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Executive Director

Annual activity report 2022

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Introduction

The consolidated Annual activity report provides an overview of the activities and achievements of the European Medicines Agency (EMA) in 2022. The EMA Annual activity report 2022 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 2022 comprises five main parts and annexes, as follows:

Part I: Key achievements in 2022. 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 2022 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 2022; 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.

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 2022 work programme of the Agency, adopted by the Management Board at its meeting in December 2021,
- having regard to the annual report 2022 of the Agency adopted by the Management Board on 16 March 2023,
- having regard to the Annual activity report 2022 of the Agency presented to the Management Board at its meeting of 7 June 2023,

1. Recognises that in 2022 the impact of the COVID-19 workload remained significant for EMA and the Network. The Agency demonstrated its ability to develop and adapt, by streamlining its regulatory processes while maintaining the highest standards for quality, safety and efficacy of medicines.
2. Praises the Agency and the European Medicines Regulatory Network (EMRN) as a whole, for the support to the public health response to the new waves of pandemic by focusing on ensuring the availability of the best scientific expertise in the EU for the approval of new vaccines and therapeutics.
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 COVID-19 pandemic and appreciates the good collaboration in the network.
4. Acknowledges the results presented in the Annual activity report 2022 and recognises 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, the EU Beating Cancer Plan, pharmaceuticals in the environment, the chemicals strategy for sustainability and the European One Health Action Plan against antimicrobial resistance.
6. Recognises the Agency and the EMRN preparatory work and contribution for the revision of the general EU pharmaceutical legislation for human medicines and looks forward to the roadmap the Agency will prepare to analyse the effects linked to the implementation of the EC proposal, once adopted.

ACTIVITIES

7. Notes the work on marketing authorisations via the centralised procedure, both in human and veterinary medicines, which resulted in 2022 in EMA recommending for marketing authorisation 89 new human medicines, including 41 new active substances, and 10 new veterinary medicines, including 3 new active substances and 2 vaccines.

8. Is pleased that 8 PRIME-designated medicines were recommended for approval, helping patients to benefit as early as possible from promising medicines that target unmet medical needs, by reducing the evaluation time for SME products which started under accelerated assessment by an average of 6.7 months.

9. Appreciates the Agency's confirmation of 21 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.

10. Welcomes the completion of the developments identified in the 1st Open call by EUnetHTA21, those initiated from the 2nd Open call, as well as the agreement with payers' community to have prospective evidence planning as priority topic.

11. Commends the Agency for its collaboration with the European Network for Health Technology Assessment (EUnetHTA21), which spans across many aspects of scientific collaboration between different decision makers along the life cycle of medicines, contributing to the EU objective to foster wider patient access to innovative medicines.

12. Notes however that few joint scientific advice took place in the recent years and wishes to further enhance collaboration between HTA bodies and the Agency in the domain of joint scientific advice.

13. Is pleased with the Agency's involvement and commitment in the EC/HMA initiative ACT EU to transform clinical trials in the European Union for the benefits of patients, leveraging the momentum of the Clinical Trials Regulation.

14. Welcomes the Agency's revision of Policy 0044 on the handling of competing interests of Scientific Committees' members and experts and of Policy 0058 on the handling of competing interests of Management Board Members in view of the new responsibilities of the Agency in the areas of medical devices and in vitro medical devices.

15. Congratulates the Agency for successfully onboarding from the European Commission the responsibility to provide administrative, technical, and scientific support to the twelve expert panels for medical devices, and the 193 experts that constitute them, in accordance with the Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123).

16. Commends EMA for the continuous extraordinary effort on its communication, media monitoring and social listening activities, as well as its commitment to ensure patients experts' involvement, for replying promptly to requests for information and to deliver communication campaigns on key public and animal health topics.

17. Congratulates the Agency for the engagement with the NCA Coordinators and Topic leads in the context of the EU4Health Joint Action on Capacity Building for the Development of the Skills Work Packages in collaboration with the EU Network Training Centre, as well as for the training that EMA provided to stakeholders in the animal health sector in the form of webinars or other initiatives to ensure a smooth and appropriate implementation of the new regulation.

PUBLIC HEALTH EMERGENCIES

18. Praises the Agency for drawing lessons learned from the COVID-19 pandemic and positively building on this to establish the approach for future emergencies.

19. Congratulates the Agency for successfully deploying the new crisis response provisions for the first time following the WHO declaration of monkey pox as a public health emergency of international concern (PHEIC).

20. Commends the use of real-world data from routine clinical practice to monitor the safety and effectiveness of COVID-19 and monkey-pox vaccines, in order to generate timely RWE supporting the response to both outbreaks.

LEGISLATIONS

21. Commends EMA for the positive implementation of the Regulation (EU) 2019/6, the Veterinary Medicinal Products Regulation, which became effective on 28 January 2022. The Regulation aims to boost innovation and increase availability of safe and high-quality veterinary medicines for treating and preventing animal diseases. It also supports actions against antimicrobial resistance (AMR). Recognises the scale of the change introduced by the new legislation and that the sector is in the period of transition before the intended benefits can be maximised.

22. Congratulates the Agency and the European Medicines Regulatory Network for the implementation of the Regulation (EU) 536/2014, Clinical Trials Regulation (CTR) which took effect on 31 January 2022, bringing about standardization in the processes of submitting, evaluating, and monitoring clinical trials across the EU.

23. Praises the Agency for the swift implementation of the requirements, meeting the legal deadline set in 2022, as listed in the Regulation (EU) 2022/123 on the EMA extended mandate, which reinforces the Agency's in crisis preparedness and management of shortages of medicines and medical devices. Work continues on other aspects of the legislation with legislative deadlines in 2023.

INFORMATION MANAGEMENT SYSTEMS

24. Welcomes the go live of the Clinical Trials Information System on 31 January 2022. The system offers a publicly accessible database for healthcare practitioners, patients, and the general public as well as serving as sole access point for the clinical trial sponsors and regulators to submit and evaluate clinical trials data. Expects further improvements in the system to facilitate the work of the parties involved.

25. Appreciates the development of the new IT systems aiming at simplifying regulatory processes and reduce the administrative burden for veterinary medicine developers. These systems include the Union Product Database (UPD), the Union Pharmacovigilance Database (EVV), and the Manufacturing and Wholesale Distribution Database (MWD). Expects further improvements in the system to facilitate the work of the parties involved and praises the Agency for keep involving stakeholders and partners through the establishment of the Veterinary System Improvement Advisory Group (VSIAG) for the prioritisation of new or improved functionalities in the UPD and EVV systems.

DATA ANALYTICS AND METHODS

26. Congratulates the Agency for the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®) in collaboration with the Erasmus University Medical Centre Rotterdam. The system aims at providing EMA and national competent authorities with reliable real-world evidence on diseases, patient populations, and the effectiveness and safety of medicines, including vaccines.

27. Welcomes the selection of the first data partners that collaborate with DARWIN EU and help to generate real-world evidence that can be used in scientific evaluations and regulatory decision-making.

28. Commends the continuous engagement with Committees, NCAs and multiple stakeholders via the DARWIN EU Advisory Board, the integration of the system with business process and the progress of the pilot studies planned with EMA Committees.

29. Applauds the Agency for the launch of the expansion of the current ESVAC system to include other antimicrobials in collaboration with the Substance Management Services (SMS) with regards to the integration of the antimicrobial list and associated mapped terms in the SPOR system.

30. Praises the progress made throughout 2022 of the Antimicrobial Sales and Use data (ASU) project and the achievements of the milestone of completing the integration with Eurostat data.

COLLABORATION WITH ACADEMIA

31. Commends the Agency contribution to the STARS project and the implementation of its recommendation in the EU-IN academia interest group.

32. Is pleased of EMA collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) for the launch of the Cancer Medicines Forum with academia to optimise cancer treatments in clinical practice.

INTERNATIONAL COLLABORATIONS

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

34. Welcomes the collaboration with international partners to tackle shortages issues, at the level of ICMRA and the Global Regulators Working Group in the area of disruptions due to manufacturing quality issues.

35. Commends EMA for involving 5 authorities (Australia, Canada, Japan, Switzerland, WHO) in the OPEN pilot which brings additional expertise and enrich scientific discussions while promote convergence to increase public confidence and for arranging for Israel MOH to assist to ETF and CHMP meetings.

36. 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.

37. Supports the continuous collaboration of EMA as part of the wider EU engagement strategy for the establishment of the African Medicines Agency.

GOVERNANCE AND PROCESS IMPROVEMENTS

38. Congratulates the Agency for completing the transition of its project portfolio to the new Scaled Agile Framework (SAFe) methodology.

39. Commends the involvement of partners and stakeholders in the new governance model through the Network Portfolio Advisory Group (NPAG), which includes HMA and Management Board Members and through the Network ICT Advisory Committee (NICTAC) which includes four IT Directors and experts from NCAs and European Commission.

40. Welcomes the publication of the Agency's Technology Capability Investment Plan (TCIP) and of the EMA Cloud Strategy, and their objectives to develop the Agency into a customer-focused digital hub that provides high quality data and information services to the European medicines

regulatory network, and to enable the transformation of its business processes and way of working.

FINANCES AND HUMAN RESOURCES

41. Is pleased that the European Parliament has granted, on 10 May 2023, the discharge regarding the implementation of the budget of the Agency for the financial year 2021.

42. Notes that the Agency's final budget for 2022 amounted to EUR 417,471,000; 87.95% derived from the evaluation of medicines and other business-related activities, 11.98% from the European Union budget to fund various public health and harmonisation activities, and 0.07% from various sources.

43. Is pleased that the agency met the key budget implementation indicators both for budget 2022 (96.80% implementation) and for funds carried over from the previous financial year (95.11 % implementation).

44. Notes the 2022 provisional accounts and looks forward to giving an opinion on the EMA 2022 final accounts, following the receipt of the European Court of Auditors' observations on the provisional accounts.

45. Notes the finalisation of the implementation of the performance and development programme, which introduces continuous performance management and emphasizes staff development and career progression.

46. Acknowledges that the Agency managed to reach 99.40% occupancy rate for temporary agents, and notes that during 2022 the total number of statutory staff joining EMA amounted to 83, while the total number of statutory staff leaving the Agency during the same year amounted to 46.

AUDITS AND INTERNAL CONTROLS

47. Notes the results of the audit of the European Court of Auditors, confirming the reliability of the 2021 accounts and the legality and regularity of the transaction underlying the accounts of the Agency.

48. Notes that the report of the ECA draws attention to the uncertainty with the lease agreement for the Agency´s previous premises in London and includes two observations on management and control systems.

49. Notes that the report of the ECA includes also a follow up of eight previous years' observations, of which four have been completed, three are ongoing and two are not under the Agency's control.

50. Is pleased with the final report of the audits carried out by the Internal Audit Service of the Commission, which commends the Agency's well organised HR services demonstrating a mature organisation with internal controls aspects of HR management well embedded into its culture and operations. Notes that one recommendation stems from this audit.

51. Notes the result of the activities carried out by the Agency's internal audit capability, with 6 critical and 19 very important recommendations were issued in 2022. Invites the Agency to address the 14 major recommendations awaiting improvement actions plan as of 31 December 2022.

52. Is pleased that the Internal Control system functions reasonably well, even though some of its principles could be adjusted or improved to enhance its overall efficiency and effectiveness.

53. Notes the 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.

54. The Management Board notes the departure of the Head of Audit and subsequent appointment on 3 October 2022 (without discontinuity of service) of a Head of Audit ad interim; the current Head of Audit ad interim has served as internal auditor in AF-AUD since September 2015.

DECLARATION OF ASSURANCE

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

56. Calls for an EU action at a political level to resolve the current unsustainable situation with the EMA premises in London. Remains deeply concerned that the Agency is put in a position to act as a landlord, in a third country, diverting resources to perform an activity outside of its legal mandate. Acknowledges the Agency's efforts to address the situation, while safeguarding its financial interests.

ACKNOWLEDGEMENTS

57. Congratulates Lorraine Nolan for her election as Chair of the EMA Management Board.

58. Congratulates Christelle Ratignier-Carbonneil for her election as Vice-Chair of the EMA Management Board.

59. Welcomes Karin Kadenbach as new representatives of the European Parliament to the EMA Management Board.

60. Welcomes Despoina Iatridou, Denis Lacombe and Virginie Hivert as representatives of the civil society to the EMA Management Board.

Amsterdam, 23 June 2023

Lorraine Nolan

Management Board Chair

[signature on file]

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 European Medicines Agency (EMA) 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.

2022 in brief

During 2022, COVID-19 impact on EMA remained significant, with related workload consuming almost 40 FTEs. The focus of COVID-19 related activities shifted from pre-authorisation and authorisation activities, to mainly post authorisation ones. Following the entry into force of the Agency extended mandate in March 2022, EMA activated the new crisis response provision for the first time, after WHO declared monkey pox a public health emergency of international concern (PHEIC). The month of January marked the progress made in the implementation of two major pieces of legislation, namely the Clinical Trials Regulation and the Veterinary Medicines Product Regulation, with profound effects and changes in the way clinical trials are regulated and veterinary medicines are supervised in the EU. As part the Agency extended mandate, EMA started to host and provide the secretariat for the EU medical devices expert panels from March 2022. During the year significant development has been made also in the area of data governance, with the creation of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®) and the selection of the first data partners, in October 2022. 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

2022 marked the second full year of the COVID-19 pandemic and its unprecedented changes. EMA has demonstrated its ability to develop and adapt, by streamlining its regulatory processes while maintaining the highest standards for quality, safety and efficacy of medicines. During 2022 the Agency has leveraged its position as chair of ICMRA to progress the work on the harmonisation of international regulatory systems, it has delivered the implementation of three major pieces of legislation (Clinical Trials Regulation, Veterinary Medicines Regulation and the Extended mandate Regulation) and progress work on data governance.

All this has been achieved by fully implementing the 2022 budget, which was closed with a surplus of €10.46 million which will be returned to European Commission.

Based on all the facts presented in the report, including the management of the control system, and the positive opinion expressed by the Court of Auditors on 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

2022 at a glance

HUMAN MEDICINES

In 2022, EMA recommended 89 medicines for marketing authorisation, 41 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 2022, five 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); nine medicines received a recommendation for a conditional marketing authorisation, one of the possibilities in the EU to give patients early access to new medicines; five medicines were 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, eight PRIME-designated medicines were recommended for approval. In addition, the Agency confirmed 21 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.

COVID-19

EMA recommended 2 more vaccines for approval in 2022 and 2 new COVID-19 treatments. Through the Emergency Task Force (ETF), which was formalised as part of the Agency's extended mandate, EMA continued to assist developers working on vaccines and treatments for COVID-19, providing them with advice on the best study designs and methodologies to generate reliable data for their marketing authorisation applications.

Building on the work done in 2020 and 2021 to leverage collaborations with academics in observational research, EMA used real-world data from routine clinical practice to monitor the safety and effectiveness of COVID-19 and mpox (monkeypox) vaccines, in order to generate timely RWE supporting the response to both outbreaks. Building on this experience, a process for rapid procurement of studies in emergency situations, where rapid evidence is required to support public health and regulatory actions, has been developed in line with EMA's extended mandate.

An increased level of transparency was maintained with monthly updates issued for every authorised COVID-19 vaccine. Safety updates allowed regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health.

In relation to public health activities, as part of the work programme 2022, drawing from the lessons from COVID-19 evaluations, regulatory innovations and flexibilities were proposed, including rolling review mechanisms in public health emergency and phased reviews outside crisis.

REGULATION (EU) 2022/123 ON THE EMA EXTENDED MANDATE

On 1 March 2022, EMA's mandate was extended with the entry into force of the regulation reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices.

The Regulation required EMA to set up new bodies, such as the Medicines Shortages Steering Group (MSSG) and the Emergency Task Force (ETF). In addition, EMA took on the management of the medical device expert panels which were transferred to the Agency from the European Commission's Joint Research Centre.

As part of its extended mandate, EMA is tasked with the monitoring of events, including medicine shortages, which might lead to a crisis situation, as well as with the reporting of shortages of critical medicines during a crisis. The Agency also coordinates responses of EU countries on shortages of critical Medical devices and in vitro diagnostics occurring in crisis situations, after an initial transition period.

Under its extended mandate, EMA facilitates a coordinated EU-level response to public health emergencies by:

- reinforcing the activities of the COVID-19 EMA pandemic Task Force (COVID-ETF) in providing scientific advice and reviewing available scientific evidence on medicines with the potential to address a public health emergency, and supporting existing EMA committees with their authorisation and safety monitoring of medicines;
- coordinating independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities;
- investing in and leveraging real-world evidence to support crisis preparedness and response. This includes the establishment of a pan-European network of real-world data, DARWIN EU, which will provide EMA's scientific committees with real-world evidence from healthcare databases across the EU.

In 2022, in relation to the fulfilment of the requirements established by EMA's extended mandate for availability of medicines, the MSSG and the medicine shortages SPOC working party haven been established and are fully operational. In particular, lists of critical medicines and therapeutic groups were adopted and published, and marketing authorisation holders in scope can submit actual or potential shortages. In addition, EMA and Member States monitor events that may lead to major events or public health emergencies.

Moreover, in the month of May 2022, EMA, in collaboration with ECDC, established the EU Vaccines Monitoring Platform (VMP). The primary objective of the VMP is to conduct post-authorization research on vaccine usage, safety, and effectiveness to gather valuable real-world evidence (RWE). The VMP is a significant accomplishment for the European Health Union initiative, and it fosters prioritization, design and implementation of studies, as well as interpretation and dissemination of the related findings. The Immunisation and Vaccine Monitoring Advisory Board (IVMAB), which consists of representatives from various organizations, advises EMA and ECDC on the VMP's research agenda.

MPOX (MONKEYPOX) PUBLIC HEALTH EMERGENCY

During 2022 the Agency's new extended mandate has been put to test after the WHO declared mpox (monkeypox) outbreak a Public Health Emergency of International Concern (PHEIC). After the declaration of the PHEIC, EMA activated the dedicated structures and procedures as described in the new extended mandate. Through these EMA has coordinated actions and provided scientific recommendations on critical medicines and vaccines as well as put measures in place to avoid **shortages**. Specifically, EMA's ETF recommended - as a temporary measure - the use of US-approved

mpox (monkeypox) vaccine Jynneos to support vaccination efforts from the national EU authorities. In parallel, EMA recommended an extension of the use of the Imvanex to also protect adults from mpox (monkeypox).

DATA ANALYTICS AND METHODS

DARWIN EU®

The extended mandate also set the legal basis for the establishment of **DARWIN EU** – a federated model for collecting real-world evidence from across the European Union on diseases, populations and the uses and performance of medicines and vaccines right through their lifecycle.

During 2022, EMA and Erasmus University Medical Center Rotterdam have collaborated to create the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®), a system that aims at providing EMA and national competent authorities with reliable real-world evidence on diseases, patient populations, and the effectiveness and safety of medicines, including vaccines. The Coordination Centre oversees the network of healthcare data sources and performs studies to support scientific evaluations and regulatory decision making. The first group of data partners was selected in October 2022. The Big Data Steering Group's aim is to conduct over 150 DARWIN EU studies annually by 2025.The network acts as a pathfinder for the proposed European Health Data Space (EHDS), and will ultimately connect to the EHDS services, enabling the use of the EHDS in medicines regulation in Europe.

CLINICAL TRIALS REGULATION (CTR)

The Clinical Trials Regulation (CTR) took effect on 31 January 2022, bringing about standardization in the processes of submitting, evaluating, and monitoring clinical trials across the EU. The Clinical Trials Information System (CTIS), which supports the changes introduced by the CTR, was also launched on the same date as a sole access point for clinical trial sponsors and regulators to submit and evaluate clinical trial data. CTIS offers a publicly accessible database for healthcare practitioners, patients, and the general public. Even though the use of CTIS was not mandatory in 2022, more than 200 clinical trial applications had been authorized, and over 200 were still under review with the new system by the year's end. To strengthen the system ahead of its compulsory use for clinical trial applications on 31 January 2023, the European Medicines Agency (EMA) worked closely with clinical trial sponsors and Member States to address technical issues, provide proactive assistance to the CTIS user community, and enhance the system.

ACT EU

In January 2022 EMA, the European Commission, and HMA launched ACT EU to transform clinical trials in the European Union for the benefit of patients, leveraging the momentum of the CTR. The ACT EU steering group established key deliverables for each of the initiative's ten priority actions, including the facilitation of innovation, stakeholder engagement, and regulatory network collaboration. ACT EU published monthly statistics and a survey on the CTR and made progress in developing methodology to support innovation. The key actors in scientific advice collaborated to provide a mapping on voluntary procedures and launched the second phase of its pilot on simultaneous national scientific advice.

VETERINARY MEDICINES

In 2022, EMA recommended ten veterinary medicines for marketing authorisation. Of these, three had a new active substance, which had not previously been authorised in the EU. Among the ten medicines recommended for marketing authorisation, two were vaccines, one of which had been developed by means of a biotechnological process.

IMPLEMENTATION OF REGULATION (EU) 2019/6

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) became effective on 28 January. The regulation boosts innovation and increases availability of safe and high-quality veterinary medicines for treating and preventing animal diseases. It also supports actions against antimicrobial resistance (AMR).

The new rules aim to limit AMR, while ensuring necessary treatments are available. EMA has developed new IT systems to simplify regulatory processes and reduce the administrative burden for medicine developers. These systems include the Union Product Database (UPD), the Union Pharmacovigilance Database (EVV), and the Manufacturing and Wholesale Distribution Database (MWD). The Collection of Antimicrobials Sales has been complemented by the collection of Antimicrobial Use Data (ASU) project which was also initiated in January 2022, and its first data is expected to be submitted to the system in 2024. EMA provided support to ease the transition to the new systems through a dedicated support service, webinars, and information sessions.

Additionally, the Veterinary System Improvement Advisory Group (VSIAG) was established to prioritize new or improved functionalities in the UPD and EVV systems. By December 2022, nearly all data held in Member States was uploaded into the UPD thanks to the strong collaboration between national authorities and EMA.

CONTRIBUTING TO EU PRIORITIES

In 2022, 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 (23 cancer medicines were authorised in 2022), EMA continued to contribute to the implementation of the ambitions of the EU Beating Cancer Plan. In addition, in 2022, EMA, in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), launched the Cancer Medicines Forum with academia to optimise cancer treatments in clinical practice.

In 2022, EMA continued to provide support to the implementation of the EU Strategy for COVID-19 vaccines (COM/2020/245 final) and the EU COVID-19 Therapeutics Strategy (COM/2021/355 final/2), which aim to coordinate efforts by Member States in the development and access to COVID-19 vaccines and therapeutics.

As one of the EU decentralised agencies at the forefront of the EU's response to COVID-19 pandemic, EMA's activities in 2022 have contributed to the implementation of the new European Health Union legal framework (see more details in the section above on the EMA extended mandate). In addition,

EMA significantly increased its interactions with the Health Emergency Preparedness and Response Authority (HERA) to support their work and ensure complementarity of activities.

In 2022, 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, from design and production through use and disposal. In particular, in 2022, 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 of reduction of the impact on AMR and the environment of pharmaceutical manufacturing and consumption.

In January 2022, the new veterinary medicines legislation (Regulation EU 2019/6) became applicable which introduces a whole set of tools for promoting responsible use of antibiotics and fighting AMR, such as making them available only on veterinary prescription, after examination and diagnosis, and limiting the preventive use of veterinary antimicrobials, and which strengthens the rules and procedures for the environmental risk assessment of veterinary medicinal products. For more information on the implementation of the new veterinary medicines legislation please refer to earlier paragraphs of this chapter.

In 2022, EMA also continued to support the European Commission on certain activities linked to the implementation of the Chemical Strategy for Sustainability published in October 2020. In particular, EMA participated in an expert group of MS experts and other EU agencies tasked with discussing the implementation of the One Substance One Assessment principle, to streamline initiatives on hazard/risk assessment of chemicals across different legislations and to increase the sharing and re-use of data across regulatory frameworks in order to avoid unnecessary animal testing.

In 2022, EMA continued to support the implementation of European One Health Action Plan against Antimicrobial Resistance, which was adopted by the European Commission in June 2017 and contains actions running until 2022. The key activity in 2022 in this area has been the completion of the implementation of the new veterinary medicines legislation (see more details in the dedicated section on Regulation 2019/6 in this document). Measures to tackle AMR in Regulation (EU) 2019/6 include:

- Mandatory collection of sales data for all EU countries and the collection of use data;
- Mandatory veterinary prescription before use;
- Need for examination and diagnosis before prescription;
- Implementation of best practices to prevent from and minimise disease and therefore the need for using more antimicrobials;
- Reinforced ban on the use of Antimicrobials for Growth Promotion (AGP) and to increase yield;
- Ban on preventive use of antibiotics in groups of animals;
- Restrictions on metaphylactic use of antimicrobials;
- Possibility to reserve certain antimicrobials for use in humans only;

- For imported animals and animal products from outside the EU: ban on the use of AGPs and antimicrobials reserved for human use.

To implement the above, EMA provided scientific and technical recommendations as requested by the Commission to support associated delegated and implementing acts, such as: list of antimicrobials reserved for use in humans (Implementing Regulation EU 2022/1255); and format of the data to be collected on antimicrobials used in animals (Implementing Regulation EU 2022/209).

