centre
EUR	Euro

Term/ abbreviation	Definition
EURD	European Union (EU) reference dates and frequency of submission of periodic safety update reports (PSURs)
EURS	European Review System for eCTDs
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVIP	European Vaccination Information Portal
EVV	Union Pharmacovigilance Database
EVVet	veterinary EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EWG	Expert Working Group
EWP	Efficacy Working Party
EXB	EMA Executive Board
EXPAMED	Expert Panels on Medical Devices
FAIR	Findable, Accessible, Interoperable and Reusable
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FTE	Full-time equivalent
FWC	Framework contract
GBT	WHO-Global Benchmarking Tool
GCP	Good clinical practice
GLP	Good laboratory practice
GMDP	Good manufacturing and distribution practice
GMP	Good manufacturing practice
GVP	Good pharmacovigilance practice
HaDEA	European Health and Digital Executive Agency
HCD	Healthcare Data team
HCP	Healthcare professional
HCPWP	Healthcare Professionals Working Party
HDH	French Health Data Hub
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
IAC	Internal audit capability
IAS	Commission’s Internal audit service
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report
ICT	Information and communication technologies
ICTRP	International Clinical Trials Registry Platform
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards

Term/ abbreviation	Definition
IHD	Instant Health Data
INN	International non-proprietary name
INNO	Innovations in Healthcare
IPA	Instrument for Pre-accession Assistance
IR	Implementing Regulation (of the Clinical Trials Regulation)
IRIS	Platform facilitating the exchange of regulatory and scientific information between EMA and organisations developing medicinal research products for potential use in the European Union
IT	Information technology
ITF	Innovation Task Force
IVDR	In vitro Diagnostics Regulation
IVMAB	Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
KPI	Key performance indicator
LMS	EU Network Training Centre Learning Management System
LRSM	Lifecycle Regulatory Submission Metadata
LTT	Line to take
MA	Marketing authorisation
MAA	Marketing authorisation application
MAGHP	marketing authorisation for global health products
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
MB	Management Board
MDIG	Medical Devices Implementation Group
MDR	Medical Devices Regulation
MDSSG	Medical Devices Shortages Steering Group
MEDEV	Medicine Evaluation Committee
Member State	Member State of the European Union
MEP	Member of the European Parliament
MHLW	Ministry of Health, Labour and Welfare, Japan
MINERVA	Metadata for data discoverability and study replicability in observational studies project
MLM	Medical literature monitoring
MON VS	Monitoring Value Stream
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MRP	Mutual recognition procedure
MS	Member State of the European Union
MSP AG	Multi-Stakeholder Platform Advisory Group
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA VS	Managing the Agency Value Stream
MWD	Union Manufacturers and Wholesale Distributors Database
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority

Term/ abbreviation	Definition
NDB	EU Network Data Board
Network	European medicines regulatory network
Network Strategy	Common strategy to 2020 for the European medicines regulatory network
NFR	New Fee Regulation
NICTAC	Network ICT Advisory Committee
NISG	Nitrosamines International Steering Group
NITAG	National immunization technical advisory groups of WHO
NRG	Name review group established by CHMP
NTC	EU Network training centre
NTWP	Novel Therapies and Technologies Working Party
OLAF	European Anti-Fraud Office
OMS	Organisation Management Service
OPEN	Opening our Procedures at EMA to Non-EU authorities
PACMP	post approval change management protocols
PAES	Post-authorisation efficacy study
Parliament	European Parliament
PASS	Post-authorisation safety study
PCO	patients' and consumers' organisation
PCWP	Patient and consumer working party
PDCO	Paediatric Committee
PE	Performance evaluation
PECP	performance evaluation consultation procedure
PHECT	Public Health Emergency Clinical Trials
PI	Programme increment
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/Pharmacodynamic
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
POC	Point of Contact
POEG	CTIS Member State Product Owners Experts Group
PPHOVA	Pilot project on harmonisation of old veterinary antimicrobials
PPMT	Public Procurement Management Tool
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PRIMo4	EFSA Pesticide Residues Intake Model revision 4
PROD	production environment
P-SMEG	Pilot Signal Management Expert Group
PSUR	Periodic safety-update report
PSUSA	PSUR single assessment
QIG	Quality Innovation Group

Term/ abbreviation	Definition
QRD	EMA Working Party on Quality Review of Documents
RACI	Responsible, Accountable, Consulted, Informed
RAGNA	Regulatory Agencies Global Network against AMR
RDCA-DAP	Rare Disease Cures Accelerator-Data and Analytics Platform
RFI	Request for information
RMLs	maximum residual limits
RMP	Risk Mitigation Plan
RPA	Robotic Process Automation
RSS	Regulatory Science Strategy
RSV	Respiratory syncytial virus
RW	Real world
RWD	Real world data
RWE	Real-world evidence
SA	Scientific advice
SADC	Southern African Development Community
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SciCoBo	Scientific Coordination Board
SCOMRA	Scientific Conference on Medical Products Regulation in Africa
SDDC	software-defined data centre
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
SNE	Seconded national expert
SOC	Security Operations Center
SOP	Standard Operating Procedure
SPC	Summary of product characteristics
SPD	Single Programming Document
SPMP	Shortage prevention and mitigation plan
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
SPOR	Substances, Products, Organisations, Referentials
SRA (WHO)	Stringent Regulatory Authority
SSA	Signal and Safety Analytics
STAMP	Expert Group on Safe and Timely Access to Medicines for Patients
SUMMA	see EC SUMMA
SWP-V	Committee for Veterinary Medicinal Products (CVMP) Safety Working Party
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TEHDAS	Joint Action Towards the European Health Data Space
TF	Task force

Term/ abbreviation	Definition
TFAAM	HMA-EMA Task Force on Availability of Medicines
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration, Australia
TIA	Transfer Impact Assessments
TLM	Technology Lifecycle Management and Information Security Value Stream
TRIP	Topics of innovation, Relationships between external and internal topics, Identification of challenges and opportunities, Proposals for action.
TRS	EMA Regulatory Science and Innovation Task Force
UAT	User Acceptance Test
UI	User interface
UPD	Union product database
US	United States of America
UX	user experience
VGVP	Veterinary good pharmacovigilance practices
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform
VNRA	variations not requiring assessment
VRA	variations requiring assessment
VS	Value Stream
WG	Working group
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WP	Working party
WS	Work stream
XEVMPD	Extended EudraVigilance medicinal product dictionary