In addition, with the entry into application of Regulation 2019/6 in early 2022, the collection of data on sales *and use* of antimicrobials has become mandatory for Member States, and in 2022 EMA started developing and testing a web-interface to allow Member States to report sales and use data, as well working with Member States to develop harmonised protocols for data collection and analysis.

As regards human antimicrobials, in 2022 the Agency continued to support international harmonisation efforts with the US FDA and the JP MHLW/PMDA.

In 2022, EMA continued to provide significant scientific support to the European Commission with regards to the preparation of the legislative proposals included in the Pharmaceutical Strategy for Europe, notably for the revision of the basic pharmaceutical legislation and the regulations on orphan and paediatric medicines, by participating in expert group meetings and responding to targeted consultations of the Commission.

In 2022, EMA contributed to the EU objective to foster wider patient access to innovative medicines. It did so mainly via its collaboration with the European Network for Health Technology Assessment (EUnetHTA21), which spans across many aspects of scientific collaboration between different decision makers along the life-cycle of medicines. The EMA-EUnetHTA21 collaboration focuses in particular on: parallel scientific advice to medicine developers with HTA bodies and EMA, information exchange between regulators and HTA bodies about the outcome of the EMA's regulatory assessments in support of joint Relative Effectiveness Assessments by HTA bodies and discussion of post-authorisation data generation, such as optimising patient registries, to better serve data needs for various decision-makers. EMA also supported the European Commission in preparing the implementing and delegated legislation which is necessary for the application of Regulation (EU) 2021/2282 on health technology assessment.

LEGAL OVERVIEW

The Legal Department continued to timely support the Agency's core business throughout 2022. Amongst many examples of assistance provided to the scientific functions, 79 legal scrutiny of CxMP scientific opinions were performed and 335 paediatric decisions reviewed, in 99% of the cases within the 5 days statutory deadline.

Extensive legal assistance was necessary in the context of the preparatory work for the implementation of the new EMA Fee Regulation. Also, key legal input were provided to prepare all amendments approved by the Management Board to Policy 0044 on the handling of competing interests of Scientific Committees' members and experts, and to Policy 0058 on the handling of competing interests of Management Board members.

852 initial decisions concerning requests for access to documents were co-signed by legal officers after a careful legal check, with only 11 confirmatory decisions (appeal letters) issued in 2022. As of 31

December 2022, 3 cases were pending in 2022 before the EU General Court concerning requests for access to documents.

The number of judicial challenges against EMA and /or the European Commission has increased further last year. The most common allegations concerned breaches of pharmaceutical law, manifest errors in EMA's scientific assessments and a number of procedural violations. During 2022, the Legal Department has worked on 21 Court cases, without any outside counsel's assistance. Amongst several successful defences in pharma law cases, it is worth mentioning the appellate proceedings (Joined Cases C-438/21 P, C-439/21 P, C-440/21 P) against the judgment of the General Court of 5 May 2021 in Case T-611/18, *Pharmaceutical Works Polpharma v. EMA*, unfavourable to EMA. On 6 October 2022, Advocate General Medina proposed in her Opinion that the Court of Justice should set aside the judgment of the General Court and order the applicant to bear the costs of the proceedings. EMA's decision to invalidate a marketing authorisation for a generic product containing dimethyl fumarate as active substance should thus be upheld. On 16 March 2023 the Court of Justice sided with EMA and annulled the General Court's judgment of 5 May 2021, ordering the applicant to pay all costs of the proceedings.

In its judgment of 2 March 2022 in *D&A Pharma v Commission and EMA*, T556/20, the General Court found that EMA applied correctly its Policy 0044 on the handling of competing interests in respect of two experts providing advice to the Committee for Medicinal Products for Human Use. This very favourable judgment was appealed and a final ruling by the Court of Justice is expected in 2023. EMA has also intervened beside Germany and Estonia in the appellate proceedings against the judgment of the General Court of 28 October 2020 in *Pharma Mar v Commission* (the *Aplidin* case). The Court of Justice's judgment is expected in 2023. The outcome of this case may affect EMA's capacity to use a sufficient number of scientific experts for the preparation of opinions delivered by EMA Committees.

SCALED AGILE FRAMEWORK (SAFE)

Agile and transparent delivery of EMA IT capabilities

EMA embarked on its Agile transformation following endorsement by the Management Board in June 2021, guided by Agile principles and the Scaled Agile Framework (SAFe), which are broadly considered as best practice across industry. The framework has been tailored to EMA and its role as a regulatory body working for human and animal health in Europe, without compromising its core principles. The benefits realisation of Agile and SAFe for EMA and its partners and stakeholders range from better alignment between business and IT, faster and incremental delivery of technology, increased transparency and easier management of changing priorities.

Involvement of partners and stakeholders

During 2022, the governance model for EMA information management has been solidified, with the Network Portfolio Advisory Group (NPAG), comprised of HMA and Management Board Members, attending Agile ceremonies on a quarterly basis, and reporting on progress at HMA and Management Board meetings. Furthermore, the Network ICT Advisory Committee (NICTAC), which includes four IT Directors and experts from the NCAs and a European Commission representative, has been meeting regularly to discuss interoperability and technical topics impacting the NCAs, including two face-to-face

meetings. The NICTAC has also actively liaised and represented the overall NCA IT community, as well as supported two NCA IT community meetings hosted by the EU Presidency Member States. Quarterly System Demos were launched in 2022, with up to 1300 participants per ceremony, providing an integrated view of new features delivered by Product Teams and the opportunity for impacted stakeholders to share their feedback on incremental product delivery.

The protocol for Subject Matter Experts (SMEs) and Product Owners (POs) was launched in 2022 to establish the inclusion of impacted partners and stakeholders - at this stage focused on NCAs and Industry- in Product Teams, to directly contribute to IT system solution development and delivery.

Agile portfolio management guided by value delivery

Following a successful pilot to test the new Agile way of working, the EMA IT portfolio was transitioned to the Agile way of working during 2022. Value Streams were established that align with its core mission and EMA's value delivery, and Product Teams were operationalised within them, following the Agile cadence of ceremonies. Five Agile product deliveries were successfully completed and went live in 2022.

Future direction of technology implementation

The Agile transformation is underpinned by EMA's Technology Capability Investment Plan (TCIP) and the Cloud Strategy, both published in 2022. The TCIP aims to develop the Agency into a customer-focused digital hub that provides high quality data and information services to the European medicines regulatory network. The IT Cloud Strategy details how EMA will fully transition to the cloud by 2025, enabling it to transform its business processes and way of working, for example meeting its needs for a secure and regulated exchange of data at the European and global level.

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 2022 forecast/target
	Results within +/- 10% (included) of the 2022 forecast/target
	Results 10%-25% below the 2022 forecast/target
	Results more than 25% below 2022 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 2022 forecast/target
	Results within +/- 10% (included) of the 2022 forecast/target
	Results 10%-25% above the 2022 forecast/target
	Results more than 25% above 2022 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	2019 result	2020 result	2021 result	2022 forecast	2022 result
Total scientific-advice and protocol-assistance requests	674	784	853	865	833
Parallel scientific advice with international regulators requests	2	6	3	6	5
Joint scientific advice with HTA bodies requests	20	2	2	8	4
Scientific advice for PRIME products	26	37	59	30	37
Protocol assistance	137	143	163	146	129
Novel technologies qualification advice/opinions	16	15	25	22	21
PRIME eligibility requests received	60	69	52	50	45
Applications for orphan medicinal product designation	233	235	251	280	269
Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	671	735	778	801	755
Requests for classification of ATMPs	70	74	66	60	51

1.2 Initial evaluation activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
New non-orphan medicinal products	33	43	43	42	35
New orphan medicinal products	27	28	29	29	32
Similar biological products	13	12	10	15	11
Generic products, hybrid and abridged products	29	24	28	19	18
Scientific opinions for non-EU markets (Art. 58)	0	0	3	1	1
Paediatric-use marketing authorisations	0	0	0	1	2
Number of granted requests for accelerated assessment	13	12	12	10	4
ATMPs marketing application authorisation requests received[2]	-	-	3	9	1
COVID-19 related product applications received[3]	-	-	14[4]	8	2

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

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Average assessment time for new active substances and biosimilars (days) – *reversal of traffic lights*	192.8	192	183	205	189.8
Average clock-stop for new active substances and biosimilars (days) – *reversal of traffic lights*	178.1	166	149	180	182.1
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	43%	50%	27%	60%	31.30%
% of initial marketing authorisation applications that had received centralised scientific advice	68%	70%	78%	80%	62.20%

1.3 Post-authorisation activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Type IA variations	3,886	3,989	3,809	3,870	3,586
Type IB variations	2,425	2,675	3,102	3,013	3,354
Type II variations	1,123	1,274	1,390	1,319	1,388
Line extensions of marketing authorisations	27	35	27	28	31
Renewal applications	107	99	123	73	132
Annual reassessment applications	25	24	27	31	27
Transfer of marketing authorisation applications	63	36	95	60	74
Article 61(3) applications	286	211	396	175	236
Post-authorisation measure data submissions	776	990	1,272	925	1,278
Plasma master file annual update and variation applications	17	28	20	25	17

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Average assessment time for variations that include an extension of indication – *reversal of traffic lights*	165	167	177	180	175.19

1.4 Referrals

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Pharmacovigilance referrals started	8	2	3	5	4
Non-pharmacovigilance referrals started	7	6	10	8	5

1.5 Pharmacovigilance

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Number of signals peer-reviewed by EMA	1,806	1,888	2,477[5]	1,900	1,605
Number of ICSRs for CAPs (reports received)[6]	-	-	2,989,903	2,700,000	2,273,735
Number of signals assessed by PRAC (validated by EMA)	50	39	55	40	39
PSURs (standalone CAPs only) started	554	525	568	546	557
PSUSAs started	246	304	322	331	316
Number of imposed PASS protocol procedures started	12	4	7	4	5
Number of imposed PASS result procedures started	3	4	11	6	2

1.6 Inspections and compliance

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
GMP inspections	386	130	247	205	96
GLP inspections	0	0	0	1	1
GCP inspections	137	59	36	87	75
Pharmacovigilance inspections	9	16	15	11	12
PMF inspections	111	40	122	122	84
Notifications of suspected quality defects	175	170	178	250	206
Medicinal products included in the sampling and testing programme	67	81	75	94	85
Standard certificate requests received	2,565	3,115	3,753	3,928	3,849
Urgent certificate requests received	2,399	1,647	1,659	1,260	1,147
Parallel distribution initial notifications received	2,468	3,172	2,555	2,100	1,816
Parallel distribution annual updates received	4,270	11,624[7]	4,816	5,300	5,509

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Standard certificates issued within established timelines (30 working days)	28%	80%	99%	90%	100%
Average days to issue standard certificate - *reversal of traffic lights*	59.60	23.59	12.81	15	3.90
Urgent certificates issued within established timelines (2 working days)	97%	98%	99%	98%	100%
Parallel distribution initial notifications checked for compliance within the established timeline	37%	90%	99%	98%	99%

[5] Value corrected.
[6] New indicator introduced in 2021 Work Programme.
[7] The figure includes a backlog of annual updates received in 2018 and 2019.

1.7 Committees and working parties

Workload indicators

Procedure	2019 result	2020 result	2021 result[8]	2022 forecast	2022 result
Number of reimbursed meetings	321	52	2	94	106
Committee meetings[9]	76	75	78	31[10]	76
Trainings[11]	29	4	0	1	2
Workshops	4[12]	2	0	1	9
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	212	112	1	61	66
Number of virtual meetings/connections (audio-, video- and web-conferences)	3,443	5,409	13,227	6,500	5,700
Number of reimbursed delegates	6,015	1,003	30	2,500	1,980
Number of non-reimbursed delegates	523	60	0	250	178
Herbal monographs, new	0	3	3[13]	3	3
Herbal monographs, reviewed[14]	13	14	18	28	28
Herbal monographs, revised	2	8	2	3	2
EU herbal List entries	0	1	0	1	0

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%	100%	100%

[8] Values corrected.
[9] Indicator updated to include Management Board meetings (from 2019).
[10] In 2022 committee meetings will be held physically and remotely.
[11] Includes EU Network training centre meetings.
[12] Due to the relocation of the Agency and associated logistical challenges, as well as the lack of facilities in the new temporary premises, the 2019 actual number of workshops delivered has been significantly lower than in previous years. These are expected to gradually increase again, as the Agency resumes activities post-relocation.
[13] Not included: two new public statements finalising the assessment of two substances that did not lead to the establishment of a monograph.
[14] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Pillar 2 – Public health activities

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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	On track	EMA statement on interchangeability published.
Support the STAMP scientific advice pilot for repurposing established medicines	1.1 (ECP 1, ECP 4)	A number of prioritised established medicines are enlisted in the pilot	On track	Candidate projects submitted through the call to academia/not-for profit organisations in the context of the repurposing pilot have been screened and a small number have been selected to continue through the SA procedure and will benefit of SA fee reduction based on a specific ED decision established for the purpose of the pilot.
• 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	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	On track	Parallel Joint Scientific Consultations (JSC) completed for the developments identified in the 1st Open call by EUnetHTA21, and initiated for those from the 2nd Open call; experience monitored jointly by EMA and EUnetHTA21 also to inform the establishment of a future framework under the HTA Regulation; Agreement with payer community to have prospective evidence planning as priority topic.
• 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	Analysis of learnings completed and proposals established for guidance update to optimise the CHMP assessment report as reference for HTA, in line with CHMP work plan item; Product-specific discussions agreed as priority as part of the EMA/EUnetHTA21 work plan; Regular debriefings of payers on regulatory outcomes in the context of MEDEV meetings.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
• Set up and operate a Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative 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	3.1 (ECP 1)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	On track	- QIG group set-up, membership confirmed, chair elected; mandate developed and adopted; academic engagement and contact points, stakeholder engagement, website and press release issued, international contacts with FDA nd PMDA established, 3 WS established on Priority topics, Listen-learn focus groups and product-specific support. - ICH M4Q EU drafting group set-up + support group consisting of key WP experts, contribution to drafting progress as per ICH timelines. Step 1 anticipated in 2024 - Training material in development as per ICH timeline
• Develop guidance on information required to implement decentralised manufacturing and batch release for ATMPs • Deliver tailored engagement with academics and the community of ATMP developers • Strengthen support to development of ATMPs	3.1 (ECP 1)	Increased support to the integration of scientific and technological progress in the development of ATMPs	On track	- Training program targeted to ATMP developers developed and successfully rolled out in collaboration with EATRIS as part of the EU-funded ADVANCE project. - Development of a draft reflection paper on new active substance related to biologicals, with specific sections for advanced therapies released for public consultation in November 2022 to support developers and assessors for this aspect. - EMA ATMP Support Pilot Program for academic developers launched in September 2022. - First candidate selected in September 2022 and support officially initiated in October 2022.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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	Adaptation of GMP guidance: Several GMP guidance are under revision at IWG in collaboration with PIC/s for convergence at different stages of finalisation. Good progress was made. Following the publication of revised Annex 1, training activities for the revised annex are being prepared in collaboration with PIC/s. The concept paper for the revision of Annex 11 has been published, and work for Chapter 4 under planning with PIC/s. Training collaboration with PIC/s: IWG group on training has been kicked off and is looking to devise an inspection strategy paper that describes the areas for training on GMP required for the EU Network, leveraging ongoing initiative on training from the HMA MAWP, the EU4Health initiative and the EU NTC collaboration with PIC/s. EU-US MRA: All 3 areas of the MRA expansion work further progressed. On vaccines and plasma derived products the extension has been delayed to July 2025. On veterinary products assessments of systems further progressing, with all EU MSs to be assessed by FDA by end 2024. On the recognition of third country inspections a equivalency report is currently being prepared.
• 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 (ECP 4)	Promoted supply chain resilience and reliability of supply of APIs and medicinal products	On track	The name of the guide has been updated to "Good practices for the prevention and management of human medicinal product shortages". The draft document was circulated to industry associations for comments. Comments from 6 Industry Associations were received and compiled. TWG1 is drafting the reply to those comments (discussion expected at the next TWG1 meeting on 25 January and a summary will be presented to the Steering Committee on 1 February). This topic is included as part of one of the sessions of the multi-stakeholder workshop scheduled on 1-2 March.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
• Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	6.2 (ECP 2)	Improved benefit/risk communication	**On track**	Focus group has been selected with CHMP/CAT members. Pilot activities agreed to be conducted by Q2 2023
• Draw lessons from COVID-19 evaluations • Develop simplifications/reductions of post-authorisation procedures • Review of the scientific advice offering to provide more agility • Analyse experiences gained to allow exceptions to the use of paper package leaflets	6.2 (ECP 2)	• Regulatory innovations and flexibilities to accelerate the availability of medicines are identified, and where feasible, are progressed for implementation	**On track**	1/ Proposals as part of the pharma strategy of rolling-reviews mechanisms during public health emergency. Proposals for phased reviews outside crisis for most promising candidates. Proposals to optimise labelling, post-authorisation activities for CMA/MA under EC, PV procedures. Proposals to support innovation and future-proofing. 2/ Development of a CMDh/EMA concept paper for variations to optimise and future-proof variation framework (due May 2023).

Inspections

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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)	Delayed	- caucus review completed (principles and Annex 1) - EWG Hybrid meeting held at EMA in Sep 2022 which involved external experts/stakeholders
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)	Delayed	- caucus review completed (principles and Annex 1) - EWG Hybrid meeting held at EMA in Sep 2022 which involved external experts/stakeholders

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	Delayed	- caucus review completed (principles and Annex 1) - EWG Hybrid meeting held at EMA in Sep 2022 which involved external experts/stakeholders

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in 2022
Meeting secretariat improvement	Implementation of a new operating model for working parties, of the support to medical devices expert panels (EMA extended mandate), and meeting secretariat operating improvements	- Successful implementation of the new model for the working parties. - re-organisation of the clinical, non-clinical and methodology domains - appointment of members to 10 working parties, with the election of chair and vice-chairs - organized the launch of the Oncology ESEC in the clinical domain - organized training for the use of Teams for WP secretariats and for new members of the WPs - successful launch of the use of Teams for the new operational model for the working parties and drafting groups - drafting and publication on 3 year rolling workplans and annual priority plans at the domain level for the non-clinical and methodology domains - Successful handover in March 2022 without any delays to procedures or any disruptions for experts

Project title	Long term objective	Achievements/results in 2022
		- All expert contracts were signed before the procedure was transferred to EMA - 34 CECP screening procedures; 7 CECP opinion procedures and 1 PECP procedure were handled within the legal time frame - Contracting and payment procedures were developed and implemented, both contracting and payment procedures have been executed successfully - 1 Ad Hoc Advice was delivered on request from the MDCG was handled incl. seeking feedback from ECDC - The first F2F Coordination committee meeting was held - Process improvements to increase predictability from applicants have been introduced - Survey to NBs was conducted to estimate future submissions

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Innovation Task Force briefing requests (Vet)	6	5	6	5	0
Scientific advice requests received[15]	21	31	23	30	39
Requests for classification as MUMS/limited market, of which[16]	34	29	14	n/a	n/a
Re-classification requests	9	4	5	n/a	n/a
Requests for classification as limited market under article 4(29) and eligibility under article 23	n/a	n/a	3	25	21

[15] Validated requests.
[16] Regulation (EU) 2019/6 became applicable on 28 January 2022, changing the framework for limited market products, on same date Policy 0075 and classifications issued under it ceased to be valid.

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Scientific advice procedures completed within set timeframes	95%	100%	100%	100%	100%

2.2 Initial evaluation activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Initial evaluation applications	23	15	9	27	22
New MRL applications	3	1	0	2	0
MRL extension and modification applications[17]	4	1	3	2	1
MRL extrapolations	0	0	0	0	0
Art. 10, Biocides	0	0	0	0	0
Review of draft Codex MRLs[18]	0	3	0	0	16

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Initial procedures completed within legal timeframes	100%	100%	100%	100%	100%

2.3 Post-authorisation activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Variations applications, of which:[19]	568	637	679	n/a	74
Type IA variations	356	380	350	n/a	45
Type IB variations	139	195	241	n/a	16
Type II variations	73	62	88	n/a	13
Line extensions of marketing authorisations[20]	2	2	2	n/a	n/a
Transfers of marketing authorisations	24	9	8	5	0

[17] Includes reviews requested in line with Art 11 of reg. 470/2009.
[18] From 2022 includes also Codex extrapolations.
[19] These actuals refer to variations submitted in January 2022 under Regulation (EC) 1234/2008, which is not anymore applicable to veterinary medicinal product since Regulation (EU) 2019/6 became applicable on 28 January 2022.
[20] These actuals refer to variations submitted in January 2022 under Regulation (EC) 1234/2008, which is not anymore applicable to veterinary medicinal product since Regulation (EU) 2019/6 became applicable on 28 January 2022.

	Variations requiring assessment, of which[21]					252
	Variation requiring assessment level 1	n/a	n/a	n/a	n/a	2
	Variation requiring assessment level 2	n/a	n/a	n/a	n/a	75
	Variation requiring assessment level 3	n/a	n/a	n/a	n/a	70
	Variation requiring assessment level 4	n/a	n/a	n/a	n/a	105
	Variations not requiring assessment	n/a	n/a	n/a	n/a	392

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Post-authorisation applications evaluated within the legal timeframes	100%	100%	100%	100%	100%

2.4 Arbitrations and referrals

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Arbitrations and Community referral procedures initiated	9	3	0	4	5

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Referral procedures managed within the legal timelines	100%	100%	100%	100%	100%

2.5 Pharmacovigilance activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Periodic safety-update reports (PSURs)[22]	159	160	188	n/a	n/a
Total adverse-event reports, of which:	70,392	66,901	80,709	120,000	167,546
Adverse-event reports (AERs) for CAPs	33,656	30,297	43,334	60,000	95,959
Adverse-event reports (AERs) for NAPs	36,736	36,604	37,365	60,000	71,587

[21] 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 (https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency).
[22] With the implementation of Regulation (EU) 2019/6, PSUR for veterinary medicinal products are no longer required.

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
PSURs evaluated within the established timeline	96%	98%	97%	n/a	n/a[23]
AERs for CAPs monitored within the established timelines	95%	97%	96%	95%	n/a[24]

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	On track	The draft "Guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy" has been published in November 2022 for 3 months public consultation. The draft "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy" is expected to be adopted by CVMP and published for consultation in Q1 2023.
Engage with EU and international risk assessment bodies with a view to aligning methodology for estimating consumer exposure to residues, including dual-use substances	3.1 (ECP 1)	• Analysis of existing models • Evaluation of findings and recommendation on harmonised approach	Completed	The expert group met 5 times in 2022. The EMA/EFSA joint report including recommendations was finalised after 2 and a half months public consultation, adopted by CVMP and endorsed by EFSA Scientific Committee in December 2022. The final "Report on development of a

[23] With the implementation of Regulation (EU) 2019/6, PSUR for veterinary medicinal products are no longer required.
[24] The new systems are not yet 100% up and running and several products have not yet been migrated, therefore, at the moment it is not possible to calculate the percentage of AERs monitored by the established timeline.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				harmonised approach to human dietary exposure - Assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin" was sent to EC on 14 December 2022.
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	The finalisation of the signal management process document has been delayed following receipt of additional comments from the European Commission regarding the legal basis and interpretation of some of the approaches outlined. Discussions are ongoing while, operationally and throughout 2022, P-SMEG and the PhVWP-V, CVMP and CMDV have continued assessing and progressing the signals sent by MAHs in a consistent manner.
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 planning activity to establish and publish the incidence data in 2023 has taken place and agreed within the relevant Epic.
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	Delayed	The set-up of the 2 initial groups has been postponed to 2023.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Improve communication of veterinary pharmacovigilance to the general public	3.1 (ECP 1)	Establish PhV communication framework	Completed	One additional training webinar on the topic of signal management was organised on 27 October 2022. The framework for communication of veterinary pharmacovigilance was established, and relevant trainings were provided during 2021-2022. Whether the main purpose of this activity is completed, the development of future improvements on the information that is currently made publicly available by the PhV systems will require further interactions and discussions with stakeholders also during 2023 and 2024.
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	Suspended	The activity is suspended until further input will be required from EC.
Develop further guidance on when the use of persistent, bio accumulative and toxic substances in	3 (additional RSS recommendation)	PBT guidance developed and published	Completed	The final "Reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU)

Action	MAWP strategic goal	Expected result	Status	Achievements/results
animals can be justified				2019/6" has been adopted by CVMP in October 2022 and published on the EMA website.
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 on identified topics for discussions is ongoing (e.g., AMR in the environment with EFSA). Generally, cooperation with other Agencies and academia is being initiated on a case-by-case basis. In 2022 the ERAWP started cooperating 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 2022.
Expand current ESVAC system to include other antimicrobials	4.1 (ECP 1)	Collection of data expanded to include all antimicrobials	On track	In the second half of 2022 collaboration with the Substance Management Services (SMS) with regards to the integration of the antimicrobial list and associated mapped terms in the SPOR system continued.
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member	4.1 (ECP 1)	Establish and implement new process for JIACRA report to be led by EMA and CVMP in cooperation with EU MSs	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

Action	MAWP strategic goal	Expected result	Status	Achievements/results
State input and ensure EMA oversight				adopted by CVMP in November 2022. A call for nomination of experts will be circulated in Q1 2023.
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	On track	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 are currently being analysed and will support the drafting of the guideline on denominators and indicators during Q1-Q2 2023, in particular the assignment of the appropriate denominators for use.
Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals	4.1 (ECP 1)	Define new requirements Develop guidance on new requirements	On track	The ASU Protocols (for sales and use) have been published on 9 January 2023 on EMA website. The publication of these documents is in line with Article 8 of the Commission Delegated Regulation (EU) 2021/578. They contain technical requirements that Members States need in order to collect and report to the Agency data on the volume of sales and on the use of antimicrobial medicinal products in animals. The documents were developed by EMA together with experts from the 2022 ASU Product Owners group and in consultation with the ESVAC Network.
Inform policy decisions via	4.1 (ECP 1)	Actively participating to policy development	On track	Technical estimates for the years 2014-2020 were

Action	MAWP strategic goal	Expected result	Status	Achievements/results
enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food				updated (following corrections to data during the preparation of the 12th ESVAC report) and 2021 estimates were also prepared. The expert groups (EMA, EFSA, ECDC) working on the 4th JIACRA report have provided their respective data (data lock point 12 January 2023) and the statisticians group is working on the analyses.
Participate in international initiatives to reduce the risk of AMR	4.1 (ECP 1)	Actively participating in international fora	On track	EMA participated in Q3-Q4 of 2022 to 5 meetings of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) activities, continuing to lead on key action activity 1.1 under the new TATFAR work plan to 2026, and contributing to others, e.g., 2.3 (risk analysis for foodborne AMR) and 4.2 (policy dialogue) as well as the TATFAR plenary conference. EMA participated in the second half of 2022 to the following AMR related events or groups: - WOAH (founded as OIE) AMR WG in October 2022 (face-to-face) and relevant virtual subgroup meetings; - Joint RKI/BfR/DGHM meeting on antimicrobial resistance, 15-16 November 2022; - EAAD event organised by ECDC on recent initiatives on AMR, 17 November 2022; - OneHealth EJP

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Stakeholders Committee on 22 November 2022.
Update existing guidelines, and initiate new guidance as needed	4.3 (ECP 3)	Develop relevant guidance	On track	The draft "Concept paper on the development of a guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6" was adopted by CVMP in September 2022 for a 4 months public consultation.
• Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received • Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper	4.3 (ECP 3)	Reflection paper finalised and published	Delayed	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms	4.3 (ECP 3)	Framework developed Communication with stakeholders	On track	Due to ongoing discussions with the EC on the alternatives to antimicrobials the whole activity has been reconsidered. Further discussions will need to take place on the definition and requirements for alternatives to

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				antimicrobials. In the meantime, in Q1 2023, a draft guideline on bacteriophages (an alternative to antimicrobial use) has been published for consultation and a concept paper on indications to reduce the need for the use of antimicrobials is to be published during 2023.
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	The consultation phase on the "Concept paper on update to the CVMP's reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health" ended in January 2022, the comments received are being reviewed and the final document is expected to be published in September 2023. The work on the "Reflection paper on criteria to determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted in regard to Article 107(3) of Regulation (EU) 2019/6" has been currently suspended. A Q&A document is being developed on the inclusion of clinical breakpoints in the SPC for generic antimicrobial VMPs and is expected to be finalised in 2023.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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 track	The concept paper has changed its name to reflect the ongoing discussions with the EC on alternatives to antimicrobials and now makes reference to a future guideline on potential claims for products that can contribute to the reduction of the need for antimicrobials. The timelines for the finalisation of the concept paper and start drafting the guideline are being revised.
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 is being developed on reporting of sales and use of antimicrobials per animal species. 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.
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	Delayed	The work on the guidelines on data quality, safety and efficacy requirements for limited market products not eligible under Art.23 has been paused awaiting for further clarifications from EC.
Develop a regulatory framework for authorisation, under exceptional circumstances, of vaccines for emerging health threats and benefit-	4 (additional RSS recommendation)	Guidance developed and implemented	Completed	The Guideline on data requirements for authorisation of immunological veterinary medicinal products (IVMPs) in exceptional circumstances has been

Action	MAWP strategic goal	Expected result	Status	Achievements/results
risk monitoring post-approval				finalised and published in January 2022.
Develop appropriate and proportionate guidance to maximise opportunities offered by Regulation (EU) 2019/6 for promoting availability of vaccines (vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers)	4 (additional RSS recommendation)	Guidance developed and implemented	Completed	The Procedural advice for vaccine platform technology master file (vPTMF) certification has been adopted in January 2023. Training events for assessors of NCAs on the scientific and procedural guidance for VAMF and VPTMF will be organised in 2023, once practical experience is gained from handling the first applications.
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	Due to organisational changes at OIE (now WOAH), there were no activities on the project in the second half of 2022.
Promote responsible use of antiparasitics in the EU	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	On track	The revised VICH guidelines on efficacy of anthelmintics have been published in June 2022 for public consultation, the comments are being revised by the expert working group and a final draft is expected in 2023. The following efficacy guidance documents related to antiparasitics and antiparasitic resistance have been finalised or progressed in 2022: Reflection paper on resistance in ectoparasites, adopted by CVMP in

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				January 2023; 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), adopted by CVMP in November 2022 for 3 months public consultation, RP is expected to be finalised in 2023; Questions and answers document on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products' adopted by CVMP in December 2022.
Prepare for and implement Veterinary Medicines Regulation	6.1	Prioritised guidance, processes and IT systems in place in time for implementation	On track	The Veterinary Medicines Regulation became applicable on 28 January 2022. Procedures have been aligned with the changed requirements. The development of required IT system is on track: - Union product database (UPD): MVP completed and live as of 28 January 2022, work on post-MVP improvements is ongoing; Project closed and transitioned to Agency value stream model in Q4 2022. - Union Pharmacovigilance Database (EVV): MVP completed and live as of 28 January 2022, work on post-MVP improvements is ongoing; Project closed and transitioned to Agency

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				value stream model in Q3 2022. - Antimicrobial Sales and Use (ASU); Submission component go live scheduled for end 2022; analytics component scheduled for go live in Q2 2023 (50% complete); Project transitioned to Agency value stream model in Q4 2022. - Manufacturer and Wholesale Distributors Database (MWD): MVP completed and live as of 28 January 2022. Project closed in for Q4 2022 following delivery of post-go live improvements. Recommendation to EC: - The "Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products" has been published in May 2022; - 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))" is under drafting and expected to be finalised in 2023

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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 has been discussed at the informal CVMP Presidency meeting in October 2022, the draft is expected to be released for consultation in Q2 2023 and finalised by beginning of 2024.
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. Several meetings are planned during 2023, including an EMA Veterinary Medicines Info Day 2023 in Q3 2023 and an CVMP Interested Parties Meeting, and meeting with stakeholders on bacteriophages will take place in Q3 2023.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in 2022
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	The EVVet3 project aims to provide a "Union veterinary pharmacovigilance system", by bringing the database in line with the requirements of Regulation (EU) 2019/6 and the Commission implementing regulation (EU) 2021/1281 on good pharmacovigilance practice by 28 January 2022 and on delivering possible improvements beyond that date as well as the VICH guidelines relating to pharmacovigilance reporting	Go-live 28 January 2022 *Transferred to Agile governance, under UPhV epic in Monitoring Value Stream*
UPD - Union Product Database [continues]	Providing a Union Product Database system regarding Veterinary products according to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018	Go-live 28 January 2022 New version released every 3-4 weeks Improvements to all UPD components *Transferred to Agile governance, under UPD epic in Product Lifecycle Management Value Stream*
ASU - Collection of Antimicrobials Sales and Use Data [new]	• The Collection of Antimicrobial Sales and Use data (ASU) project collects information on how antimicrobial medicines are used in animals across the European Union (EU) • The objective obtains reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR	Completed integration with one external party (Eurostat) *Transferred to Agile governance, under ASU epic in Monitoring Value Stream*
MWD - Union Manufacturers and Wholesale Distributors Database	The EudraGMDP database is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates	Go-live 28 January 2022 Project delivered and closed

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
New scientific, regulatory and telematics curricula developed	2	2	1	1	1
Number of training events advertised to the EU Network	40	46	77	60	76
Number of reimbursed training events to the EU Network	12	1	0	5	4
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	10	7	15	14	11

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Number of users registered to the EU NTC Learning Management System	5,121	5,290	5,916	n/a[25]	6,610
Number of NCA experts registered to the EU NTC learning management system	3,143	4,297	4,872	n/a[26]	5,485

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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	In the second half of 2022 the Executive Board mandated the Digital Innovation Lab (DigiLab) to explore opportunities to realise automations of administrative work across the Agency. As a result, DigiLab collected 34 ideas for automation and following prioritisation and endorsement by the Digital Acceleration Leadership Team (DALT), DigiLab and the Analytics centre of Excellence (ACE) started 14 projects to deliver efficiency gains through automations across the Agency. DigiLab also holds a pipeline of ideas for

[25] Indicator to be reformulated as of 2022.
[26] Indicator to be reformulated as of 2022.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				automation for 2023. In addition to the projects mentioned above, DigiLab delivered in collaboration with the ACE team in TDT, or the RPA team in I-SP-BPA , amongst others, the following automations; i) the automatic categorisation of emails for the Accounts receivable team in A-FI-ACC, ii) the automatic generation of a list with clinical breakpoints for anti-microbial medicines for the H-TA department, iii) a pilot version of the EURD List Database to realise efficiency gains in the maintenance and publication of the EURD List on EMA's website for the H-TA department. DigiLab also brought Virtual Reality technology to the Agency and delivered a pilot of the very first training session for all EMA staff using VR headsets hereby delivering immersive training experiences in the field of cybersecurity. The Digital Innovation Lab (DigiLab) worked with the Analytics Centre of Excellence (ACE) to pilot five potential solutions to business challenges. The pilot to adopt the use of QR codes is being finalised, and the following four solutions are being implemented: the Discoverer tool which helps to find specific scientific information in certain documents faster, two validation tools to compare documents and the tool to automate registration of applications submitted to EMA. In 2022 ACE worked on different initiatives in parallel such as: Document Identification Validation System (DIVS), New Certificates tool (CPS), including new type of submission in the existing Assisted Validation System (AVS) to automate the

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				registration of the submissions, Discoverer, Speech to Text, the implementation of Chatbots at EMA deploying the first chatbot at EMA for Talent Acquisition, a document comparison tool for Parallel Distribution service, Improvements in the ASK-EMA automatic triage system, the implementation of a Product Name validation for the new vet regulation, PEDAR to identify personal data, etc. ACE also provided support during the solve phase in the DigiLab process with its knowledge and capacity to design the best solution to solve the business requirements. Besides these activities, DigiLab and ACE engaged with other medicines agencies in the network to exchange knowledge and experiences on experimenting with new technologies and the acceleration of the adoption of novel technologies across the Agency.
Establish an EU collaboration on AI with other Agencies in the EU Network	2.2 (ECP 2)	Use of trustworthy and human-centric artificial intelligence for increased collaboration amongst EU Agencies and Member States (Develop and promote AI community) whilst seeking efficiency gains and demonstrating the overall	On track	The collaboration has been established being EMA one of the leading agencies of the collaboration. The AI community met during the first semester to show different use cases among the agency in the network. The Leading Agencies organised the first EU AI Talk live together at the end of the year to present AI projects in each agency and their implementation across the network.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		added-value and contribution of EU agencies and Members States to the EU AI Strategy		
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 EUNTC	On track	- Analysis of outcome of surveys to HMA and LMS users on training needs and priorities in the Network -Work initiated with EU NTC Training Steering Group members on EU NTC priority topics relating to the strengthening of core activities in capacity and capability building for the network, preparing the network for the future, ensuring sustainability (through adequate resources) and increased collaboration with stakeholders - Development of a Learning Toolkit to support course organisers and curriculum - Initiation of work on the development of an engagement portal which will provide a single point of access to the EU NTC LMS containing the EU NTC training courses - Development of a digital knowledge-sharing academy with the aim of building digital literacy, capability and capacity at EMA with intended future expansion to the EMRN. Introductory modules targeted at EMA staff have been developed on a number of topics (digital mindset, digital wellbeing and design thinking) - Additional EU NTC courses have been added to the new domain for international

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				regulators in the EU NTC LMS, with the intention to open these courses up in a pilot in Q2 2023 to up to 5 staff members of regulators with a confidentiality agreement or from accession and pre-accession countries - In the context of the EU4Health Joint Action on Capacity Building, engagement with the NCA Coordinator and Topic leads for the Sustainability and Development of Skills Work Packages regarding areas of possible connection with the EU NTC and how EU NTC can support the work of the Joint Action through its already existing governance and operational structure, methodology in the establishment of curricula, and involvement in the development and delivery of training
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 (drug device combinations), In Vitro Diagnostics and borderline products	On track	Activity (drafting of the integrated pathways roadmap document) started in Dec 2022. Planning of workshops and drafting of relevant guidance documents will be 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	On track	See integrated pathways. A mapping exercise of the currently available medical device expertise (including NCAs) will be presented in the integrated pathways roadmap document which is currently under development.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		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		

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in 2022
ECTD4: Implementation and adoption of eCTD v4.0 standard	The project aims at implementing the next generation standard defining the message for exchanging regulatory submission information electronically between applicants and Regulatory Authorities.	*[will restart in 2023]*
IRIS: Platform to support regulatory business processes of the Agency	The IRIS platform will provide a single space for applicants and EMA to submit requests, communicate, share information and deliver documents concerning regulatory and scientific procedures	GCP Inspections in IRIS from April 2022 Variations process started development in Q1 2022 H Var form for CAPs go live Q4 2022 *Transferred to Agile governance, under 2 epics in Product Lifecycle Management Value Stream, one under the Research & Development Value stream and one under the Monitoring Value stream.*
Other Digital Business Transformation initiatives	Bringing about innovative digital tools for the Agency	Digital Innovation Lab started five new DigiLab projects and worked with Analytics Centre of Excellence

Project title	Long term objective	Achievements/results in 2022
		(ACE) to pilot five solutions to business challenges. First Chatbot launched in May 2022. Virtual Reality proof of concept completed. EMA Digital Academy pilot with three modules.

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Data Analytics and Real World Interrogation Network (DARWIN EU) Deliver a sustainable platform to access and analyse healthcare data from across the EU. 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)	Data Analytics and Real World Interrogation Network (DARWIN EU) established and operational	On track	- Contract signed with Erasmus MC in Feb 2022, following tender procedure - Package of communication activities surrounding the launch, incl. a multi-stakeholder information webinar with ~700 attendees - Milestones 1, 2 and 3 completed successfully, with activation of Phase II in Aug 2022. Milestone 4 is due on 7 February 2023 - DPIA finalised in August 2022, with an update foreseen in early 2023. A workshop to share the learnings with the network of NCA data protection officers held in November 2022 - Shortlist of 10-15 Data partners for onboarding agreed, with onboarding of data partners and a press release in November 2022 - Studies shortlist for phase I agreed and four studies initiated and at analysis stage (as of December 2022) with results due in early 2023, realising the first benefits for the network and stakeholders - Continued engagement with EMA committees, NCAs and with multiple stakeholders via the DARWIN EU Advisory board - Engagement with HTA and payers' bodies including via a workshop in October 2022, and with ECDC for identifying use cases for conducting pilot studies
• Submission of Raw Data in	2.1 (ECP 2)	Determine the regulatory and	Delayed	•Raw data pilot launched summer 2022. Selection criteria for the procedures to be

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Regulatory Submissions • Build capability and capacity to receive, store, manage and analyse raw data		public health benefit of analysis of raw data		included in the proof-of-concept pilot were endorsed by CHMP during the PROM meeting in May 2022 (Q2 2022). •In response to feedback from the EMRN project milestones were amended from the 2022 plan to allot more time for preparation and to prolong the pilot. As of end of 2022, 65% of total deliverables have been achieved. Of note, all 2022 deliverables were achieved. •Industry Focus Group on Raw Data established in August 2022. •Pilot's design phase completed in September 2022; pilot's protocol completed, internal and external guidance developed, data protection impact assessment completed. •First pilot procedure selected and raw data for this procedure submitted in October 2022.
Data standardisation in medicines regulation across the lifecycle of a medicine: Develop a data 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	2.1 (ECP 2)	Enable effective interrogation of scientific information across the lifecycle of medicines and for multiple types of users within and across regulatory procedures. Drive up the quality of data submitted to EMA through the use of standards	On track	Clinical Trial Navigator: •Collaboration with ICH M11 on development of logical model for clinical study protocols started in Q4 2021 and was ongoing in 2022 •Development of conceptual & logical model for clinical study protocols progressed and on-going. First draft is used for Proof of Concept of using FHIR messages Q1 2023 and external consultation on model expected for Q1 2023. •Work on FHIR messaging initiated in Q2 2022 •Proof of concept for using FHIR messages for standardised clinical trial protocols initiated in Q4 2022 •Successful transition of project to SAFe/Agile in Q4 2022 Scientific Explorer: •Demonstration for the Advanced Analytics Scientific Advice pilot made in Q2 2022 •Development of UI in Q3 2022 •Contract with Cortiical.io signed in Q4 2022 •Successful transition of the project to SAFe/Agile in Q4 2022 •Participation in PI planning (Dec 2022) with Cortical.io as Enabler Data governance: •Data Standardisation Strategy published in Q1 2022 •EMA data board established in Q3 2022, work started on developing a data

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				governance framework and data strategy for EMA.
Metadata, Data Quality Framework and Catalogues Project: Enable data discoverability. 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 the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable). Upgrade the current EU PAS database to support the registration and transparency for observational studies	2.1 (ECP 2)	Data discoverability enabled for the Network	Delayed	1. Completed a comprehensive review of existing data quality frameworks available in literature and/or developed by other regulators and organisations, with the view of using it as an input for the drafting of a Data Quality Framework intended for regulatory purposes 2. Conducted an in-depth stakeholder workshop consultation with a view to drafting and improving the Data Quality Framework 3. Published a draft Data Quality Framework for written public consultation 3. Developed a methodology to identify databases to include in the EMA Database Catalogue, to engage with database holders and collect the metadata required 4. Collected metadata for an initial set of 24 real-world data sources to be included in the EMA Database Catalogues 5. Drafted technical requirements for EMA Database Catalogues technical implementation 6. Published a Metadata Good Practice Guide for public consultation
• Strengthen EU Network on methodology and RWE in committee advice and assessment • Develop Big Data learning initiative where submissions on complex methodology and RWE are forecast and tracked, work with international partners on RWE to develop roadmap and guidance, drive the creation of guidance documents in the methodological area, drive the creation of the	2.2 (ECP 2, ECP 4)	Improved preparedness of the EU Network for applications with RWE and complex methodology. Systematic learnings from submissions with RWE and complex methodology. Published roadmap for collaboration with international partners. The Methodology Working Party is operational and publish a workplan for methodology guidelines.	On track	•Establishment of Methodology Working Party with first meeting taking place in Q2 2022. •MWP 3-year workplan adopted by CHMP in Q4 2022. •Establishment of Methodology European Specialised Expert Community (ESEC) initiated in Q4 2022. •Support to network was provided through the creation of temporary Drafting Groups (DG) in Q3 and Q4 2022. • ICMRA statement on international collaboration to enable RWE for regulatory decision-making in Q3 2022 and Draft ICH Reflection Paper in on RWE guidelines (terminology and discoverability) in Q4 2022. • EMA-University of Groningen publication on the contribution of real-world evidence in EMA regulatory decision making in Q4 2022.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Methodology Working Party				
• RWE process and analysis • EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	2.1 (ECP 2)	Enable better regulatory decision making through the provision of the high-quality RWE	On track	* All mentioned Committees had at least one pilot study initiated (x/y: x studies initiated of y study requests): CAT (1/1), PDCO (4/6), COMP (4/5), SAWP (3/5), CHMP (1/2). Of these, 7 were completed in 2022: PDCO (2), COMP (3) and SAWP (2). * Training materials were prepared, and all newcomers are onboarded using the TDA Companion Booklet on analytics and a module on Databases descriptions. * First version of the RWE portal developed intended for launch and wider distribution across the Agency in Q1 2023 * A total of 50 studies have been requested and/or offered, of which 25 studies were feasible to be conducted via the Agency's in-house databases (20), framework contracts (1) or DARWIN EU® (4)
Establish a multi-stakeholder, neutral, platform, to enable new approaches to clinical studies and to position the EU as a preferred location for innovative clinical research	3.2 (ECP 1)	Establish a framework, mandate and objectives for a multi-stakeholder platform for discussion of new approaches for Clinical Studies	On track	*As per the adopted ACT EU workplan for 2022-2026 a concept paper setting out the framework, mandate and objectives of the MSP was to be discussed within the Network in Q3 2022. The ACT EU SG agreed on the approach to the concept paper in December 2022, with the final adoption and publication of the concept paper scheduled for Q1 2023. The kick-off meeting is now planned to take place in Q2 2023. *On 4 October 2022, there was a dedicated ACT-EU multi-stakeholder workshop on the topic of decentralised clinical trials. *On the basis on the above, the activity status is considered to be on track.
• Work with stakeholders, the EU Medicines Regulatory Network and the European Commission to promote and facilitate the conduct of complex clinical trials and other innovative clinical trial designs	3.2 (ECP 1)	Using the multi-stakeholder framework from 3.2.1.11 develop action plan and workstreams on complex clinical trials	Delayed	*Question & Answer document on Complex Clinical Trials published in June 2022. *Workshop on decentralised clinical trials planned for Oct 2022, and final recommendation paper on DCT planned for end of 2022
Promote increased information sharing on clinical trial design, conduct, results and best practices. Build on	3.2 (ECP 1)	Using the multi-stakeholder framework from 3.2.1.11 develop action plan and	On track	In 2022 ACT EU has delivered a number of outputs which promote information sharing on clinical trial design, conduct, results and best practices, further enabling education and training to accelerate innovative change: *Training strategy (adopted by ACT EU

Action	MAWP strategic goal	Expected result	Status	Achievements/results
this information and the multi-stakeholder platforms to enable further education, training and sharing of best practice in order to accelerate innovative change		workstreams on complex clinical trials		Steering group in Dec 2022) *Publication of Recommendation paper on decentralised elements in clinical trials(DCT) (December 2022) *Publication of Q&A document on complex clinical trials (June 2022) *Communication campaign to raise awareness of the Clinical Trial Regulation (CTR) 31 January deadline (October 2022). ACT EU Priority action 6 (Communications) has also supported the dissemination of information on key clinical trial guidance, such as the DCT recommendation paper. *Survey to capture issues encountered by sponsors to comply with the CTR (July 2022) with actions addressed at the level of EMA (CTIS), CTCG and CTAG. *Agreement with DG DIGIT to develop a stand-alone ACT EU website. It is further envisaged that the multi-stakeholder platform will serve as a hub to discuss stakeholder priorities, with a view to accelerating innovation in clinical trials.
Go live of 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	Update CTIS Sponsor handbook: in Nov 2022 Sponsor End-user training, organised for EMA by DIA - 8 sessions CTIS bitesize talks: 9 CTIS walk-in clinics: 10 Two CTIS info events OMS troubleshoot sessions for CTIS users 4 sessions SME & Academia training support to use CTIS sandbox - 3 sessions 1 Demonstration for CTIS stakeholders event in Jan 2022 Continuous updating of training materials Continuous service desk, third line support. For IT delivery: continuous big fixing and hypercare delivery. From August 2022 to Jan 2023: burndown of the transition scope of 163 items
Full Implementation of the EU-DPR and monitoring of compliance	6.2	• 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	On track	1. Monthly activity reports to EMA-EXD; 2. Advice on data protection matters including tenders, procurements, legislative proposals, policy and guideline reviews and international transfers of personal data; 3. Participation at DPO Network meetings and working groups; 4. Records of processing activities & data protection notices: 70 (review/updates); 5. Data Protection Impact Assessments completed/under finalisation: •DARWIN EU® Coordination Center •Lifecyle Regulatory Submissions Raw Data Pilot •Update of EudraVigilance DPIA (from version 2019) •Use of Microsoft Office 365 at EMA

Action	MAWP strategic goal	Expected result	Status	Achievements/results
		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		•Business Intelligence forAdministration* (BI@Admin)•Talent Hub* (*under finalisation); 6. Joint Controllership Arrangements: •EudraVigilance –(endorsed by EMA Management Board in June 2022) •Lifecyle Regulatory Submissions Raw Data Pilot; 7. International Transfer of Personal Data (Chapter V of EU DPR): •Impact Assessment Report –analysis of data protection and administrative impact including set of recommendations to facilitate EMA compliance with EU DPR • Compliance with informal Supervisory Opinion of the EDPS on the use of the Standard Contractual Clauses (SCCs) by EU institutions (June 2022) - conduct of Transfer Impact Assessments in the following areas: TIAs performed in 2022 Signal and Safety Analytics project tool, MIRO Enterprise Digital Whiteboard tool, Drug Information Association (DIA) Service Concession, ZohoService Desk for DARWIN EU®, SAP Fieldglass (ongoing), Balsamiq & Moqups, Plexus Task Management: •International Transfer of EudraVigilance data * EDPS consultation on international transfers of unredacted case narratives originating from EudraVigilance by certain MAHs * Liaison with CBER FDA and CDC -case narratives & country information were removed from VAERS public website and WONDER database on 18 Nov * Consultation of German DPA about non-compliance of certain MAHs * Letter to all QPPVs to emphasis data protection accountability and adherence to EV Access Policy • Arrangement concerning data protection requirements for international personal data transfers EMA to Health Canada * Meeting with EDPS to discuss their comments * Follow-up meeting with HC to address EDPS comments –final draft text under review by the specialised International MOU lawyers at Global Affairs Canada; 8. Management of Data Breaches (Article 33 & of EU DPR) - data breaches recorded in EMA Central Register: •Q1 2022 –11 breaches –2 EDPS notifications •Q2 2022 -8 breaches –1 EDPS notification •Q3 2022 -6 breaches •Q4 2022 -5 breaches 9. Data Protection Training • Workshop organised on lessons learned on the DARWIN EU® DPIA • Training plan for data scientists of the EU

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Regulatory Network focusing on health data based on modular approach and classroom sessions

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements 2022
- Lifecycle Regulatory Submission Metadata	Identify relevant data sources and by defining and standardising the structure of the information (i.e. defining the 'metadata' and supported through relevant standards), the scientific information will become more accessible	Scientific Advice advanced Analytics (Scientific Explorer) pilot: • Pilot completed and successful and demo of UI to business • Contract with vendor signed for next delivery phase • Successful transition of the project to SAFe/Agile under Research and Development Value Stream Clinical Trial Navigator: • ICH M11 (for clinical study protocols) published for public consultation • Development of conceptual & logical model for clinical study protocols using FHIR messages progressed. • Data Standardization Strategy endorsed by EXB, HMA and MB and published at EMA website Successful transition of the project to SAFe/Agile under Research and Development Value Stream
- Lifecycle Regulatory Submission Raw Data	Report on review of experience with IPD at EMA and other international regulatory agencies and develop protocol for IPD	CHMP Raw data pilot design completed: business process and operating process, Data protection impact assessment, change management, Guidance and templates for stakeholders, selection of EMA contractor to support raw data analysis) CHMP Raw data pilot execution initiated: pilot launch communication, first pilot procedure selected, and raw data submitted, establishment of Network Advisory Group on Raw Data and Industry Focus Group on Raw Data. *Transfer to Agile governance in Research and Development Value Stream planned for 2024*

Project title	Long term objective	Achievements 2022
Observational Studies DARWIN EU * Real-world Metadata and Rapid Analytics merged with DARWIN into one project in Nov 2021	Establish a network of data, expertise, and services to support better decision-making by EMA and NCA scientific committees on the benefits and risks of products via rapid access and analysis and increased reliability, validity and representativeness of EU health data	Quality Framework • public consultation on Data Quality Framework for EU medicines regulation completed DARWIN EU ® • Coordination centre selected, established and operational • First 10 data partners onboarded • First 4 studies initiated • Integration with business processes and pilots with EMA scientific committees progressing as planned, solid demand for RWE studies • Data protection impact assessment completed • EMA use case selected in the EHDS2 pilot • Workshop with HTA and payers identifying use cases Real-world Metadata and catalogues • Metadata list adopted and published on Big data website • public consultation on RW metadata Good Practice Guide completed Successful transition of the project to SAFe/Agile under Research and Development Value Stream.
- Real-world Metadata, Quality Framework and Catalogues	Conduct external studies to identify data sources of real-world data, define and collect metadata and deliver a data quality framework.	*Move to the Research & Development Value Stream*
- Observational Studies Rapid Analytics	Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	*[Included above]*
- Signal and Safety Analytics	Increase saleability and efficiency in processing of signals & safety data	Collection of IT and business/functional requirements for the design of the new EVDAS platform/eRMR solution/ADR website Preferred technological product selected following Proof of Concept exercise with vendors

Project title	Long term objective	Achievements 2022
		Data protection impact assessment initiated Successful transition of the project to SAFe/Agile under Monitoring Value Stream
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR)	The project aims at delivering Clinical Trials Information System (CTIS) to support the harmonisation of the assessment and supervision processes for clinical trials throughout the EU	Go-live 31 January 2022 Post-go-live releases Communication and training ongoing Hypercare period until July 2022
Safety Implementation Regulation - cooperation in safety assessment (CTIS scope extension)	Implementation of IT systems to support cooperation in safety assessment in the context of the clinical trials	Go-live 31 January 2022 Continued communications, training programme and related documentation First Annual Safety Report submitted in CTIS in June

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure	2019 result	2020 result	2020 result	2022 forecast	2022 result
Innovation Task Force briefing meetings	29	27	36	35	34
Innovation Task Force Art 57 CHMP opinion requests	4	0	0	2	1
Business Pipeline briefing meetings[27]	-	-	15	21	21
Regulatory assistance, including SME briefing meetings[28]	-	-	180	183	207[29]
Requests for SME qualification	536	518	504	516	412
Requests for SME status renewal	1,235	1,205	1,293	1,260	1,432

Performance indicators

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Satisfaction level of SMEs[30]	n/a	89%	98%	80%	n/a[31]

[27] New indicator introduced in Work Programme 2021.
[28] New indicator introduced in Work Programme 2021.
[29] 200 Requests received for administrative assistance and 7 SME briefing meetings on regulatory strategy.
[30] New indicator introduced in Work Programme 2021.
[31] No info day was held in 2022.

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 on shortages at the level of the Global Regulators Working Group continues with meetings taking place every 2 months. Bilateral collaboration established with the US-FDA with meetings taking place on a quarterly basis.
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	Submission of manuscript analysing Enabling Technologies submitted to EMA. Analysis impact of respective of Enabling Technologies in Publications and Clinical Trials
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	1. Delivered horizon scan report on 25 technologies to EU IN following collaborative work with JRC and WHO 2. Delivered HS ad hoc report on Big Data technologies to BDSG for revision of workplan 2022-2023 which will lead to EU-NTC implementation and discussed findings with Big Data Stakeholders for reflection in their activities
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. Contributed to STARS project and implementing its recommendations in EU-IN academia interest group 2. Evaluated proposal for engagement in Dutch Education Consortium (resulting in planning to contribute in 2023)

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				3. Preparing workshop with EIThealth on genome editing
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. Additional monthly dissemination of upcoming TRS stakeholder interactions to WP and groups eg CTCG 2. Monthly presentation and discussion of upcoming meetings with EU-Innovation Network 3. Network comprehensively involved in Horizon scanning report on anti-microbial resistance, inform on signals from horizon scanning in the field of big data and on 25 technology topics ("Health horizons" publication, inter alia in EU IN) 4. TRIP successfully included in EMA's Scale Agile Framework (SAFe) Value Stream Research and Innovation, EPIC agreed, budget released and product started in EMA's SAFe Programme Iteration #6.
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. HS deep dive report on Antimicrobial resistance delivered to EMA and EMAN, prepared workshop to inform EMA AMR strategy 2. HS ad hoc report on big data technologies to inform BDSG agenda and Big Data Stakeholder Forum 3. HS ad hoc report to SCG on single-country developments to inform network preparation 4. Contributed to EU IN HS report on FMT

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				5. Published HS report on 25 technologies identified from collaborations with JRC and WHO
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	On track	The MSSG and the medicine shortages SPOC Working Party have been established and are fully operational. List of critical medicines for COVID-19 and mpox (monkeypox) were adopted. Both lists have been published in the EMA website. List of main therapeutic groups was also established and published as per the requirement if the legislation. The i-SPOC registration was launched. MAHs in scope of the list of critical medicines for COVID-19 and mpox (monkeypox) are submitting actual or potential shortages of their products from 15 July 2022. EMA is also collecting demand data from NCAs and matching supply with demand. EMA together with Member States monitors events that may lead to major events or PHEs.
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	On track	EMA organised at the PCWP-HCPWP annual meeting with all eligible organisations on on 15 November 2022 a session on availability. A multi-stakeholder workshop is scheduled for 1-2 March 2023 with all stakeholders in the supply chain which will be publicly broadcast.

Pillar 3 - Programmes and Projects

Project title	Long term objective	Achievements/results in 2022
EUMSD database	To support development of functional specifications for the EUMSD database, together with a plan for the implementation of national IT systems, and consultation with stakeholders	• Feasibility study concluded • Governance endorsed, including establishment of MSSG WG • Network PO, MAH and NCA SMEs appointed
Digital workspace (TRIP)	To use a Digital workspace for capturing, filtering and scientifically assessing HS signals by users from the Horizon Scanning team (TRS) and by Regulatory Observatory members (experts across the Agency, and eventually the EMRN)	[not started]
EMA's Regulatory Science Observatory	To support review of TRS operations with a view to optimise, create synergies and efficiencies leading to fulfilling our mandate as a EMA's Regulatory Science Observatory. Operations to review include the Business Pipeline, Horizon Scanning, Innovation Task Force as well as Academia and SME liaisons	Launched a project with Deloitte to review and optimise TRS' first points of contact services in November 2022. The project ends in 2023.
EMA extended mandate implementation - Monitoring and mitigating shortages of critical medicinal products and management of major events - Monitoring and mitigating shortages of critical medical devices - Medicinal Products with the potential to address public health emergencies (PHE) - Support of medical device expert panels		• Set up of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) • Set up of the Medicines Shortages Single Point of Contact (SPOC) Working Party • iSPOC registration available since July 2022 for all MAHs in the Union (in IRIS platform) • Establishment of List of Main Therapeutic Groups (MTG) – hospital care • Establishment of 2 lists of critical medicines under Regulation (EU) 2022/123 for ongoing PHEs (COVID-19 and

Project title	Long term objective	Achievements/results in 2022
		mpox (monkeypox)) to close monitor supply/demand of those listed products • Deployment of IT tactical reporting solutions to NCAs/Industry to report data set required • Monitor events by EMA/NCAs, including medicines shortages (e.g., energy crisis, antibiotics, thrombolytics)
Shortages (new mandate)	EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand	Regulation (EU) 2022/123 adopted 25 January 2022 iSPOC registration tool go-live in June 2022 *Transferred to Agile governance, under ESMP epic in Monitoring Value Stream*

Clinical Studies and Manufacturing (TCS)

Following organisational changes through 2022, the Clinical Studies and Manufacturing Task Force has been dissolved. Its activities have been taken over by Human Division and by Health Threats and Vaccines Strategy Advisory Function and are reported accordingly in this Annual Activity Report.

Advisory functions (International affairs, Internal audit, Legal department)

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Interactions with FDA	454	644	696	700	692
Interactions with MHLW/PMDA	96	132	117	150	119
Interactions with Health Canada	125	224	138	200	165
Interactions with any other stakeholders	506	866	920	700	950
Number of information and/or document exchanges	461	988	976	900	991
Number of teleconferences organised (including OPEN, but excluding ICMRA)	142	235	230	150	240

	ICMRA executive committee and full membership TC[32]	n/a	52	30	25	24
	International stakeholders' visits (fellowships, experts, observers)[33]	n/a	1	3	5	2
	Organisation of International awareness sessions	n/a	0	0	2	0

Pillar 2 – Public health activities and Business Services

Achievements

AF-HTV

Action	MAWP strategic goal	Expected result	Status	Achievements/results
• Foster development of POC diagnostics for human and veterinary use	4.2 (ECP 1)	• Inclusion of diagnostics in the discussion on new business model on the antibacterial agent	Suspended	Needs rethinking based on an agreed revised AMR strategy
Define approaches for review of data with international regulator	4.6	Build on the experience acquired with COVID to establish the approach for future emergencies.	Delayed	With the pandemic fading away, it will be possible to reflect on the lesson learned and provide proposals for the framework
Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA.	On track	Several communications activities conducted in the context of COVID and mpox (monkeypox) including joint EMA-ECDC recommendations
Engage with public health authorities and NITAGs to better inform	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute.	On track	NITAGs meetings are attended regularly and feedback provided. Several occurred during 2022 covering both COVID, MPX and general strategy

[32] New indicator introduced in 2020 work programme.
[33] New indicator introduced in 2020 work programme.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
vaccine decisions				
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	First IVMAB meeting held in December 2022, research agenda discussed at the meeting. Several studies ongoing.

AF-IA

Action	MAWP strategic goal	Expected result	Status	Achievements/results
COVID-19 and ICMRA secretariat	1.1 (ECP 1, ECP 4)	• Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration • Regulatory communication	On track	Support to EMA Executive Director as chair and management of the ICMRA secretariat continued in the second semester of 2022, including coordination of the ICMRA Summit and Plenary meeting in November in Dublin (first face-to-face ICMRA plenary meeting since 2019). Emer Cooke began new 3-year term of office as ICMRA Chair until September 2025, meaning EMA will continue to provide Secretariat coordination until then.
Nitrosamines	1.1 5.5 (ECP 1, ECP 4)	Participation in Nitrosamines International Steering Group (NISG)	On track	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 vet medicines	On track	Extension to Veterinary medicines Process is at final stages. Decision making process is ongoing. Commission Decisions on the assessment schedule and recognition of FDA-Centre for Veterinary Medicines are pending. From FDA side it was confirmed they are ready and have completed the assessment of 14 Member States NCAs as previously agreed. Progress continued on NCAs audits (currently only Italy and Malta are pending) and submission of assessment packages to FDA. Extension to vaccines and plasma derived products. JSC agreed to postpone the decision on whether to include vaccines and plasma derived products in the MRA scope; this should be done on the basis of the experience from joint/observed inspections and due to COVID-19 pandemic it was not possible to get such experience yet. Preparatory work is ongoing. Inspection plans have been exchanged between EMA and FDA and joint/observed inspections are

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				being organised. Technical group (EU+FDA) was set up. FDA provided answers to EU questions on FDA procedures, roles and responsibilities for vaccines and plasma derived products. EU started planning for FDA audits for vaccines and plasma derived products. Improvement of MRA for human medicines A number of topics have been discussed between EC/EMA and FDA to increase the efficiency of the MRA in place. Recognition of FDA third country inspections GMDP IWG agreed with 1-year EU pilot procedure for 2023 ; some additional info from FDA is awaited; pilot will run in parallel with the Reliance Initiative for PIC/S authorities. Joint Sectoral Committee meeting took place on 30 June. In addition to the JSC meeting there were two technical meetings in March between EMA and EC and FDA to discuss amongst others MRA related topics. FDA conducted two inspections in India (Bio E DS and DP sites) on behalf of EU, under the EU-US MRA. First third-country biological inspection recognised under MRA.
Article 58 – EU-M4all	1.2 (ECP 1)	Support to developers and promotion of parallel art 58 and centralised submissions	On track	<u>Submissions and approvals:</u> The thirteenth, fourteenth and fifteenth medicines have been recommended by EMA under EU Medicines for all (EU-M4All). One of these is also the first one with a CAP and a parallel EU-M4All opinion. A new application for SO received and validated. Participation in monthly champions meeting H-Division counterparts. <u>Pre-submission interactions with potential</u>

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				applicants: 4 pre-submission interaction Pre-submission interactions on potential use of Art 58 for generics of COVID-19 therapeutics. Scientific advice interactions 3 Scientific advices provided. Technical Review meetings with SA/WHO to review and improve processes around expert nomination, information sharing and expert input. Translation of CHMP SO into National Marketing Authorisations Technical discussions with 4 Opinion Holders to understand their challenges and how EMA could better support applicants in the post opinion phase
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	Collaborative registration procedures 9 QIS validated for CRP since January 2022, for new marketing authorisations and post-authorisation updates. Presentations given in the following meetings to promote collaboration and reliance: Monitoring the Safety of Marketed Medicines and Vaccines: Learning from International Good Practices - World Bank Group - February 2022 Second Facilitation meeting for Janssen Ebola registration in Africa with 14 NRAs and WHO- May 2022 EU regulatory system Collaboration pathways and reliance - EU-Africa pharma and healthcare webinar May 2022 WHO-EMA Collaborative Registration Procedure – Advocacy workshops with national regulators in Africa, Asia and Latin America, June 2022. Egyptian Drug Authority and PhRMA workshop – Implementation of Reliance, October 2022 ALIMS -Medicines and Medical Devices Agency of Serbia- Annual symposium, October 2022 EPH – European Public Health conference, November 2022 10th Annual CRP meeting, December 2022

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				Regulatory reliance discussions with industry EFPIA-EMA meeting on reliance, September 2022 Novartis-EMA meeting on reliance, October 2022 Regulatory Reliance Topic - 9th Meeting of the Industry Stakeholder Platform on the operation of the centralised procedure, November 2022
Develop International collaboration and reliance including through Confidentiality Arrangements	6.5	Update existing and putting in place new confidentiality arrangements	On track	Work started on a new tripartite Confidentiality Arrangment between European Commission/EMA and MFDS (South Korea). Ad hoc CA with New Zealand Medsafe on mpox (monkeypox). Significant progress on the Administrative Arrangement with Health Canada which will allow exchange of confidential information avoiding redaction of Personal Data. A new draft has been agreed between EMA and Health Canada which takes into account comments previously received from the European Data Protection Supervisor (EDPS). Draft submitted to the EDPS for final agreement before finalisation.
Capacity building 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	6.1	Increased visibility of EMA - Training on acquis Communautaire of candidate and accessing countries	Delayed	Duration of the project extended to the end of 2023 by decision of the European Commission. Training plans for 2023 discussed and agreed with candidate countries and potential candidates.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Supply chain	5.2	Work with project on shortages, on API with priority countries China project on API	On track	EMA participated regularly in the meetings and work of the Global Shortages and API clusters. In addition, contacts and a meeting took place with FDA to discuss specific shortages due to Ukrainian crisis. A more systematic bilateral collaboration with FDA in the shortages area has been established. Increasing requests for shortages-related information from international partners.
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	Delayed	Continuous formal contacts with Chinese authorities. Interactions with Indian authorities on ICH and PIC/S have begun.
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	5 authorities (Australia, Canada, Japan, Switzerland, WHO) included in the OPEN pilot, with Israel MOH participated in ETF and CHMP. One-year review completed and published in the March 2022 management board meeting documents. Stakeholder Meetings: Process review meetings with Australia, Canada, Japan and Switzerland. OPEN presented at DIA Europe (March 2022), PCWP/HCPWP meeting (June 2022), and Industry stakeholder meetings (June and November 2022). Engagement with CHMP chair, H-TA and others on operationalisation of OPEN as part of CHMP work plan for 2022 ongoing.
Active participation in WHO activities, international fora, and communication to	1.1	Promote convergence of global standards and contribution to international	On track	Participation and support to activities related to the framework for evaluating and publicly designating regulatory authorities as WHO listed authorities (WLA) Participation in Athens ICH and IPRP as part of EC, Europe delegation and support the IPRP subgroup on reliance

Action	MAWP strategic goal	Expected result	Status	Achievements/results
stakeholders, including but not limited to ICDRA, DIA, ICH, IPRP.		fora		Participation in DIA Euro and Annual Global meetings. Participation in RAPS Convergence meeting. WHO ICDRA preparations on hold pending WHO 'go/no go' decision for 2022 meeting. WHO awareness session for EMA staff and network, July 2022 DIA – CMC – collaboration and reliance session, September 2022 WHO EMA strategic discussion on interactions, including a session EMA-WHO-SwissMedic October 2022
Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	5.3	Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	Delayed	No additional comment
Promote increased international cooperation in the area of supply chain security, in particular through efforts to coordinate and integrate initiatives at the level of ICMRA	5.1	Assure product supply chain and data integrity	On track	The 2 pilot programmes on collaborative hybrid inspections and collaborative assessment have started, several applications for the pilots have been received from the pharmaceutical industry, some of them accepted.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
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	Delayed	Pilot project to extend EU Network Training Centre access to non-EU Regulators has progressed. Decision was taken that first phase of the pilot will include extension to International Authorities with whom EMA has a Confidentiality Arrangement in place and Authorities from candidate countries (including Ukraine). Draft vision document on Opening the EU NTC to non-EU regulators has been developed. Communication to concerned Authorities took place; Authorities were requested to identify contact points and members who will have access to the EU NTC platform.
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	Delayed	No specific trainings were delivered. Pilot project to extend EU Network Training Centre access to non-EU Regulators has progressed. Decision was taken that first phase of the pilot will include extension to International Authorities with whom EMA has a Confidentiality Arrangement in place and Authorities from accession countries (including Ukraine). Draft vision document on Opening the EU NTC to non-EU regulators has been developed. Communication to concerned Authorities took place; Authorities were requested to identify contact points and members who will have access to the EU NTC platform.
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	Suspended	No international awareness sessions for non-EU regulators were organised in second half of 2022 due to COVID-19 priorities and restrictions.
Collaborating with EC/EMA to develop a joint long-term strategy for targeted and	6.1	Capacity building through training	Suspended	No progress on this activity. (although note engagement with India on PIC/S membership - see above).

Action	MAWP strategic goal	Expected result	Status	Achievements/results
effective training programs on pharmaceutical GMP/GCP in China and India				
ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA meetings	1.1 ECP 1 ECP 4	Communication	On track	ICMRA plenary meetings held in July (virtual) and in November (face-to-face) in Dublin. Virtual Executive Committee meetings held monthly. ICMRA policy TC meetings (now renamed regulatory forum to allow discussions other than related to COVID as the pandemic is easing) held every 2 months. Discussion on reorganisation and rationalisation of the ICMRA work on-going. Emer Cooke began new 3-year term of office as ICMRA Chair until September 2025, meaning EMA will continue to provide Secretariat coordination until then.
Communication of information, answer to queries, internal coordination. Monitoring of the matrix of the tracking of interactions. Organisation of cluster meetings, teleconferences and preparations of visits, missions' preparation, support to FDA, Health Canada, PMDA	1.1 ECP 1 ECP 4	Support to the International Affairs Division and its specific activities	On track	-Update of 2 guidance, including the International guidance for sharing documents -Work programme report on the overall 2022 activities -organisation of 100+ cluster meetings, teleconferences -12 documents redacted -690+ interactions with FDA -160+ interactions with Health Canada -110+ interactions with PMDA/MHLW -900+ interactions with other stakeholders -Managing 30+ ICMRA meetings

Action	MAWP strategic goal	Expected result	Status	Achievements/results
and other international partners, fellowships and expert visits. Selected redaction of documents.				
Support EU and EU/MRA team meetings	5.2	Reliance and supply chain integrity	On track	For the EU / US FDA MRA support was provided to two technical meetings with FDA in March (one at EMA and other at EC), technical meetings between EC/EMA and FDA in preparation for the extension to vaccines and plasma derived products as well as to the JSC meeting in June. In addition, support has been provided for several operational meetings (internal, EC, FDA).

Action	MAWP strategic goal	Expected result	Status	Achievements/results
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building through providing adequate guidance, and other support as needed as part of wider EU engagement strategy	On track	Development of the Action Document for Regional dimension and management of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa to support DG INTPA annual program and EMA funding Participation in different meetings in support of the operationalization of AMA and support to local vaccine manufacturing. TEI MAV+ workshop - regulatory environment for local production of pharmaceuticals in Southern Africa May 2022 EMA-Partnerships for African Vaccine Manufacturing (PAVM) - Virtual Meeting to discuss BioNtainer African project May 2022 Preliminary discussions (with Quality Innovation Group) with industry on innovative technologies for local vaccine manufacturing in Africa, June 2022. 8th AMRC - African medicine regulators conference June 2022 TEI MAV+ regulatory workshop - "Enabling a strengthened and harmonized regulatory environment for local production of pharmaceuticals in Africa – Focus on the East African Community Region (EAC) August 2022 7th AMRH partners platform October 2022 AMRH Partnership platform meeting December 2022 Discussion meetings to support the ToRs for the Technical Committee for Evaluation of Medical Products EMA has representative on Advisory Committee for the creation of the AMA. Submission of an article for DIA Global Forum (publication on 09/07/2022) and DIA podcast Rwanda Welcomes African Medicines Agency Home a conversation with David Mukanga (Bill and Melinda Gates Foundation)

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2019 result	2020 result	2021 result	2022 forecast	2022 result
Number of cases of patient/consumer engagement[34] in EMA (medicines-related) activities	769	594	485	570	n/a[35]
Number of cases of healthcare professionals' engagement [36] in EMA (medicines-related) activities	212	176	202	350	n/a[37]
Number of messages circulated via 'Early Notification System'	411	612	1,206	500	646
Number of EMA communications pro-actively sent to stakeholders	128	178	182	190	206
Number of EPAR summaries and EPAR summaries updates published	286	297	239	200	204
Number of summaries of orphan designation published	117	154	167	150	178
Access to documents, requests received	783	597	710	750	676
Access to documents, documents released	1,429	1,024[38]	1,136	1,500	1,128
Requests for information received	7,200	7,055	12,500	10,000	7,342
Number of documents published on EMA website	9,012	5,963	6,712	7,500	6,403
Number of pages published and updated on EMA website	3,383	2,511	3,064	3,500	2,851
Number of press releases and news items published	143	217	220	170	164
Numbers of press briefings conducted		3	19	15	15
Numbers of social media posts published		484	975	900	704
Completed requests for interviews and comments by media representatives	1,476	1,770	5,000	1,800	1,269
Number of reports, brochures, leaflets laid out or printed, social media visuals	206	357	989	800	811

[34] 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.
[35] 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] https://www.ema.europa.eu/documents/report/stakeholder-engagement-report-2018-2019_en.pdf.
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.
[36] 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.
[37] 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] https://www.ema.europa.eu/documents/report/stakeholder-engagement-report-2018-2019_en.pdf.
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.
[38] 2020 figure updated from dataset completed in February 2021.

Performance indicators

Performance indicators related to core business		2019 result	2020 result	2021 result	2022 target	2022 result
	Satisfaction level of patient and consumer organisations	n/a[39]	92%	n/a	n/a[40]	n/a
	Satisfaction level of healthcare professional organisations	n/a[41]	90%	n/a	n/a[42]	n/a
	Triage of incoming requests received via AskEMA within set timelines[43]	n/a	n/a	100%	100%	99.00%
	Responses to Access to Document (ATD) requests provided within set timelines	89%	90%	92%	90%	88.50%
	Responses to Request for Information (RFI) within set timelines (for EMA)	96%	82%	85%	95%	87.00%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their Request for Information (RFI)	84%	83%	81%	80%	68.00%
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"[44]	n/a	78%	n/a	80%	76.00%
	Average rating of pages on corporate website during the year[45]	3.4	3.7	3.2	3.5	3.2

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements/results
• Design communication campaigns in collaboration with relevant stakeholders to proactively approach to 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	Completed	. Strategic plan for stakeholders engagement finalised and agreed internally (by SCORE). . Implementation of the agreed consolidated approach to scientific publications has been initiated . Review of policy on scientific publications has been finalised . Process for Open Access updated and 18 requests have been processed within expected timelines . 64 manuscripts have been peer-reviewed . 37 scientific articles have been published . Lines To Take on COVID-19 circulated to the Network regularly (frequency adapted to the pandemic situation) . Content of COVID-19 updated regularly on corporate website and key information shared with the EU regulatory Network and international partners . CTIS launch campaign delivered, including new clinical trials website; campaign was reprised in December 2022 to support preparation for 31

[39] Due to BCP next survey expected in 2020.
[40] Survey carried out every 2 years.
[41] Due to BCP next survey expected in 2020.
[42] Survey carried out every 2 years.
[43] New indicator introduced in 2021 Work Programme.
[44] Survey carried out every 2 years.
[45] Error identified in previous years' calculations: 2020 and 2021 corrected.

Action	MAWP strategic goal	Expected result	Status	Achievements/results
				January 2023 deadline, videos and other communication materials were produced in all EU languages and shared with NCAs . UPD launch campaign delivered, including new veterinary medicines information website (January-February) . European Immunization week campaign delivered (April) . European Antibiotic Awareness Day (EAAD) and World Antibiotic Awareness Week (WAAW) communication campaigns delivered, together with partners from network and ICMRA. . Other minicampaigns delivered: iSPOC registration, interchangeability of biosimilars; best practice guides for HCPs on preventing shortages. . Participation with a booth and information materials in both, DIA Europe and DIA US conferences

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results 2022
ePI pilot	This e-PI pilot project for human medicines (CAPs and NAPs) will provide the initial building blocks towards creation of electronic product information (summary of product characteristics, package leaflet and labelling) for EU medicines. Product information is currently only provided in PDF format.	ePI set-up project closed in Q1 2022 ePI pilot launched in Q2 2022 *Transferred to Agile governance, under ePI epic in Product Lifecycle Management Value Stream*
European Medicines web portal	Providing a unified and harmonised web-portal giving access to information on medicinal products	*Not started but being assessed under the Product Lifecycle Management Value stream how and when to restart this epic.*

Information Management Division

Workload indicators

Procedure		2019 result	2020 result	2021 result	2022 forecast	2022 result
	Number of Telematics information services provided by EMA	25	25	25	28	28
	Number of ongoing Telematics IT projects where EMA is the delivery organisation[46]	3	5	5	9	12
	Number of ongoing non-Telematics IT projects where EMA is the delivery organisation[47]	8	8	8	13	13

Performance indicators

Performance indicators related to core business		2019 result	2020 result	2021 result	2022 target	2022 result
	Satisfaction of EMA internal and external users	80%	92.8%	95.8%	80%	96.00%
	Availability of corporate/Telematics IT systems and corporate website	98%	98.2%	99%	98%	98.20%

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in 2022
DREAM Replacement Agency Document: Management system end of lifecycle and need to be replaced	The objective is to replace the Agency Document Management System, which is at end of lifecycle with a modern, flexible, collaborative	Functional and technical design completed Migration process planned Staff training started
Data Centre 2.0	Impact assessment of moving the Agency data centre to a cloud system	Project delivered and closed in Q4 2022
Security Awareness Integration of Critical Systems Identity Management PKI Infrastructure Data Sharing	Reinforce the Information security of the Agency IT systems	Contracts/procurement process ongoing
External User Journey	Facilitate the external users to get access to Agency systems in a secure way	Project delivered and closed Q4 2022
SPM&S Substances and products management services EU SRS	Implementation of ISO Identification of Medicinal Products standards to apply interoperability	Development of interface and data migration to support IRIS

[46] Since the Agency is adopting the Agile framework, this indicator is no longer relevant.
[47] Since the Agency is adopting the Agile framework, this indicator is no longer relevant.

Project title	Long term objective	Achievements/results in 2022
	and consistency to the information shared across the regulatory authorities within the EU and internationally and hand over of the European Substance Registration System to the Agency I-DIV	EU SRS handover to the Agency done in Q4 2022 Has been moved to Agile value stream: PMS in Product Lifecycle Management SMS in Research and Development

Administration Division

Performance indicators/Forecast activity

Performance indicators related to core business	2019 result	2020 result	2021 result	2022 target	2022 result
Posts on the Agency establishment plan filled	98.65%	100%	98%	100%	99.40%
Total TA staff recruited against vacant posts	36	51	70	50	45
Staff turnover rate (staff leaving against total no. of staff TA & CA) – *reversal of traffic lights*	7.25%	4.81%	5.10%	7%	5.3%
Average time to run selection procedures from vacancy notice to establishment of reserve list	79% < 3 months	88% < 3 months	65%[48]	average< 3 months	3.1 calendar months
Revenue appropriations implemented	96.29%	104.30%	99.87%	97%	98.35%
Expenditure appropriations implemented	98.56%	98.83%	96.38%	95%	96.80%
Payments against appropriations carried over from year N-1	94.94%	95.49%	92.87%	95%	95.11%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1 – *reversal of traffic lights*	2.19%	4.62%	5.75%	10%	4.34%
Title 2 – *reversal of traffic lights*	10.79%	20.71%	24.31%	20%	26.38%
Title 3 – *reversal of traffic lights*	29.16%	31.47%	37.59%	30%	40.06%
Payments made within 30 days' time	97.59%	96%	96.6%	98%	97.98%
Receivable overdue for more than 30 days (including provision for bad debts)	7%	6%	2.89%	<10%	2.54%

[48] The current average selection procedure time is 2.92 months, and it has been influenced by the increase in workload linked to the Covid-19 pandemic and extended mandate. Specifically, 50% of selection procedures were standard (single post) and their average completion time was 2.78 months; 38% of selection procedures were medium selections (a few posts for multiple requirements) and their average completion time was 2.8 months; 12% were large selection procedures (multiple requirements across the Agency) and their average completion time was 2.9 months.

Achievements

Action	MAWP strategic goal	Expected result	Activity status	Achievements January 2022-December 2022
Develop and implement a framework for integrated planning and monitoring activities	6.2	Finalisation of the Human Medicines Division business processes and full implementation of the time & capacity model	Completed	Full mapping of the activities In H division and the other Agency's divisions completed during the 2023-2025 planning exercise. Data validated by the HoDiv ready for monitoring in 2023
Implement the revised human resource and talent management strategy (HR strategy)	6.2	• The HR strategy will consolidate practices into 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 Q4 2022	On track	1. Benchmarking completed 2. Problem statements have been identified 3. Challenges and ambitions identified 4. 3 workshops with staff and 2 workshops with managers took place 5. Engagement meetings with senior management took place 6. Draft prioritised roadmap (implementation plan) is in place
Implement a competency management framework	6.2	• Implementing the competency framework (behavioural and technical competencies); revised role descriptions with embedded competency profiles and proficiency levels of competencies leading to higher effectiveness, contributing to job	Completed	- Competency framework developed and implemented in 2022 - Competencies and related proficiency levels embedded in role descriptions for each role at the Agency in 2022 - Competencies and their proficiency levels are assessed at appraisal and used to identify areas for development as of 2023 appraisal exercise - Governance process implemented in 2022 to ensure competencies are kept up to date and relevant or modified in order to be fit for purpose and aligned to the talent needs of the Agency - Development offer (former Learning offer) in 2023 enables competency-based

Action	MAWP strategic goal	Expected result	Activity status	Achievements January 2022-December 2022
		satisfaction and development opportunities • A number of other deliverables will be proposed for prioritisation under the Agile HR approach (e.g. career paths, career coaching, 360 evaluations), but given the organisational capacity to uptake the new practices, the implementation is expected to extend over a number of years		search for development activities - The process of analysing learning needs, performed by the Competency development team every year, was enhanced in order to get visibility into competency development needs and offer relevant development initiatives
The 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 Q4 2022, the HR and Finance systems replacement were confirmed and prioritised to start the work in 2023. The selected HR tool implementation will start in Q3 2023, following the analysis and technology selection. Regarding the Finance system replacement, there is an ongoing gap analysis to assess the feasibility for EMA to join the EC SUMMA programme.
Implement the Agency's new intranet and migrate or develop related content	6.4	The new intranet implemented. Content is gradually rolled out taking into account the business capacity	Completed	- New intranet launched on 5 October 2022, consisting of the minimum viable product (MVP) key features and functionalities and over 75% of the content migrated from the old to the new intranet; gradual roll out of further features and content areas planned for 2023

Action	MAWP strategic goal	Expected result	Activity status	Achievements January 2022-December 2022
				- New intranet editors for all content areas identified and onboarded; training designed to be provided in Q1 2023 - New community owners identified, and access granted to editing individual community pages for each organisational entity - Communication and change management activities implemented for user engagement and gradual transition from old to new intranet, to be concluded in 2023
Further develop the procurement and contract management practices and implement the procurement tool	6.4	• The procurement and contract management process are further improved with the further developed vendor management and market research capabilities • A tool supporting procurement processes implemented	Completed	Business units were on-boarded as planned. Since October 2022, the Finance department provides centralised procurement service to all divisions, except A-ST-FSS, which will remain with de-centralised procurement. The documentation for procurement was revised and new guidelines are in place, i.e.: vendor management, market consultation, IT sourcing strategy. Furthermore, following an extensive market analysis, A-FI-PPS prepared and implemented (from 1 January 2023) PPMT, a tool to support the procurement process, as part of the European Commission's e-procurement suite. Procurement- and contract managers as well as operational initiating agents and responsible authorising officers were trained on the tool.
Implement the revised risk management process	6.4	• The new process adopted and implemented • The tool facilitating risk management implemented	Completed	RM IT tool working according to requirements. Top down risks identified and assessed. Mitigating actions developed, monitoring in progress.

Action	MAWP strategic goal	Expected result	Activity status	Achievements January 2022-December 2022
Implement the project governance in line with Agile development approach	6.2	The Agile portfolio office implemented in line with the implementation of the Agile governance and taking into account lessons learned from the ongoing pilots	On track	All the P3i portfolio was transitioned under the Lean/Agile governance by the end of the 2022.
New Fee Regulation: optimisation and review of revenue and expenditure process	6.3	Implementation of the New fee regulation with an optimised and more efficient revenue and expenditure process	On track	The Epic started in December with the onboarding of the consultant company that will assist in the analysis and impact assessment throughout the year 2023 for its implementation in 2024. The draft legislative proposal on the New fee Regulation was published by the EC on 16 December 2023.
Improve efficiency of certain administrative processes	6.3	The identified improvement in the accounts receivable and customer data management processes implemented	On track	Business analysis completed Q12022. The implementation of SAP FIN AR enhancements was completed between Q2 2022 and Q4 2022. The CMD process improvement is to be mastered within OMS (SPOR) and implemented in the context of the New Fee Regulation which analyses the revenue and expenditure process flows. 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 pre-payment of fees at submission.
Implement the financial and administrative aspects of the extended mandate (related to medical device experts)	6.3	The processes to manage procurement and payment processes in relation to the medical device expert panels are implemented	Completed	The financial circuits are embedded in the day-to-day activities of FSS and PPS.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results 2022
Optimisation of the Administration supporting tools	Providing modern digital tools to support administration processes, increasing efficiency of processes, staff (as customers) satisfaction with improved services and reducing manual work	Intranet: technical configuration completed Risk Management: technical configuration completed
SAP Finance	Replacement of the Agency financial IT system due to its end of life	Options are being assessed for replacing old SAP Finance

2. (a) Management

EMA is headed by the Executive Director, who is appointed by the Agency's Management Board. The Executive Director is the legal representative of the Agency. She is responsible for all operational matters.

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 2022 included:

- **Election of Lorraine Nolan as Chair of the EMA Management Board:**
    - At its March meeting, the Board elected Lorraine Nolan as chair of the Board for a three-year period. Dr Nolan is Chief Executive of the Health Products Regulatory Agency (HPRA) in Ireland, a post she has held since January 2016. She served also as vice-chair of EMA's Management Board since March 2019 and has been a member of the Board since March 2016.
- **Election of Christelle Ratignier-Carbonneil as Vice-Chair of the EMA Management Board:**
    - At its June 2022 meeting, the Board elected Christelle Ratignier-Carbonneil as vice-Chair of the Board for a three-year period. Dr Ratignier-Carbonneil is Director General French National Agency for Medicines and Health Products Safety (ANSM) in France, a post she has held since December 2020. She has been a member of EMA's Management Board since December 2020.
- **New representatives of the European Parliament and Civil Societies on the Board**
    - In May 2022, a new representative of the European Parliament, Karin Kadenbach, was nominated to the Management Board. Ms Kadenbach is a former member of the Committee on the Environment, Public Health and Food Safety (ENVI) The mandate of Mr Anthony Borg, the second European Parliament representative to the Board, was renewed for another term.
    - The Board welcomed, in June 2022, three new civil society representatives. Despoina Iatridou, Senior Veterinary Policy Officer Federation of Veterinarians of Europe (FVE) and Denis Lacombe, Chief Executive Officer of European Organisation for Research and Treatment of Cancer (EORTC), have been appointed as representatives of veterinarians' and doctors' organisations respectively. Virginie Hivert, Therapeutic Development Director of EURORDIS (Rare Diseases Europe), will be one of the new representatives of patient organisations. Marco Greco was re-appointed as a civil society members to the Board and will represent patient organisations.

The most significant issues discussed at the Management Board in 2022 included:

- **Operation of Clinical Trials Information System, implementation of the Clinical Trials Regulation and the launch of ACT EU initiative:**
    - Following the launch of the Clinical Trials Information System (CTIS) and the Clinical Trials website on 31 January 2022, the Board was updated at every MB meeting on the progress of the operation of CTIS and on the extensive EMA support provided to improve user experience.
    - At the December MB meeting, the Agency informed the Board that the system delivered the functionality required for new clinical trial applications and that it would be continuously enhanced in preparation for compulsory use as of 31 January 2023. The Agency committed to update the Board on a weekly basis on the progress towards stabilisation and full functionality of the system. The Board also agreed to review the current rules on disclosure of certain clinical trial documents and a review of CTIS transparency measures for 2023.
    - On 13 January 2022, the European Commission (EC), the Heads of Medicines Agencies (HMA) and EMA launched an initiative to transform how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). The Board was regularly informed about current state of play of the ACT EU initiative and the activities of the ACT EU Steering Group following the endorsement of its mandate by the Management Board via written procedure.
- **Update on the implementation of Veterinary Medicinal Products Regulation and European Veterinary Big Data strategy to 2027:**
    - At each meeting, the Board was given status reports on the implementation of Veterinary Medicinal Products Regulation (EU) 2019/6 since its coming into application on 28 January 2022. The implementation programme delivered the Union Product Database (UPD), an upgraded system for pharmacovigilance reporting and management of safety signals, as well as changes to a total of nine IT systems over the course of the last four years.
    - The Board also welcomed the adoption of the European Veterinary Big Data strategy to 2027, developed jointly by HMA and EMA. It outlines a vision for fostering data-driven, digital innovations in veterinary medicines in the EU, building on the Veterinary Regulation.
- **Implementation of Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123)**:
    - At the March 2022 MB meeting, the Board was informed of the plans and steps for implementing the new EU regulation reinforcing EMA’s role in crisis preparedness and management for medicinal products and medical devices (Regulation (EU) 2022/123), which became applicable on 1 March 2022.
    - The Board adopted the composition of the new Emergency Task Force (ETF), which took over the activities of the previous COVID-19 EMA pandemic Task Force (COVID-ETF). The new ETF became fully operational in mid-April, after the Management Board and European Commission gave a positive opinion on its Rules of Procedure.
    - The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) was also established by EMA in accordance with the Regulation (EU) 2022/123. The

MSSG became fully operational in May 2022 following the adoption of its rules of procedure by Management Board.

- The Board was also informed on initial plans to implement the new tasks for shortages of medical devices, which will become applicable in February 2023, and received updates at a few Board meetings on the experiences and activities carried out by the Expert Panels on medical devices, which were successfully transferred from the European Commission to EMA on 1 March 2022.

- **Response to COVID-19 and mpox (Monkeypox) public health emergencies:**
  - At each meeting, the Board was given status reports on recent scientific evaluations related to COVID-19 vaccines and therapeutics.
  - The Board was also informed of the ongoing work on COVID-19 lessons learned review, including updates from the HMA/EMA Tactical group on resourcing to tackle the current resourcing issues within the Network.
  - The Board was also informed on the Agency's activities related to the response to mpox (monkeypox) outbreak, which was the first new Public Health Emergency of International Concern (PHEIC) declared by the WHO since EMA's extended mandate came into operation. The Management Board also approved the updated ETF composition to reflect the mpox (Monkeypox) public health emergency in addition to the covid-19 pandemic.
- **Activities of the joint EMA-HMA Task Force on Availability of Medicines**
  - At the June MB meeting, the new composition of the Task Force on Availability of Medicines (TFAAM) was adopted by the Board. A revised work programme and an extension of the mandate of the task force for three more years were also adopted by the Board.
- **Regulatory and coordinating actions arising from the war in Ukraine:**
  - The Board was informed about the Agency's regulatory and coordinating activities to prepare for potential medicine-related consequences arising from the Russian invasion in Ukraine. This included the monitoring of possible shortages of medicines in the European Union (EU) driven by changes in demand and in supply, as well as a proactive assessment of the availability of suitable alternatives in the EU for essential medicines used in the Ukraine to make sure that refugees can continue their treatment uninterrupted, if needed.
- **EMA's independence policies for competing interests of Scientific Committee members, Experts and Management Board members**
  - In March, the Board endorsed the EMA 2021 annual report on independence.
  - Following agreement on the proposed principles for revising EMA's EMA's independence policies (Policies 0044 and 0058) in October 2022, the Board adopted the proposed revised policies for competing interests of Scientific Committee members, Experts and Management Board members, via written procedure in December 2022. These revisions follow the entry into application of the recent changes to EMA's mandate and the new Medical Device and in vitro Medical Device Regulations, which increase EMA's role in the MD/IVD area.
- **Review of activities of the Working Parties of EMA:**

- The Board was provided with progress updates status on the implementation plan of the new operational model of the working parties of EMA at the June and October MB meetings. The first phase of the project concluded in September 2022 and focused on the reorganisation of the working parties for the non-clinical, methodology and clinical domains. In addition, the pilot phase of the European Specialised Expert Community (ESEC) started in the second quarter of 2022. In preparation for the second phase of the implementation plan, the methodology and timelines of the quality domain were agreed to be postponed by the Board until 2023, considering the fundamental dependencies with the core business.

- **Periodic reports from Chairs of Scientific Committees and Working Parties to the MB**

  - To inform MB members about the work of the scientific committees and working parties, Chairs of these groups were invited to an exchange with the Board on aspects of their activities. In October, the ETF co-chairs, Bruno Sepodes and Marco Cavaleri, were invited in in view of the key role that the ETF currently plays in both the COVID-19 and mpox (monkeypox) emergencies. Also the CAT chair, Martina Schuessler-Lenz, was invited to update the Board on the work of the committee.

- **Activities of the joint EMA-HMA Steering Group on Big Data:**

  The Board was regularly informed about the implementation of the Big Data Steering Group (BDSG) workplan. The Board was also informed of the finalisation of the European Medicines Regulatory Network's Clusters of Excellence discussion paper that aims to embed data analytics in the daily work or medicines regulators.

- **Information Management update:**

  Regular updates on the 'Agile' transformation of EMA and new portfolio report on the status and progress of the Network portfolio have been provided to the Board at each Board meeting in 2022. The Board also noted the Technology Capability Investment Plan (TCIP) for 2022-2025.

Significant additional items adopted or decided by the Management Board in 2022 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 2022, these activities involved:

  - adopting the Board's assessment of the Executive Director's Annual Activity Report for 2021;
  - adopting the 2023-2025 Programming document, including the 2023 budget;
  - adopting the EMA's annual report for 2021; and
  - delivering an opinion on the Agency's final accounts for 2021.

- **Revised Fee Implementing Rules and Cooperation Agreement:**

  - The Board adopted a revision of the Fee Implementing Rules coming into force on 1 April 2022 and covering changes in fees to reflect the inflation rate adjustment, scientific advice fee incentives deriving from EMA new mandate and include the. fees for vaccine antigen master files and vaccine platform technology master files for veterinary medicines

- In October, the Board adopted a revision of the Cooperation Agreement which consists of the addition of a paragraph in Section I of Annex I clarify that the Cooperation Agreement covers the scientific advice services provided by NCAs to the Agency through ETF members appointed as scientific advice co-ordinators outside of a declared public health emergency.

- **Internal audit and advisory activities at the European Medicines Agency:**
  - In June, the Management Board adopted the Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency and the annual report for 2021 on the internal audit and advisory activities at EMA.
  - In December, the Management Board adopted the audit strategy 2023-2025 and the audit plan 2023.
- **12th annual report: MUMS/limited market scheme for veterinary medicines** The board endorsed the twelfth and final annual report on the operation of the Minor Use Minor Species (MUMS)/limited market scheme for veterinary medicines in March.

2.2. Major developments 2022

COVID-19 Pandemic

2022 was still characterised by a significant level of COVID-19 related activities, with a shift from pre- and initial marketing authorisation activities to post-authorisation activities. Overall COVID-19 related workload consumed almost 40 FTEs throughout the year. Despite this continuous effort EMA managed to deliver all its legal obligations, while maintaining the highest standards for quality, safety and efficacy of medicines.

Implementation of EU Regulations

During 2022 three major regulations entered into force, namely the EMA extended mandate, the Clinical Trials Regulation and the Veterinary Medicines Regulation. The Agency worked tirelessly to comply with the implementation deadlines and succeeded to meet them. The implementation of these legislations brings concrete benefits to medicines and clinical trials regulation as well as entrust specific powers to EMA, making it better prepared to tackle future crisis. On this specific aspect, the EMA extended mandate new provisions were put to test few months after entering into force, when WHO declared mpox (monkeypox) a public health emergency of international concern.

Safe agile Methodology implementation

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. The advantages of Agile and SAFe that are realized by EMA and its partners and stakeholders include improved business and IT alignment, quicker and incremental technology delivery, enhanced transparency, and simpler management of shifting priorities.

2.3. Budgetary and financial management

Budget overview

The total 2022 budget (revenues and expenditure), as adopted by the EMA Management Board on 15 December 2021, amounted to EUR 417,471,000, representing a 10.08% increase compared to the 2021 budget (EUR 379,228,000).

One amending budget of EUR 4,344,000 was adopted by the Management Board in August 2022 to increase revenue due to higher than originally planned inflation. This increase was compensated by a reduction of the EU contribution, higher payment to National Competent Authorities (NCAs) linked to the higher fee revenue and salary adjustment for the period January – June 2022.

The draft financial outturn, a surplus of approx. EUR 10.46 million, representing 2.40% (6.13% in 2021) of total revenue, which is a positive result considering that 87% of the revenue derives from fee paying services. Part of the surplus is due to the postponement of some expenditures to 2023. (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 C1 cash revenue entered in the accounts as of 31 December 2022 amounted to EUR 414,862,609.76 (2021: EUR 382,156,343.70).

Of total C1 income, 87.95% (2021: 89.40%) derived from the evaluation of medicines and other business-related activities,11.98% (2021: 9.85%) from the European Union budget to fund various public health and harmonisation activities, and 0.07% (2021: 0.75%) from various sources.

Assigned revenue (external, R0, and internal, CL), which is handled outside the adopted budget, totalled EUR 21.08 million (2021: EUR 25.45 million).

Expenditure (commitments and payments)

Of the adopted budget, i.e. fund source C1, commitments totalled EUR 408,324,836.93 which represents 96.80% of the final appropriations (2021: EUR 365,490,700.73, or 96.38%). Payments totalled EUR 301,496,618.72, or 73.84% of the total commitments (2021: 274,400,002.19, or 75.08%).

Appropriations carried forward from 2022 to 2023

Automatic carry-forward

Automatic carry-forward to financial year 2023, C1 to C8, totalled EUR 106,828,218.21, or 26.16% of the total commitments (2021: 91,090,698.54, or 24.92%).

Implementation of appropriations carried forward from 2021 to 2022

Automatic carry-forward from financial year 2021 to 2022, i.e., fund source C8, totalled EUR 91,090,698.54 (2021: EUR 75,300,936.06). Payments against these appropriations equalled EUR 86,635,520.77, or 95.11% of appropriations (2021: 69,928,804.85 or 92.87%) and EUR 4,455,177.77 were cancelled (2021: EUR 5,372,131.21).

Appropriations from external and internal assigned revenue

The Agency’s available appropriations in 2022 included external and internal assigned revenue. In accordance with the revised Financial Regulation which came into effect on 1 July 2019, 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 and grants received from the EU budget to fund projects within the IMI, IPA programmes as well as the pilot for the electronic Product Information. In 2022, EUR 1,242,453.70 were received, and expenditure amounting to EUR 1,116,338.34 incurred.

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 2022, EUR 24.9 million were received (including amount carry forward from previous years), and expenditure amounting to EUR 20.9 million incurred.

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, increased expenditure due to exchange rate fluctuation, etc.

During 2022 no transfer exceeded the 10% ceiling for transfer between titles, thus requiring Management Board approval. Of the ten transfers, all involved expenditure appropriations.

The transferred expenditure appropriations were primarily needed to cover additional commitments for scientific studies related to the COVID-19 pandemic, as well as extended support to NCAs in performing some processing of COVID vaccine-related to Individual Case Safety Reports (ICSR) in the wider context of the vaccination campaigns and to support the monitoring of vaccine safety, interims services and contribution to European Schools.

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 13,490,163.07 remained unused, corresponding to 3.20% of final appropriations (2021: EUR 13,737,299.27, 3.62%).

The underuse of commitment appropriations is considered to be within the acceptable range, with 1.60% (2021: 3.19%) of appropriations cancelled in title I (staff expenditure), 5.45% (2021: 11.91%) in title II (infrastructure and operating expenditure) and 3.64% (2021: 1.61%) in title III (operational expenditure).

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%[49]. 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 2022, 711 payments (2021: 886) out of a total of 35,157, i.e., 2.02% of all payments, were made later than 30/60/90 days after receipt of a valid invoice (2021:26,076 or 3.4%). This resulted in default interest of EUR 2,242.88 being paid to suppliers and contractors (2021: EUR 5,095.00).

Procurement

Over the last few years, the Agency has experienced significant changes in its internal and external working environment, which has required additional procurement of goods, services and works.

In 2022, the procurement team was involved in further supporting strategic developments like DARWIN (data analytics) and EXPAMED (remunerated experts for medical devices) as well as the procurement needs for a continued increase in IT projects and external resource needs. Furthermore, the procurement team was driving the centralisation of procurement activities for the agency including the introduction of a part of an e-procurement suite.

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

In 2022 EMA completed 23 procurement- and 16 reopening of competition procedures and benefitted from three procurement procedures led by the European Commission or other EU agencies.

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

Cost and benefits of controls

In 2022, EMA allocated approximately 17 FTEs for control activities (amounting to 2.1M euros or 0.50% of the Agency's 2022 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 absence of critical recommendations stemming from audits, 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

In order 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, no reservations were reported.

For the list of budget lines sub-delegated to another AOD, see table below:

Expenditure group Revenue group	
Staff	Chapters 13, 14 Articles 110, 113, 114, 115, 118, 119 Items 1113, 1114, 1115, 1602, 1603, 1604, 1701 GL items OTHER, 401101, 401181, 401300, 401701
Talent acquisition	Chapter 12 Items 1116, 1601
Meetings	Article 300, Item 2500
Facilities	Chapters 24, 26 Articles 200, 203, 204, 205, 209, 220, 221, 230 Items 1700, 2359; GL item 400006
Training	Chapter 15 GL item 401500
Business consultancy	Item 2800
Audits	Item 2801
Business continuity	Item 2358
Other revenue	Article 200, Titles 5, 6, 7, 9
Financial charges	Article 232
Memberships	Item 2501
Fees	Title 1, Article 201
Evaluation of Medicines	Article 301
Legal matters & Insurances	Articles 201, 233, GL item 400006
IT hard-/software & maintenance	Items 2110, 2114
IT consultancy	Items 2115, 3105
Scientific data management	Item 3031
Information & communication	Chapter 27
Translations	Article 302
External experts	Item 3032
Scientific studies & services	Item 3030

2.5. Human resources management

In 2022, the key developments regarding staff and human resources management included:

- **Human Resources Strategy**

In 2022, HR started the development of the HR Strategy intended to facilitate delivery of HR programme, products and initiatives to respond to ever changing external challenges and bring value to the core units management and staff in 5 areas:

- Desirable place to work
- Managed wellbeing
- Sustainable Organization
- Managed Talent
- Agile Human Resources

The HR Strategy is designed on the basis of the information gathered via the external benchmarking, considering organisational priorities and focus areas, and designed in a transparent and consultative process, engaging senior management, operational management and staff. It resulted in a first draft of a strategy itself, as well as prioritised roadmap of activities. The work will continue in 2023.

- **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 2022 included:

- Implementation and roll out of the revised competency framework and job architecture, applicable from January 2022, which lays the strong foundations for the revision and continuous improvement of talent management processes at EMA
- Embedding further the Performance and Development programme deliverables, aimed at implementing a holistic and continuous approach to performance management for all Agency staff (e.g. a new methodology for setting smart performance objectives, revised probation assessment, revised appraisal assessment, continuous performance management with flexible feedback), as well as to foster staff development and career path opportunities (e.g. mentoring, internal mobility, development objectives).
- Launch of new concepts enhancing the growth and development, such as career reflection programme, interviewing and feedback, setting development objectives based on role competencies.
- **Recruitment and selection**
- In 2022, in the area of recruitment and selection, the effort continued to fill COVID related positions granted by the EC, as well as those relating to the Extended Mandate.
- To supplement on a temporary basis the statutory workforce, notably in case of abnormal workload or to provide specific services, for general corporate or specialised scientific/highly technical support tasks, we completed an interagency (EMA, Europol, Eurojust) open tendering procedure and signed a total of six new framework contracts.

- Substantial effort was put to revise, simplify and streamline the selection process, taking into account embedding newly implemented Competency Framework. It resulted in introducing a new Hiring Manager Guidelines and revising Careers at EMA guidelines for candidates.

- **Impact of COVID-19 pandemic on HR management activities throughout 2022**

  A TW framework applied from 1 February 2022, which was designed to respond to EMA management decisions on mandatory presence in the office.

  The pilot return to the EMA building was however temporarily paused until end of March, in accordance with the Dutch government COVID-19 safety measures. Mandatory presence in the office was accordingly suspended (unless presence was necessary in the interest of the service). Voluntary presence in the office remained possible for those colleagues who wished to come to the office, subject to not exceeding the building and floor capacity currently limited at 50% and respecting existing safety measures in the building.

  As of 28 March, mandatory presence was required on a monthly basis, and colleagues expected to come to the office at least 40% of their working time (i.e. 8 days in a regular month/or 2 days a week on average, pro-rated for colleagues working part-time or on leave).

- **Several HR implementing rules were adopted in 2022.**

The list of these can be found in Annex 4.

- **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 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.

- **Staffing**

During 2022, the Agency recruited 83 statutory members of staff (45 TA and 38 CA).

11 national experts were seconded to the Agency, 40 trainees and 107 new interim assignments provided services to the Agency.

The total number of joiners therefore amounted to 241.

During the same year, 46 statutory staff members (26 TA, 20 CA) and 6 SNEs left the Agency.

79 interim assignments were terminated, and 38 trainees ended their contract in 2022.The total number of leavers was 169.

Turnover for TA and CA was at the rate of 5.3%.

The occupancy rate amongst temporary agent staff was 99.4%.

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 authoristation applications, while also dealing with specific COVID-related activities. During 2022 EMA continued the implementation of its strategy to achieve efficiency gains, focus on two specific dimensions: a) process improvement; b) digitalisation.

As part of the process improvement dimensions, during 2022 the Agency worked on:

Agile governance

In 2022 the Agile transformation of the agency continued, with the aim of providing increased transparency, a reduced administrative burden and clearer accountability, through a new governance model and way of working. In 2022 the Network Portfolio was transitioned to the Agile methodology and governance structure, namely existing within the Value Stream structure and following the Agile cadence of ceremonies. In addition, the protocol for the inclusion of external representatives was successfully launched (the roles of Subject Matter Experts and Network Product Owners) and the governance bodies with external representatives - the Network Portfolio Advisory Board and the Network ICT Advisory Committee – launched in autumn 2021, were solidified.

Integration of Inspections in IRIS platform

During 2022 the Agency finalised the integration of GCP and GVP inspection in IRIS. EMA coordinates inspections for human and veterinary medicines under the centralised procedure, or in the context of a referral, on request from EMA's Committee for Medicinal Products for Human Use (CHMP) or the Committee for Medicinal Products for Veterinary Use (CVMP). The system will improve efficiency, transparency, and collaborative work as part of EMA's digital transformation programme. The key benefits of IRIS for Inspections are:

- Efficiency gains for EMA, MAHs/applicants and the EU/EEA regulatory network;
- Harmonisation across different inspection types;
- More accurate financial transactions, reducing the risk of late payments to NCAs;
- Automation of notification to stakeholders;
- Fewer data quality checks;
- Use of master data such as Organisations, Referentials, Substances and Products (SPOR);
- Increased security, reducing the risk of unintentional disclosure of confidential information;
- Streamlined and secured processes for information exchange (no use of Eudralink and no file import/export in DREAM will be necessary);
- Inspection reports and related key data will be securely available in real time to the network;
- Better knowledge management;
- Easier reporting on inspection data in EMA annual/mid-year reports;
- Better overview of scientific/regulatory data and quicker searches.

As part of the digitalisation dimension, in 2022 the Agency focused on:

Digitalisation activities

In the second half of 2022 the Agency Digital Innovation Lab (DigiLab) explored opportunities to realise automations of administrative work across the Agency. As a result, DigiLab collected 34 ideas for automation and following prioritisation and endorsement by the Digital Acceleration Leadership Team (DALT), DigiLab and the Analytics centre of Excellence (ACE) started 14 projects to deliver efficiency gains through automations across the Agency. In addition to the projects mentioned above,

DigiLab, in collaboration with other entities, worked on the automation of a number of the Agency's process, across the Agency. In 2022 ACE worked on different initiatives in parallel such as: Document Identification Validation System (DIVS), New Certificates tool (CPS), including new type of submission in the existing Assisted Validation System (AVS) to automate the registration of the submissions, Discoverer, Speech to Text, the implementation of Chatbots at EMA deploying the first chatbot at EMA for Talent Acquisition, a document comparison tool for Parallel Distribution service, Improvements in the ASK-EMA automatic triage system, the implementation of a Product Name validation for the new vet regulation, PEDAR to identify personal data, etc.

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

Internal Audit Service (IAS)

In accordance with their Strategic Internal Audit Plan set in 2019, the Human resources and ethics audit, took place in 2022. Only one important recommendation was issued.

Internal audit capability (IAC)

The following internal audits engagements took place in 2022: "Disaster Recovery Planning and (IT) Business Continuity Plan, Digitalization: implementation, benefits and readiness (staff and network's), Organisation and impact of transitional operational measures taken in the BCP period and Safety communications (GVP Module XV). In addition, an External Quality Assessor confirmed the Agency's internal audit function continues to generally conform to the international Standards issued by the Institute of Internal Auditors (IIA). The Head of Audit ad interim was appointed as from 1 October 2022 following the departure of the previous Head of Audit who had joined in February 2021.

Based on the results of the internal audits carried out at EMA in 2022, 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 during the business continuity period encompassing a range of deprioritised activities due to both EMA's move to Amsterdam and the Covid crisis provide reasonable assurance regarding the achievement of the business objectives.

This opinion is issued with due consideration to existing business continuity arrangements and takes account of the exceptions described in findings (including major recommendations) outlined in the audit reports issued in 2022, for which management has prepared improvement action plans and monitors the implementation continuously.

European Court of Auditors

The European Court of Auditors (ECA) adopted its Annual report on EU agencies for the financial year 2021[50] on 20 September 2022.

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, and two observations on management and control systems.

The report includes also a follow up of eight previous years' observations, of which four have been completed, three are ongoing and two are not under the Agency's control.

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.

In addition, in 2022, the European Court of Auditors published a Special report on the EU the COVID-19 vaccine procurement *19/2022: EU COVID-19 vaccine procurement*, together with the Replies of the European Commission to the European Court of Auditors report.

[50] Annual report on EU agencies for the financial year 2021 (europa.eu)

Observation on the management and control systems[51]	
Observation number	**Description**
10	We found a number of procedural deficiencies in two audited recruitment procedures, which undermine the principles of transparency and equal treatment (a) The vacancy notices did not clearly link the selection criteria with the phases of the procedure (such as pre-selection, written and oral tests). They also did not establish the number of points candidates needed to achieve in order to be placed on a reserve list, or the number of candidates that would be placed on a reserve list. (b) Some members of the selection committee had declared conflicts of interest in connection with some candidates. Yet, the final evaluation report did not describe how these conflicts of interest had been addressed. (c) In one of the two procedures, the selection committee had opted not to evaluate all the published selection criteria and instead evaluated the candidates on one additional criterion that had not been included in the vacancy notices. For some criteria, there was no clear guidance on how to award points.
11	In a procurement procedure for a framework contract with a maximum period of four years, the EMA set the financial and economic capacity requirement at €11 million of annual turnover: the maximum level allowed by Point 19 of Annex I of the Financial Regulation considering that the estimated value of the contract was €22 million. However, the actual value of the contract was only half as much as the initial estimate. The EMA's overestimation of the contract value meant that the threshold it used was almost twice as high as the Financial Regulation would have allowed if the EMA's estimate had been closer to reality. A lower threshold could have allowed more companies to submit tenders.

Follow-up of previous years' observations[52]		
Year	**Court's observations**	**Status of corrective action** (Completed / Ongoing / Outstanding / N/A)
2016-2017-2018	The Agency has been tasked by Parliament and Council with the implementation of the Regulations on Pharmacovigilance (1027/2012) and Clinical Trials (536/2014), requiring the development and implementation of two major pan-European IT systems. In the absence of the necessary own internal resources, the Agency 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 Agency should speed up the implementation of the mitigating action not only for the completion of the ongoing IT projects but also to get ready for significant new projects.	Completed for Pharmacovigilance Ongoing for Clinical Trials
2016	The founding Regulation requires an external evaluation of the Agency and its operations by the Commission only every ten years.	N/A
2019	When running a public procurement procedure, contracting authorities must divide contracts into lots, if appropriate, paying attention to the need to facilitate broad competition. Technical specifications must allow bidders equal access to procurement procedures, and may not have the effect of creating unjustified obstacles to open competition.	Completed
2019	EMA launched a procurement procedure combining two completely unrelated services in the same lot. This may have limited the number of potentially interested tenderers from submitting an offer for either set of services, thus impairing fair competition. In addition, the Agency extended the duration of contract from four to six years. Extending contracts in this way is only allowed by the Financial Regulations in exceptional and substantiated cases. In this case, there was insufficient ground for such an extension.	N/A
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	Ongoing

[51] Ibid, page 178
[52] Ibid, page 179-181

Follow-up of previous years' observations[52]		
	position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts.	
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.	Ongoing
2020	The selection panels in recruitment procedures are only appointed by an e-mail sent by the Head of the Executive Director) without a formal authorisation by the Executive Director.	Completed
2020	In a catering and restaurant services framework contract, the 2020 prices were amended even though the contract did not permit this. Furthermore, for an audited payment of €125 954 made in March 2020, the EMA was not able to reconcile whether the amount invoiced by the contractor was correct.	Completed

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

Internal Audit Service

1 recommendation was open as of 31 December 2022 related to the recent HR and Ethics audit.

Internal audit capability

The current status of implementation of audit recommendations stemming from IAC audits includes 6 open critical recommendations and 25 very important recommendations for which the implementation of improvement actions remains ongoing.

Out of these open action plans, only 6 recommendations are overdue at year-end, similar to the previous year. These pertain to improvements in the areas of:

- 2 recommendations overdue on "IT Outsourcing" (2020 audit): Establish a sourcing strategy vendors identification, provider's performance and compliance to the contract and centralized IT tool, harmonising risk management at all levels
- 2 recommendations overdue on "Physical security management" (2021 audit): formalise a periodic physical security training programmes for all security users (staff, delegates etc) and for management and to review its risk assessment of weapons being introduced into the building and seek management to confirm the extent of acceptable preventative controls as security threat levels change.
- 1 recommendation overdue on "Organisation and impact of transitional operational measures taken in the BCP period" (2022 audit): to Establish an Agency-wide monitoring and routine follow up of action plans to take account of the level of overtime and sick leaves
- 1 recommendation overdue on ""Disaster Recovery Planning and (IT) Business Continuity Plan" (2022 audit) to build a business continuity management system supporting alignment between business continuity objectives and IT recovery objectives

In 2022, 25 major recommendations were issued (6 critical and 19 very important) as a result of four assurance engagement completed on ""Disaster Recovery Planning and (IT) Business Continuity Plan", "Digitalization: implementation, benefits and readiness (staff and network's)", "Organisation and impact of transitional operational measures taken in the BCP period" and "Safety communications (GVP

Module XV)". As outlined in the table below, 14 of these major recommendations awaited action plans as of end of 2022.

1. The **Disaster Recovery Planning and (IT) Business Continuity Plan** audit included **3 Critical** and **4 very important recommendations**. These included to build a business continuity management system supporting a proper alignment between business continuity objectives and IT recovery objectives, incident escalation process and related communication channel leading to Business continuity plan invocation, recovery point objectives and aligning these with BCMP and assessment, supplementing the cloud strategy with the implementation plan reflecting the strategic options related to IT disaster recovery, backup policy and retention, backup policy and retention. Strengthening the IT disaster recovery plan with objectives, Ensuring that restoration procedures and IT disaster recovery are tested annually.
2. For the engagement on **Digitalization: implementation, benefits and readiness (staff and network's)**, the IAC issued **1 critical and 6 very important recommendations**. These pertained to establishing clear objectives and prioritisation criteria for projects and initiatives aligned with EMA and the Network's objectives. Systematically ensuring their decision-making is based on set acceptance criteria, ensuring lean business case support the Portfolio Board decision making, ensuring full compliance with Article 29 of the Financial Regulations, the with systematic action plans to follow-up on the conclusions of the evaluation reports within the consolidated annual activity report and regularly reported to the Management Board. Agency to review controls in place when downloading packages online, Agency to strengthen its quality control, assurance and acceptance testing (QAT) of IT system development
3. **Organisation and impact of transitional operational measures taken in the BCP period** issued **4 very important recommendations** including greater integration of activities and deliverables into the planning system, aligning the inventory of IT applications with them to better support BCP/ IT prioritisation. Agency-wide monitoring and routine follow up of action plans to take account of the level of overtime and sick leaves and to establish continuous expert capacity reporting to help identify available capacity in the network.
4. **Safety communications (GVP Module XV)** resulted in **2 critical and 5 very important recommendations** including to implement the European medicines web-portal. to establish and maintain a shared mapping of all means/tools of safety communication, streamline the overall guidance on safety communications for the EU Network and its stakeholders, and to map mechanisms ensuring the dissemination and access of EMA's safety communication-related documents marked as 'Confidential' is carried out by EMA, EMA decision-makers to plan for the delivery of the new ENS platform initiative, streamline the overall guidance on safety communications for the EU Network and its stakeholders.

Major recommendations with "open" status by year-end					
Rating	**On Time**	**Overdue**	**Subtotal**	**No IAP yet[1]**	**Total**
Critical	3	0	**3**	3	**6**
Very Important	8	6	**14**	11	**25**
Total	**11**	**6**	**17**	**14**	**31**

Implementation of IAC recommendations

In 2022, the IAC closed 17 very important recommendations. This is higher than 2021 and is a continued success of the dynamic process of quarterly reviews with Heads of Divisions introduced in 2021.

The implementation of the below actions led to improvements across the governance, risk management and internal control system of the operations, stakeholder and communications, administration, and information management and security domains.

Operations

- The PRIME strategy was completed which details the measures required by EMA Management, in collaboration with EU Network and other stakeholders to implement to meet the PRIME strategic goals and recommendations laid down in the EMA Regulatory Science to 2025.
- A feasibility study to identify areas for automation (including the use of electronic forms) to reduce manual handling and free up resources improve consistency and reliability was conducted for PASS.
- A cost/benefit analysis was conducted to develop an audit trail in the Fee PASS Database.
- The merger and rationalisation of tracking tools (including dedicated email addresses) containing similar PAS-related information was sponsored by EMA management.

Stakeholders and communication.

- With each response to Requests for information (RFI) satisfaction surveys are sent automatically ensuring regular reporting of qualitative and quantitative stakeholder information centrally to respective division management.

Administration

- Annual reporting to Executive board of the outcome of security strategy and objectives.
- The Agency's security risk assessment was completed to support agile decision making on key security risks for the EMA building, and security risk was assessed for the archive site.
- Desk research of Dutch security market was conducted to understand the specificities of the Dutch security market.
- Business hypothesis for a centralized Declaration of Interest database linked with the access control system was developed to support automation of access control tied to a person's access permissions.

- A policy describing the operational framework for Supplier Relationship Management (SRM) was drafted to include all aspects of vendor performance evaluation focusing on collaboration and development more than compliance to timelines only.
- In the context of the implementation of the DIMSIS II program and its relevant tenders, a policy on the use of external contractors was established and endorsed by the DIMSIS II Steering Committee.
- A centralized tool was proposed, assessed, and established to give all stakeholders a holistic and aligned vision from framework contracts to contract delivery. Training was delivered to cover procurement aspects and explain roles and responsibilities in the contract management process.

Information management and security –

- Information security was further enhanced with periodic pen testing, purple and red teaming assessments and System configuration reviews taking place.
- Risk management procedure were updated detailing the procedure for regular, enterprise-wide assessments.

[1] Recommendations of audit engagement held in 2021 for which the IAP (Improvement Action Plan) was not yet designed in 2021.

Follow-up of recommendations issued following investigations by OLAF

No investigations were opened by OLAF in 2021 and no recommendations were issued as of 31 December 2022.

2.9. Follow-up of observations from the discharge authority

As a follow-up to the discharge decision for 2020, EMA reported in September 2022 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 2022, the Agency continued its work towards EMAS registration in accordance with the approved Environmental Policy and Environmental Management Roadmap 2020 to 2024.

The carbon emissions from the Agency activities were monitored and calculated in accordance with the Greenhouse Gas Protocol Scope 1, 2 and part Scope 3 with energy efficiencies achieved by the removal of desk-top phones and changing to cloud services. By monitoring paper consumption, it was confirmed that a lot less material was printed and that digital workflows were being maintained.

During 2022 the Agency gradually returned to perform its activities from the EMA building whilst maintaining flexible working arrangements with up to 60% teleworking on monthly basis.

In preparation for new Mission Rules for staff expected in 2023 the EMA put in place temporary rules for business travel whereby virtual participation in conferences, meetings and trainings were to be considered first, unless remote participation was not possible due to legal representation or if it would not be as effective due to the added strategic value from physical presence.

For the scientific committee meetings and working parties a decision was put in place to perform every other meeting in a virtual setting after physical meetings resumed, to manage the total amount of people at the EMA premises and as contribution to maintaining control of the Agency's carbon footprint.

With the measures to limit business travel by staff and delegates and encourage sustainable means of transport the total Tonnes CO2 emissions has been maintained at a lower level than pre-pandemic years, whilst resuming activities with physical participation.

More details of the EMA Environment Management activities and on the 2022 outcome towards objectives, targets and KPI's can be found in Annex 7.

As part of the Agency registration to EMAS an environmental statement for 2022 will be prepared with reporting of the environmental performance in compliance with the (EC) EMAS regulation 1221:2009, Annex IV, as amended.

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 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. This report links to the pharmaceutical strategy for Europe and will inform its implementation, with regard to possible legislative and non-legislative measures. It also complements the ongoing revisions of: (i) the EU regulations on medicines for rare diseases and on medicines for children; and (ii) the Regulation on the European Medicines Agency's fee system.

The following studies evaluate legislative frameworks and other activities implemented by EMA:

- **European Commission's evaluation of experience with the operation of the Orphan and Paediatric Regulations**. As part of the implementation of the European Commission's Pharmaceutical Strategy for Europe which was published on 24 November 2020, in 2021 the European Commission launched the preparation of a targeted revision of the orphan and paediatric regulations. This revision addresses shortcomings identified in a recent evaluation whose results were published by the European Commission on 11 August 2020.
- **Evaluation of experience with shortages of medicines**. in December 2021 the European Commission published a study on medicines shortage The study reviews activities carried out

by EMA and National Competent Authorities in this area between 2004 and 2020 and proposes measures to be considered in the 2022 during the preparation for the revision of the EU basic pharmaceutical legislation.

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.

- **Revision of rules on fees payable to the European Medicines Agency** .Based on the outcome of the evaluation of the EMA fee system finalised in 2019, the European Commission prepared an update of the legal framework on EMA fees, and the legal proposal for the revised EMA's fees regulation was published on 14 December 2022.

3. Assessment of the effectiveness of internal control systems

3.1. Effectiveness of internal control systems

3.1.1. 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.

3.1.2. Ex-ante 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	2020	2021	2022
Number of transactions verified	53,354[53]	38,447	27,151[54]
Number of transactions rejected	437	511	513
• of which related to manual adjustments, technical rejections or interface issues following the decentralised verification	106 (24%)	119 (23%)	301 (59%)
• of which other issues (incorrect currency, calculation errors, wrong allocation, etc.) or procedural issue (missing document, change of requirement, wrong cost centre, etc.)	331 (76%)	392 (77%)	210 (41%)
Overall rejection rate	0.8%	1.3%	1.9%

Register of exceptions

EMA registered in 2022

- 6 financial exceptions
- 14 financial non-compliances

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.

3.1.3. Ex-post control system

Operational

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 the ex-post controls is to ascertain that the processes and procedures are correctly implemented, and that they comply with the applicable provisions. 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 (Head of Administration division, Head of Audit, Heads of Legal, Head of Finance departments, and Internal Control Coordinator) 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 2022:

- Handling of declarations of interests of experts;

- Handling of declarations of interests of staff;

- Handling of access controls in the Document Management system;

- Handling of HR personal files in Document Management system;

- Handling of hotel and travel booking services;

- Handling of Type II variations;

[53] Corrected data for 2020 in line with reviewed reporting structure.
[54] Due to automated processing, the number of verified transactions dropped by approximately 11,000.

-Compliance with the "Internal guidance on selection and acquisition of commercial off-the-shelf IT solution.

Financial, non-fee related

In addition, financial, non-fee related ex-post controls are carried out on activities that did not undergo an ex-ante verification, in line with the Executive Decision on financial circuits as well as Methodology for conducting ex-post controls for financial. They yielded major errors in the implementation of the mission budget, mitigating measures are being identified, as a result of concluding the ex-post analysis in February 2022.

Financial, Fee related

Following a calculation of comparative risk, EMA selected (i) Certificates – Human and Vet medicines and (ii) Scientific Advice – Human and Vet medicines for the ex-post controls. While regarding (i) no errors had been identified, major and minor errors were identified related to (ii). For these mitigating measures are proposed.

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 cycle.

3.1.4. 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 2022.

In total, 40 posts were identified as sensitive, compared to the number of sensitive functions in 2021 (41).

Due to organisational changes, 2 former sensitive functions no longer exist (TCS; TCS-HTV), 1 newly created function was deemed sensitive (AF-HTV) and one non-sensitive (Cybersecurity Architect and Operations Senior Lead), 39 functions retained their level of sensitivity.

Overall, 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.

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, several 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, financial or staff-related decisions.

The functions considered sensitive were recorded in the Sensitive functions register 2022. For each function, the register describes the main activities of that function, the potential risk areas, inherent risk rating, mitigating controls in place, and the residual risk rating together with its significance.

3.1.5. 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 2022, the committee reviewed 6 cases and expressed 3 favourable opinions, and 3 favourable opinion with recommendations.

3.1.6. Reconciliation of information in financial systems

Most of the Agency's operational systems are interfaced with the SAP system. During 2022, 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. No major findings were detected overall, only a glitch with the SME register caused some disruption in the discount applied in SAP retrospectively, immediately detected and removed.

3.1.7. 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) (in force since 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 2022, EMA continued to pursue the implementation of the EUDPR at full speed. The new Data Protection Officer (DPO), who was appointed from 15 January 2022, and the Assistant DPO, together with the Data Protection Coordinators (DPC) appointed per Divisions and Task Forces, coordinated 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).

During procurement and tender procedures and related data processing operations, huge efforts were devoted to the risk assessment of the potential data processors of the Agency, and the negotiations of the relevant contracts with the successful tenderers. This included a review of the Cloud security and data protection risk assessment questionnaires as applicable and the EDPS requirement to perform 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 GDPR equivalent level of data protection and the effectiveness of supplementary measures put in place by the processors to mitigate risks to data subjects. In the course of 2022, a total of seven TIAs were performed by EMA.

Based on the data protection by design principle, several Data Protection Impact Assessments (DPIAs), where completed or initiated. In this regard the following DPIAs were completed: DARWIN EU® Coordination Center, Lifecyle Regulatory Submissions Raw Data Pilot, Use of Microsoft Office 365 at EMA and the update of EudraVigilance DPIA (from version 2019). The DPIAs for the BI@Admin solution and TalentHub are close to finalisation. Furthermore, the drafting of the following DPIAs was initiated: IRIS and other procedure management platforms covering product-related scientific and regulatory

procedures at EMA, the Security Operations Center (SOC), the Agency's Data Analytics Platform, the Signal and Safety Analytics project, the use of health data based on the French Health Data Hub and the EMA Cloud strategy implementation, an important area requiring careful attention especially where this may involve the international transfer of personal data processed by EMA.

In addition, the management of security incidents including personal data breaches were supported throughout 2022 including the provision of advice and input to various data protection questions and topics (e.g., new legislative proposal, guidance review).

The topic of international data transfers possibly carried out by the Agency when performing its activities continued to be of importance in 2022. The negotiations with Health Canada to enter an administrative arrangement pursuant to Article 48(3)(b) of EUDPR continued including further interactions with the EDPS in the frame of the necessary prior authorisation to enter into this arrangement. Whilst the EDPS granted an authorisation with conditions in July 2021, EMA could not yet proceed to signature since the process is ongoing to address all further comments received from the EDPS in consultation with Health Canada. Such administrative arrangement with Health Canada would allow a faster and more efficient exchange of documents including personal data as needed in the interest of public health, in particular during a cross-border threat to public health and more broadly to jointly analyse the quality and safety of medicinal products and medical devices, whether new or already on the market globally. In addition, EMA performed an assessment of the management of personal data in documents subject to exchange by EMA with public authorities and international organisations in third countries focusing on the following areas: an analysis of the documents shared with international partners to understand the risks associated with the personal data contained within these, providing a redaction checklist and other tools to provide practical support for those preparing documents for sharing with international partners, an assessment of the redaction workload across the EMA business units involved in this activity and the assessment of a redaction tool currently under development by EMA.

In September 2022, EMA launched an EDPS consultation on international transfers of unredacted case narratives originating from EudraVigilance by certain MAHs, which led to the re-identification of data subjects by journalists. This referred to the submissions of ICSRs by these MAHs to the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (FDA CBER), which resulted in the publication of such unredacted case narratives on the U.S. Vaccine Adverse Event Reporting System (VAERS) website and the U.S. Centers for Disease Control and Prevention (CDC) WONDER website. EMA liaised with CBER FDA and CDC to remove the case narratives and country specific information from their public websites. The information was taken down in November 2022 and January 2023. In addition, upon EDPS advice, EMA also initiated a consultation of the German Data Protection Authority about non-compliance of certain MAHs with the provisions set out in chapter V of the GDPR. This was followed by a letter to all QPPVs to emphasise the need to adhere to the EV Access Policy and the rules of the GDPR and national data protection legislation where applicable.

To ensure data protection compliance and the protection of personal data, the Agency coordinated the consultations with all Member States, EU institutions and industry regarding a Joint Controllership Agreement (JCA) for EudraVigilance, the final adopted JCA was published in June 2022 (see link here). In addition, a JCA has been prepared for the Lifecyle Regulatory Submissions Raw Data Pilot (see link here) with a view to clarify the roles and responsibilities in the processing of personal data in the context of the analysis of 'raw data' from clinical studies as part of selected initial marketing authorisation applications (iMAAs) and post-authorisation applications submitted to EMA.

Emphasis was also put on the development and delivery of dedicated data protection training both to EMA and the EU Medicines Regulatory Network. In the first quarter of 2022, the DPO with the assistance of the respective DPC delivered specific training with tailor-made content and case studies

relevant for the specific activities of the departments of H-Division. The case studies were chosen also based on the suggestions of H unit's staff members. Each training course lasted at least 1.5 hours and involved all staff members working for the organisational department concerned. The rate of acceptance and appreciation for these training courses was very high. In addition, a dedicated workshop was organised by the DPO with scientific and data protection experts of the EU Medicines Regulatory Network on lessons learned on the conduct of the DARWIN EU® DPIA. Focus was also put on the development of a dedicated training programme for the EU Medicines Regulatory Network & EMA on "Data Protection in Medicines and Public Health" based on a modular approach. This included: Module 1 – Data Protection Definitions, Roles & Responsibilities, Module 2 – Data Protection Principles and Documentation, Module 3 – Legal Basis, Personal Data Breaches, Module 4 - Protection Impact Assessment and International Transfers of Personal Data and Module 5 - Rights of Data Subjects supplemented by three classroom sessions to discuss case scenarios and address questions. Furthermore, in consultation with the Head of I-Division, a dedicated data protection training course for IT Contractors and EMA I-Division staff has been developed. All trainings according to the aforementioned programmes will be delivered in Q1 2023.

3.1.8. 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 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 2022. 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, as a follow up to the trainings on ethics provided in 2021, including information on EMA's code of conduct and conflict of interest.

One administrative inquiry was opened in 2022 in relation to a claim under Article 73 of the Staff Regulations Inquiries of this kind are conducted following an instruction by the PMO and are of a purely factual nature, specifically to establish the working conditions of the claimant. The reports resulting from such inquiries are submitted to PMO as part of the procedure to assess claims under Article 73.

One case of suspected fraud/irregularity has been reported by EMA to OLAF in 2022.

3.1.9. 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 external whistleblowing reports in 2022 and followed-up on each of these cases in accordance with the Policy and SOP. Thirty cases have been closed, in 8 cases the assessment is ongoing. For 27 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 and in 11 cases EMA coordinated the investigation with the involvement of the relevant NCAs. For the reports in EMA remit, there were 5 cases of GCP non-compliance, 5 cases of GMP non-compliance and 1 case of conflict of interest.

3.1.10. 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.

3.1.10.1. Management Board

The principles to revise the policy on the handling of competing interests of the Management Board (policy 0058) were presented to the Board and endorsed in October 2022. The updated policy was adopted by Management Board via written procedure in December 2022, with an effective date from 1 January 2023. The revision resulted from EMA's new responsibilities in the area of medical devices and *in vitro* medical devices and from EMA's reinforced role in the monitoring and mitigation of shortages of medicinal products and medical devices. The main changes in policy 0058 were:

- Medical device company definition added which mirrors that for scientific committees' members and experts (no change to the definition of pharmaceutical company or to biotechnology sector);
- Medical devices (MD) included throughout the policy;
- In case of current direct or indirect MD related interests:
    - No exclusion from membership,
    - No restrictions in case of past MD related interests,
    - Restrictions will be applied for current MD related interest, i.e. no involvement as topic coordinator or in decision-making on MB agenda topics with possible impact on the MD industry and no appointment as chair or vice-chair.

In December 2022, the Management Board also adopted a revision of the Breach-of trust procedure for MB members, to align it with the revision of policy 0058.

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 2022.

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.

3.1.10.2. 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 current revision results from:

- the additional responsibilities for the Agency, following its involvement in certain medical device and *in vitro* medical device procedures, 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 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 main changes in policy 0044 were:

- A definition of a medical device company has been included, replacing the current definition of "medical device sector" (linked to ATMPs), and building on the current definition of a pharmaceutical company used in policy 0044.
- Medical device interests are reflected throughout the policy including which interests need to be declared and the principles that apply to the declared interests, as relevant.
- For CHMP, CAT, ETF and MSSG members who declare current direct or indirect medical device related interests, the necessary restrictions will be applied, i.e. they are not excluded from membership, but they will not be involved in procedures concerning medical devices linked to the declared medical device manufacturer or notified body. No restrictions will be applied in case of past medical device related interests.

Members of MDSSG are included in the revised policy and restrictions are applied in relation to medical device or pharmaceutical interests declared.

The Agency takes a proactive approach to identifying cases where the potential involvement of an expert as a member of a committee, working party, 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 and in the context of procedures regarding medical devices, needs to be restricted or excluded, due to interests in the pharmaceutical industry or the medical device industry (or the biotechnology sector for CAT members and alternates).

The Agency requires experts to provide an electronic declaration of interests (e-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 electronic curriculum vitae (e-CV) when submitting the e-DoI.

The Agency screens each e-DoI and assigns it an interest level, based on whether the expert has any interests, and whether these are direct or indirect.

The Agency then uses the information provided to determine if an expert's involvement should be restricted or excluded in specific activities of the Agency. It bases these decisions on:

- 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 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 committee members.

The Agency continued to maintain the implementation measures adopted further to the General Court Judgment on the Aplidin case: for SAGs and AHEGs, experts who are employed by universities or university hospitals performing development or manufacturing activities in respect of any medicinal products actually or potentially competing with the (candidate) product under review, are not allowed to be involved in the procedure. The Agency intervened in support of the two Member States which launched appellate proceedings in January 2021 and an outcome of the appeal is expected in 2023. Following the outcome of this appeal case Policy 0044 will be reviewed as needed, and by extension also policy 0058.

All members proposed for the Agency's scientific committees have their e-DoI screened before their formal appointment to the committee. In cases where the nominating authority appoints a member or alternate to a scientific committee 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 e-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 e-DoI and e-CV. The Agency removes from the list the experts whose e-DoI is older than a year, until they submit an updated e-DoI.

EMA has a breach of trust (BoT) procedure, which sets out how it deals with incorrect or incomplete e-DoIs by experts and committee members, as well with disclosure of confidential information. The BoT procedure was revised in December 2022 to align it to the recent changes to policy 0044.The revised BoT procedure states that it also applies to the other bodies that have been established within the Agency under the Extended Mandate (e.g., Emergency Task Force, both Shortages Steering Groups).

EMA launched two BoT procedures in 2022 and one of these will be concluded in 2023. For the BoT case concluded in 2022, a committee member did not declare a lecture honorarium received from an individual pharmaceutical company which was found to be incompatible with Committee membership and should not have been accepted. It was found that the failure to declare the financial interest was not intentional and did not occur due to gross negligence. The committee member was required to update their declaration of interest to declare the interest as consultancy and restrictions will be applied for three years regarding the products of the relevant pharmaceutical company. The committee member was required to study in detail the EMA policy on the handling of competing interests of scientific committees' members and experts, to attend training on handling of competing interests organised at the level of the committee and instructed to refrain, during membership of the committee, from accepting any financial interest from a pharmaceutical company, as well as engaging

in consultancy to a pharmaceutical company or in a strategic advisory role for a pharmaceutical company.

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 2022, delegates (2 scientific committee members: 2 CHMP, 6 working party members: 3 SAWP, 1 PCWP, 1 ONCWP, 1 drafting group) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the guidance document, 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.

In 2022, 813 e-DoIs of new experts were checked and an error was noted in 21 e-DoIs (2.6%). The nature of the errors in 2022 was that 13 of these experts failed to declare in their e-DoI their recent employment (in the past 3-year period) within a pharmaceutical company. EMA asked the experts to correct their e-DoI, resulting in a higher or same interest level being assigned to their e-DoI. This EMA ex ante/preventive check of each new expert is important and is maintained to ensure a low number error on the e-DoIs of experts.

The EC dedicated policy on the management of competing interests for EXPAMED panel members has been applied to the activities of the panels.

In 2022, the Agency undertook a project to replace the current Experts database that holds all experts' declarations of interest and CVs with a new Experts Management tool. This new tool will be launched in Q2 2023.

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

3.1.10.3. 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, 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.

The MB Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of EMA and candidates before recruitment has also been revised to reflect the legislation regarding the extended mandate for the Agency in the area of medical devices. The revised rules are effective as of 1 March 2023 and the main changes include:

- A definition of medical device company is included, aligned to the definition in policies 0044 and 0058.
- The requirement for all staff members to declare any medical device interests.
- No exclusion from employment in case of current medical device financial interests, however, staff will be restricted from involvement in procedures concerning medical devices linked to the declared company.
- No restrictions in the case of past medical devices interests.

The declaration of interests template has been revised accordingly.

In a cautious approach, following Art 11 of the Staff Regulations, in 2022, the Agency has required staff involved in the medical device related procedures (with a focus on staff members involved in the handling of the Expert Panels on Medical Devices (EXPAMED) were asked to declare interests in the medical device industry, including Notified Bodies.

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 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 on 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 line with the Commission rules on outside activities and assignments and occupation after leaving the service of 2018, applicable to the Agency by analogy. 34 requests were processed in 2022, and were authorised without restrictions.

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 2022 to 31 December 2022, staff and Seconded National Experts (SNEs) made a total of 22 applications under Article 16 of the Staff Regulations, resulting in 2 applications where no opinion was required, 14 authorisations without restrictions, 4 staff authorisations with restrictions (and 2 SNE cases with restrictions).

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 2022 is given in Annex 9.

3.1.10.4. 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 2022, 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, 15 June 2023

[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. Overall conclusions on 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, I would like to draw your attention 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 High Court of Justice of England and Wales ruling of February 2019, stating that Brexit is not a cause for frustrating the lease agreement, the Agency sought contractual possibilities to dispose of the premises and mitigate the financial burden on the EU budget, subletting its former office premises to a subtenant from July 2019, under conditions that are consistent with the terms of the head lease. The sublease term lasts until the expiry of EMA's lease in June 2039. It must be noted that since EMA remains a party to the head lease, it is financially responsible for running its former premises in the UK. As a result of this long-term liability, the Agency has to continuously divert some of its human resources away from its public health remit to the management of a commercial property in a third country, for which neither the Agency nor the EU have business use – an activity not foreseen in the Agency's founding regulation. Furthermore, the Agency is liable for the entire remaining amount payable under the contractual obligations of the head lease if the subtenant fails to meet its obligations. As of 31 December 2022, 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 €366 million. The EMA Management Board has stressed on numerous occasions the unsustainability of this situation in the long term and requested EU institutions to resolve this matter at the highest political level. The persistent volatility of global – and UK – economies, caused by the pandemic and now exacerbated by the war in Ukraine, makes the need of a resolution of this issue at political level even more evident, to allow the Agency to fully focus its resources on the implementation of its recently expanded mandate and the Union's fight against public health emergencies

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, 15 June 2023

[signature on file]

Emer Cooke
Executive Director

Annexes

Annex 1. Core business statistics

Business statistics can be found in Part I.

Annex 2. Statistics on financial management

Budget outturn	2019	2020	2021	2022
Revenue actually received (+)	€ 339,889,499.26	€ 376,246,022.54	€ 382,156,343.70	€ 414,862,609.76
Payments made (-)	-€ 292,769,994.74	-€ 290,132,295.87	-€ 274,400,002.19	-€ 301,496,618.72
Carryover of appropriations (-)	-€ 59,150,354.42	-€ 75,300,936.06	-€ 91,090,698.54	-€ 106,828,218.21
Cancellation of appropriations carried over (+)	€ 2,744,268.82	€ 2,423,908.71	€ 5,372,131.21	€ 4,455,177.77
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 0.00	€ 3.26
Exchange rate differences (+/-)	€ 1,003,466.80	-€ 585,264.08	€ 2,944,406.68	-€ 533,910.72
Adjustment for negative balance from previous year (-)	€ 0.00	-€ 8,283,114.28	€ 0.00	€ 0.00
TOTAL	**-€ 8,283,114.28**	**€ 4,368,320.96**	**€ 24,982,180.86**	**€ 10,459,043.14**

The financial outturn, a surplus of approx. EUR 10.46 million, representing 2.40% (6.13% in 2021) of total revenue collected, i.e. EUR 435.9 million, cf. the draft budget outturn for all fund sources (C1, C11, R0 and CL), was caused by unused and cancelled expenditure appropriations due to the postponement of some expenditures to 2023.

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

Title I, expenditure

- final expenditure was 1.60% (3.19% in 2021) lower than final appropriations, which is considered a good result;

Title II, infrastructure and operating expenditure

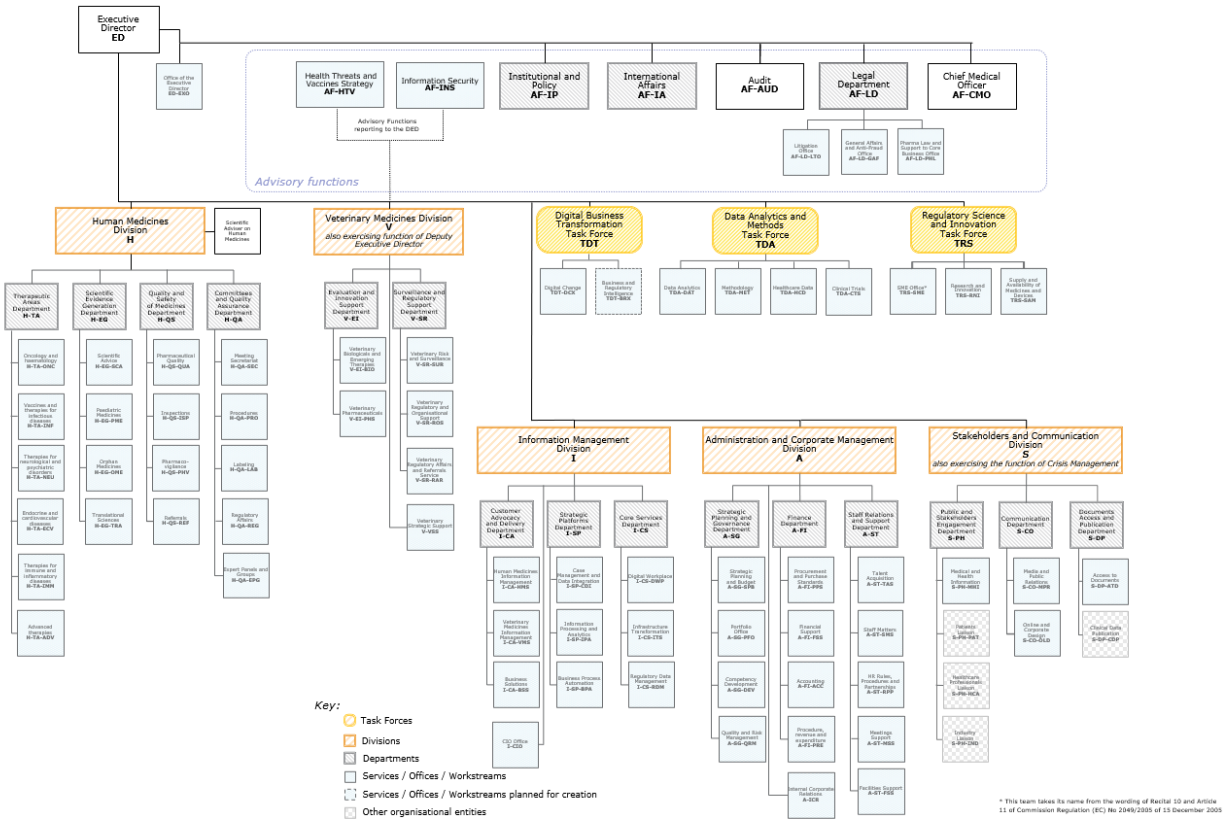
- final expenditure was 5.45% (11.91% in 2021) lower than final appropriations, with surpluses resulting from changes made to project plans, legal costs not incurred and lower financial charges linked to increase in interest rate;

Title III, operational expenditure

- final expenditure was 3.64% (1.61 in 2021) lower than final appropriations, with main surpluses stemming from lower commitments for rapporteurs and translations (driven by types of scientific applications submitted) and lower expenditure on data management due to contract prices being more advantageous than anticipated.

The ceilings/KPIs for the amounts carried forward (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: 4.34% (5.75% in 2021), title II: 26.38% (24.31% in 2021), title III: 40.06% (37.59% in 2021). Higher amounts related to IT, scientific studies and data management contributed to higher carry-forward on titles II and III.

Annex 3. Organisation chart as at 31 December 2022



Annex 4. Establishment plan and additional information on HR management

Function group and grade	2021				2022				2023	
	Authorised budget		Actually filled as of 31/12/2021		Authorised budget		Actually filled as of 31/12/2022		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		2		3		0		3
AD 14		9		9		10		9		12
AD 13		13		11		13		13		12
AD 12		45		42		50		50		57
AD 11		51		49		52		52		49
AD 10		51		47		50		50		53
AD 9		55		54		62		62		66
AD 8		71		71		77		77		87
AD 7		94		94		97		97		89
AD 6		65		65		60		60		67
AD 5		15		15		3		3		0
AD TOTAL	**0**	**472**		**459**	**0**	**477**		**473**	**0**	**495**
AST 11		2		2		2		2		2
AST 10		7		7		7		7		7
AST 9		9		9		10		10		10
AST 8		10		10		13		13		14
AST 7		19		19		19		19		25
AST 6		20		20		26		26		31
AST 5		38		38		43		43		43
AST 4		46		46		42		42		43
AST 3		32		32		23		23		12
AST 2		2		2		0		0		0
AST 1		0		0		0		0		0
AST TOTAL	**0**	**185**		**185**	**0**	**185**		**185**	**0**	**187**
AST/SC1										
AST/SC2										
AST/SC3										
AST/SC4										
AST/SC5										
AST/SC6										
AST/SC TOTAL	**0**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**
GRAND TOTAL	**0**	**657**	**0**	**644**	**0**	**662**	**0**	**658**	**0**	**682**

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 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	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
Function Group IV	110	89	90	122	94	107	122
Function Group III	81	72	94	81	89	91	81
Function Group II	10	18	0	0	1	1	0
Function Group I	0	0	0	0	0	0	0
Additional CA[1]	25	21	22	20	8	8	
TOTAL	**226**	**200**	**206**	**223**	**192**	**207**	**203**
1) Additional staff to cover Brexit-related additional work (FTE)							

Seconded National Experts	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022
Total	30	26	28	30	25	30

Interims: 107 new interim assignments provided services to the Agency and 79 interim assignments were terminated.

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	TA	AD12	Depending on function: operational or administrative
Head of Department	TA	AD09 (int.), AD10 (ext.)	Depending on function: operational or administrative
Head of Service/Office/Workstream	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
Graduate Specialist	TA	AD05	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

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
Officer (e.g. core and support functions)	CA	FGIV	Depending on function: operational or administrative
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 (Level 3)	TA	AD09	Operational
Head of Accounting and Agency's Accounting Officer	TA	AD09	Operational
Data Protection Officer	TA	AD06	Administration

Results of the screening/benchmarking exercise as of December 2022

Job Type (sub) category	2021 (%)	2022 (%)
Administrative support and Coordination	11%	14%
Administrative Support	10%	13%
Coordination	1%	2%
Operational	81%	79%
Top level Operational Coordination	0%	1%
Programme management and Implementation	27%	26%
Evaluation & Impact assessment	36%	34%
General operational	18%	18%
Neutral	8%	7%
Finance/ Control	8%	7%
Linguistics	0%	0%
Total	100.00%	100.00%

HR implementing rules adopted in 2022

	Adopted	Effective date
Comms decision C (2021) 8179 final of 16.11.2021 on payment education allowance Annex X to staff on temporary assignments while serving in third country	17/06/2022	17/06/2022
Model rules on Administrative Inquiries and Disciplinary Proceedings	17/06/2022	17/06/2022
Comms decision C(2022) 1715 of 24 March 2022 on home leave staff serving in third countries (Annex X)	6/10/2022	6/10/2022
Amendment to model decision on the prevention on psychological and sexual harassment	Initial adoption on 5/06/2017. Adoption of amended version: 6/10/2022	6/10/2022

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	**294**	**103**	**59,688**	**20,885**	**1,752**	**136,613**	**19,784**	**238,722**
1.1 Pre-authorisation activities	62	22	13,151	3,428	1,013	26,327	28	43,947
1.2 Initial evaluation activities	43	12	8,980	2,093	0	13,951	1,069	26,092
1.3 Post-authorisation activities	65	19	11,243	5,376	0	83,414	7,763	107,796
1.4 Referrals	8	1	1,159	322	0	157	153	1,791
1.5 Pharmacovigilance activities	38	19	7,850	2,895	388	11,719	4,902	27,754
1.6 Other specialized areas and activities	78	28	17,305	6,772	351	1,046	5,869	31,341
2 Evaluation activities for veterinary medicines	**41**	**17**	**8,996**	**4,478**	**58**	**5,694**	**305**	**19,532**
2.1 Pre-authorisation activities	2	0	324	91	26	594	0	1,036
2.2 Initial evaluation activities	6	2	1,171	324	0	1,137	55	2,687
2.3 Post-authorisation activities	12	3	1,788	641	0	1,691	96	4,215
2.4 Arbitrations and referrals	0	0	82	26	0	0	142	250
2.5 Pharmacovigilance activities	5	4	1,527	1,211	26	2,273	12	5,048
2.6 Other specialized areas and activities	15	8	4,105	2,185	5	0	0	6,296
3 Horizontal activities and other areas	**178**	**69**	**39,879**	**52,173**	**1,943**	**3,687**	**13,980**	**111,662**
3.1 Committee coordination	34	14	6,892	1,798	1,036	0	0	9,726
3.2 Inspection and Compliance	28	15	5,140	1,744	110	3,687	3	10,684
3.3 Partners and Stakeholders	27	8	7,308	1,638	797	0	436	10,179
3.3a Transparency and access to documents	17	9	3,657	1,109	0	0	0	4,767
3.3b Information	24	13	5,281	2,312	0	0	1,995	9,588
3.4 International activities	12	3	3,599	684	0	0	0	4,284
3.5 Information Management (incl. EU Telematics)	35	7	8,002	42,888	0	0	11,546	62,436
4 Corporate Governance and Support activities	**145**	**28**	**29,365**	**8,021**	**248**	**0**	**1,256**	**38,890**
4.1 Governance, Quality Management and Internal Audit	21	8	5,390	1,254	248	0	571	7,463
4.2 Finance	32	8	6,604	2,045	0	0	611	9,260
4.3 Information technology	27	5	6,155	1,627	0	0	0	7,782
4.4 Human resources	55	8	9,956	2,657	0	0	74	12,688
4.5 Infrastructure services	11	0	1,259	438	0	0	0	1,697
Total	**658**	**217**	**137,928**	**85,558**	**4,001**	**145,994**	**35,326**	**408,806**

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										
1. STARS	17/07/2019 (EMA's accession)	€ 6,000.00	01/01/2019 – 30/06/2022	European Commission, DG Research & Innovation, Health, Administration & Finance	Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	
2. ConcePTION	26/04/2019	€ 85,000.00	60 months as of 01/04/2019	Innovative Medicines Initiative 2 Joint Undertaking	Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	
3. PREMIER	29/06/2020	€ 47,000.00	72 months as of 01/09/2020	Innovative Medicines Initiative 2 Joint Undertaking	Prioritisation and Risk Evaluation of Medicines in the Environment	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	

4. SISAQOL	30/10/2020	€ 76,800.00	48 months as of 01/01/2021	Innovative Medicines Initiative 2 Joint Undertaking	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life endpoints	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	
Total grant agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 0.00	**€ 0.00**	**€ 0.00**	**€ 0.00**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
Contribution agreements										
1. IPA 2020-2022	19/12/2019	€ 254,919.00	01/01/2020 to 31/12/2023 (48 months)	European Commission DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	
2. ePI	13/04/2022	€ 1,500,000.00	13/03/2022 to 31/12/2023	European Commission, DG SANTE/EU4Health	Development of electronic product information (ePI) for EU medicines	Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 1,399,778.48	€ 1,399,778.48
						Number of CA	0		0	
						Number of SNEs	0		0	
Total contribution agreements						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 0.00	**€ 0.00**	**€ 1,399,778.48**	**€ 1,399,778.48**
						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**	**PA**	**CA**	**PA**
							€ 0.00	**€ 0.00**	**€ 0.00**	**€ 0.00**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	
TOTAL						**Amount**	**CA**	**PA**	**CA**	**PA**
							€ 0.00	**€ 0.00**	**€ 1,399,778.48**	**€ 1,399,778.48**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	

Annex 7. Environment management

Aspect	Environmental objectives	Environmental targets	Actions to achieve environmental objectives	2022 achievements
Direct	Energy efficiency: "EMA drives energy efficiency in line with good practices"	100% renewable energy achieved. Actions targeted to directly support the objective	Replacement scheme of IT equipment such as lap-tops and small electricity for further energy efficiency	During 2022 a majority of the desktop phones were removed without being replaced. A switch to cloud-based IT services further supports the objective.
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor the consumption of materials used (paper, plastic) to reduce or maintain levels during the pandemic	Promote reduced use of single-use materials along "circularity approach" Promote paper-less work-flows and digitisation	Monitoring of paper consumption during the year confirms that there is reduced printing in comparison with the pre-pandemic situation, despite activities resuming to take place at the office.
	Water – not relevant due to the water efficiency at the EMA building	N/A	N/A	N/A
	Waste: "EMA drives waste reduction in line with good practices"	Monitor the generation of waste to reduce the non-recyclable waste and hazardous waste	Reduce non-recyclable waste along "circularity approach"	Monitoring the generation of waste consumption during the year confirms that there is reduced amount of waste in comparison with the pre-pandemic situation, following activities resuming to take place at the office.
	Biodiversity – not relevant due to no further land being taken into use	N/A	N/A	N/A
	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] Air emissions [t]	Monitor short haul travel and the ratio of air versus train travel Measure emissions from commuting and purchased goods & services with high environmental impact	Some incoming delegate travel and staff missions resumed in the third and fourth quarter of the year. Following temporary rules put in place in June 2022 every other committee meeting has been decided to be performed virtual and staff are advised to

				participate virtually in meetings and conferences when possible unless there is a strategic value for in person participation. The ratio of short haul travel by air was significantly reduced in 2022 compared with pre-pandemic levels.
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2022-2025 with an objective to update Environmental Risk Assessments (ERA) in line with the latest scientific knowledge with a target to reach a harmonised approach on ERA	Actions as included in the SPD 2022-2025 to provide scientific support to the European Commission and the EU network to ensure that an adequate Environmental Risk Assessment for medicines, in line with the "One Health" approach is applied to ERA	Reporting on environmental risk assessments as part of the marketing authorisations are presented within the scientific achievements.

Key Performance indicators	**2020 outcome**	**2021 expected**	**2021 actuals**	**2022 forecast**	**2022 actuals**
Number of contracts with Green criteria/Green helpdesk involvement	2	2	2	3	2
Include option for offsetting carbon emissions in procured contracts	0	0	0	1	0
Monitor the rate of non-recyclable waste out of total waste with a target to reduce	36%	45%	46%	45%	55%
Monitor the share of short haul air travel with a target to reduce for the benefit of train travel where possible	10.85% (out of total travel) 98.5% (out of short haul travel)	N/A*	Short haul air travel 0.0% of total travel	10% (/total travel) 91% (/short haul travel)	Short haul air travel 5.1% of total travel
Monitor the share of train travel as part of total travel with a target to increase	0.84% (out of total travel) 1.5% (out of short haul travel)	N/A*	Travel by train 5.54% of total travel	1% (/total travel 9% (/short haul travel)	Travel by train 1.26% of total travel

Monitor virtual participation in scientific meetings, trainings and other business activities for the reduction of carbon emissions	75%**	98.5%**	98.4%	TBD**	56.5%***
Total Tonnes CO2 emissions	761.7	349	178.5	TBD**	987,8

* Due to the Covid-19 pandemic very limited amounts of travel took place in 2021.
** The outcome of virtual meetings is a result of specific measures made during the COVID-19 pandemic. Expected outcome 2021 values are based on the assumption that virtual meetings will remain throughout the year due to the Covid-19 pandemic. The forecast values for 2022 are based on a pilot with scientific meetings resuming with 50% performed face-to-face and 50% virtual meetings once the pandemic situation so allows, after which a decision will be made for the long term plan with consideration to the updated rules of procedure of each committee[55]. The forecast of total share of virtual meetings and as a result emissions from travel may be confirmed once these decisions are in place.
*** Due to hybrid working most trainings and meetings provide support to both virtual and physical presence and the data is therefore not available. For 2022 this KPI reflects reimbursed meetings.

Performance indicator	**2020 outcome**	**2021 expected***	**2021 actuals**	**2022 forecast***	**2022 actuals**
Electricity, kW	1.131.079	1.748.233	1.736.230	2.160.000	2,144.909****
Renewable energy, % (carbon neutral)	100%	100%	100%	100%	100%
Water, M3	3.955	3.366	3.660	4.500	5.958
Office paper consumption, n sheets	906.046	872.446	613.747	1.744.892	554.486
Waste total, kg	69.035	55.777	41.998	111.556	54.717
- paper, kg	13.165	7.706	5.070	15.412	5.476
- plastic, kg	1.044	1.289	763	2.579	451
- glass, kg	1.554	1.037	1.257	2.075	3.204
- food, kg	26.875	18.639	13.848	37.278	13.691
- confidential (paper), kg	1.690	1.730	1.719	3.461	1.988
- non-recyclable, kg	24.707	25.376	19.341	50.751	29.907
Purchased heat and steam	5.263	6.000	5.116	7.050	5.139
TCO2e from building	236	327,1	177,7	430	196,13
TCO2e from travel	525,7	22,3**	0,8	TBD***	791,65
TCO2e total	809,1	349,3	178,5	TBD***	987,8

* The expected outcome 2021 and forecast 2022 for building consumption is based on an average daily occupancy of 450 people in Q4, 2021 and throughout 2022

[55] Rules of procedure of EMA's scientific committees and management board, to allow for virtual meetings also during non-emergency situations.

** The expected carbon emissions from travel in 2021 is a result of the Covid-19 pandemic with very little travelling taking place and meetings being conducted virtually.
*** The carbon emissions from travel for the forecast 2022 will be based on the result from a pilot with resumed scientific committee meetings with 50% performed face-to-face and 50% virtual meetings after which a long term plan will be made. On average for the years 2012 to 2017 the CO^2 from delegate travel was 2452 Tonnes annually based on an average of 7.773 delegates.
**** Following a fire in the power intake to the EMA building in April 2022 the electricity consumption readings have not been reliable. The annual consumption is therefore based on predicted values until reliable data can be obtained.

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

Annex 8. Draft annual accounts

Following a positive opinion by the European Court of Auditors, the Agency's annual accounts for the financial year 2021 were successfully adopted by the Management Board in June 2022 and sent to the Budget authority (European Parliament and Council) by 1 July 2022.

At the time of writing, the Court of Auditors had not yet provided the Agency with their observations on the provisional accounts 2022 and therefore, the Agency’s final accounts 2022 had not been issued yet. During the assessment of the Annual Activity Report, EMA management board has been involved in the review of 20222 provisional annual accounts. The major risk for the Agency remains the management of its former office premises at 30 Churchill Place, London. Since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations, the Agency could be exposed for all the amounts remaining payable under the headlease contractual obligations.

Annex 9. 2022 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 2022:

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 (Risk Management Specialist)	1 years, 11.5 months	15/12/2022	17/01/2023`	During a period of six months, to be counted as of the date she leaves the service, she should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas she may have dealt with during her last three years of service. This 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.	19/01/2023
2	Signal Management Lead	2 years 6.5 months	4/10/2022	3/11/2022	During a period of six months, to be counted as of the date he leaves the service, he should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas he may have dealt with during his last three years of service. This 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	7/11/2022

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
3	Signal Management Lead	10 years	30/09/2022	14/10/2022	During a period of six months, to be counted as of the date she leaves the service, she should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas she may have dealt with during her last three years of service. This 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.	20/10/2022
4	Pharmaceutical Quality Specialist (SNE)	1 year	1/09/2022	12/09/2022	During a period of six months, to be counted as of the date he leaves the service, he should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas he may have dealt with during his last three years of service. This 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.	15/09/2022
5	Data scientist	12 years, 6.5 months	31/01/2022	11/02/2022	During a period of six months, to be counted as of the date he leaves the service, he should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas he may have dealt with during his last three years of service. This 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.	17/02/2022

No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
6	Scientific Committee Manager to HMPC (SNE)	2 years	31/01/2022	11/02/2022	During a period of six months, to be counted as of the date she leaves the service, she should refrain from individually liaising with any member of Agency staff with respect to the specific products and/or areas she may have dealt with during her last three years of service. This 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.	17/02/2022

Annex 10.

For procurement activities, please consult the publication on EMA's public Procurement activities 2022 | European Medicines Agency (europa.eu)

Annex 11. Administrative appropriations – Building policy

Financial Regulation, Article 110, (GFR Article 266) Building(s) covered by the appropriation of the financial year

#	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	10,721,000 (for 2022; 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
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

The Agency does not have building projects submitted to the European Parliament and the Council.

Annex 12. Annual report 2022

Please see the Agency's Annual report 2022, publicly available on the EMA corporate website.

Annex 13. Project implementation 2022

Project progress and delivery as of 31 December 2022 against what was planned in the work programme 2022 is reported using the following traffic-light system:

Time / budget	
	Project within +/-10% (included) of the plan
	Project 10%-25% behind timelines or above budget
	Project more than 25% behind timelines or above budget
	No activity/result to report

Scope	
	No change to project scope
	Minor changes (expansion or reduction) to project scope (i.e. no significant effect on budget and/or timelines)
	Significant change (expansion or reduction) to project scope (i.e. impacting project budget and/or timelines)
	No activity/result to report

The traffic lights reflect the change to the overall project timeline, budget and scope that has taken place in 2022, in comparison to what was planned and approved at the end of 2021 (i.e. as noted in the work programme 2022). Notes explaining the changes are added.

In cases where the project start or end dates foreseen in the work programme 2022 were revised in 2022, the current dates are added in the relevant cells, with the original date from the work programme 2022 shown as crossed out.

Project title	Legal basis	Long term objective	Project timeframe		Deliverables 2022	Project delivery against			Achievements/ Results 2022
			Start	End		Time	Budget	Scope	
Meeting secretariat improvement		Implementation of a new operating model for working parties, of the support to medical devices expert panels (EMA extended mandate), and meeting secretariat operating improvements	2021	2022	Establishment of a new governance for working parties per domains (quality, safety, efficacy, methodology) Develop and implement the prioritised portfolio of activities and new operating model for expert groups Implement the support for the medical device expert panels; Introduce improvements in the meeting secretariat to manage the new operating model				
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	• Regulation (EC) 726/2004, art.57(d) • Regulation (EU) 2019/6; associated implementing acts	• The EVVet3 project aims to provide a "Union veterinary pharmacovigilance system", by bringing the database in line with the requirements of Regulation (EU) 2019/6 and the Commission implementing regulation (EU)	2017	Q4 2023	Go-live (Q1/2022) Development of additional data quality functionalities Improvements to all EVVet3 components				Go-live 28 January 2022 *Transferred to Agile governance, under UPhV epic in Monitoring Value Stream*

Project title	Legal basis	Long term objective	Project timeframe		Deliverables 2022	Project delivery against			Achievements/ Results 2022
			Start	End		Time	Budget	Scope	
		2021/1281 on good pharmacovigilance practice by 28 January 2022 and on delivering possible improvements beyond that date as well as the VICH guidelines relating to pharmacovigilance reporting							
UPD - Union Product Database [continues]	• Regulation (EU) 2019/6; associated implementing act	• Providing a Union Product Database system regarding Veterinary products according to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018	Q1 2020	Q4 2023	Go-live (Q1/2022) Improvements to all UPD components				Go-live 28 January 2022 New version released every 3-4 weeks Improvements to all UPD components *Transferred to Agile governance, under UPD epic in Product Lifecycle Management Value Stream*
ASU - Collection of Antimicrobials Sales and Use Data [new]	• Regulation (EU) 2019/6; associated implementing act and delegated act	• The Collection of Antimicrobial Sales and Use data (ASU) project collects information on how antimicrobial	Q1 2021	Q4 2023	Development of functionalities to collect sales, use and population data Development of reporting				Completed integration with one external party (Eurostat) *Transferred to Agile governance, under ASU epic in Monitoring Value Stream*

Project title	Legal basis	Long term objective	Project timeframe		Deliverables 2022	Project delivery against			Achievements/ Results 2022
			Start	End		Time	Budget	Scope	
		• medicines are used in animals across the European Union (EU) • The objective obtains reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR			functionality for use data				
MWD - Union Manufacturers and Wholesale Distributors Database	• Regulation (EU) 2019/6; associated implementing act and delegated act	• The EudraGMDP database is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates	2021	Q3 2022	Go-live (Q1/2022) Development of change to the GDP module Enhanced search functionality				Go-live 28 January 2022 Project delivered and closed
eCTD4: Implementation and adoption of	• n/a	• The project aims at implementing the next generation	Q1 2023	2025	Impact analysis and pre-implementation activities including				*[will restart in 2023]*

eCTD v4.0 standard		standard defining the message for exchanging regulatory submission information electronically between applicants and Regulatory Authorities			review tool options in preparation for the implementation of eCTD v4.0 specification at the EMA (and the EU regulatory network)				
IRIS: Platform to support regulatory business processes of the Agency	• n/a	• The IRIS platform will provide a single space for applicants and EMA to submit requests, communicate, share information and deliver documents concerning regulatory and scientific procedures	2019	2025	DADI forms (eAF replacement): H Variation Form (eAF under PLM) moved to PLM Variations process (Regulatory Business Process for PLM) moved to PLM Inspections and Parallel Distribution maintenance moved to the MON Value stream ITF, SA, Orphan maintenance moved in R&D Value stream				GCP Inspections in IRIS from April 2022 Variations process started development in Q1 2022 H Var form for CAPs go live Q4 2022 *Transferred to Agile governance, under 2 epics in Product Lifecycle Management Value Stream, one under the Research & Development Value stream and one under the Monitoring Value stream.*
Other Digital Business Transformation initiatives	• n/a	• Bringing about innovative digital tools for the Agency	2021	2025	Implementation of Analytics Centre of Excellence (ACE) / Digital Innovation Lab projects. Chatbot Extended Reality / Virtual Reality EU Network Training Centre				Digital Innovation Lab started five new DigiLab projects and worked with Analytics Centre of Excellence (ACE) to pilot five solutions to business challenges First Chatbot launched in May 2022 Virtual Reality proof of concept completed

					(EU NTC) enhancements and expansion to new audiences Development of Change Management Centre of Expertise Launch of EMA Digital Academy				EMA Digital Academy pilot with three modules
Lifecycle Regulatory Submission Metadata	• n/a	• Identify relevant data sources and by defining and standardising the structure of the information (i.e. defining the 'metadata' and supported through relevant standards), the scientific information will become more accessible	2021	2023	Establish a framework and operating model for data standards Develop conceptual model for clinical study protocols and reports Scientific Advice advanced Analytics pilot: present report/demo UI Launch contracts for Standards Specification; Implementation of FHIR resources; Implementation of Fast Healthcare Interoperability Resources (FHIR) tools; Implementation & Change Management				Scientific Advice advanced Analytics (Scientific Explorer) pilot: Pilot completed and successful demo of UI to business • Contract with vendor signed for next delivery phase • Successful transition of the project to SAFe/Agile under Research and Development Value Stream Clinical Trial Navigator: • ICH M11 (for clinical study protocols) published for public consultation • Development of conceptual & logical model for clinical study protocols using FHIR messages progressed. • Data Standardization Strategy endorsed by EXB, HMA and MB and published at EMA website Successful transition of the project to SAFe/Agile under Research and Development Value Stream
Lifecycle Regulatory Submission Raw Data	• n/a	• Report on review of experience with IPD at EMA and other international regulatory agencies and	2021	2024	Initiate stepwise implementation Initiate communication and training in				CHMP Raw data pilot design completed: business process and operating process, Data protection impact assessment, change management, Guidance and templates for stakeholders, selection of EMA

		develop protocol for IPD			accordance with plans				contractor to support raw data analysis) CHMP Raw data pilot execution initiated: pilot launch communication, first pilot procedure selected and raw data submitted, establishment of Network Advisory Group on Raw Data and Industry Focus Group on Raw Data. *Transfer to Agile governance in Research and Development Value Stream planned for 2024*
Observational Studies DARWIN EU ** Real-world Metadata and Rapid Analytics merged with DARWIN into one project in Nov 2021*	• n/a	• Establish a network of data, expertise, and services to support better decision-making by EMA and NCA scientific committees on the benefits and risks of products via rapid access and analysis and increased reliability, validity and representativeness of EU health data	2021	2025	1st year of establishment of the DARWIN EU coordination centre Coordination centre set-up, inc. operational processes and governance Establish connectivity with European Health Data Space (EHDS) and existing Data Permit Authorities First catalogue of standard data analyses available Start recruiting and onboarding the data partners Start running pilot studies to support EMA committees				Quality Framework • public consultation on Data Quality Framework for EU medicines regulation completed DARWIN EU ® • Coordination centre selected, established and operational • First 10 data partners onboarded • First 4 studies initiated • Integration with business processes and pilots with EMA scientific committees progressing as planned, solid demand for RWE studies • Data protection impact assessment completed • EMA use case selected in the EHDS2 pilot • Workshop with HTA and payers identifying use cases Real-world Metadata and catalogues • Metadata list adopted and published on Big data website • public consultation on RW

					Pilot with EHDS Prepare EMA to be ready as a node Training and change management				metadata Good Practice Guide completed Successful transition of the project to SAFe/Agile under Research and Development Value Stream.
*Real-world Metadata, Quality Framework and Catalogues **	• n/a	• Conduct external studies to identify data sources of real-world data, define and collect metadata and deliver a data quality framework.	2021	2025	Adoption of the metadata list and guide Development of data sources and studies catalogue Development and adoption of data quality framework for regulatory purposes				*Move to the Research & Development Value Stream*
*Observational Studies Rapid Analytics **	• n/a	• Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	2020	2022	Finalise proof of concepts with PDCO and COMP and pilot with SAWP Start pilots with CAT, CHMP, COMP and PDCO Finalise awareness and training material Finalise change management IHD software training for H-Division champions Databases accessible in-house in OMOP common data model				*[Included above]*

Signal and Safety Analytics	n/a	• Increase saleability and efficiency in processing of signals & safety data	2021	2023	Collection of IT and business requirements for the design of the new EudraVigilance data analysis system (EVDAS) platform/ electronic Reaction Monitoring Reports (eRMR) solution/ADR website Design of the new systems and identification of possible gaps Start implementation of the new solutions Analysis of potential future needed work				Collection of IT and business/functional requirements for the design of the new EVDAS platform/eRMR solution/ADR website Preferred technological product selected following Proof of Concept exercise with vendors Data protection impact assessment initiated Successful transition of the project to SAFe/Agile under Monitoring Value Stream
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR)	Regulation (EC) 536/2014, art.80-82	• The project aims at delivering Clinical Trials Information System (CTIS) to support the harmonisation of the assessment and supervision processes for clinical trials throughout the EU	Q3 2014	2023	Go-live 31 January 2022 Finalise implementation of post go live release(s) Final acceptance of post-go-live release and business change management Continued communications, training programme and related documentation				Go-live 31 January 2022 Post-go-live releases Communication and training ongoing Hypercare period extended until January 2023

					Planning and development for further post-go-live release(s) in 2023				
Safety Implementation Regulation - cooperation in safety assessment (CTIS scope extension)	Art. 11(3) of Implementing Regulation (pending adoption) to Regulation (EC) 536/2014	• Implementation of IT systems to support cooperation in safety assessment in the context of the clinical trials	Q3 2021	2023	Go Live 31 January 2022 Finalise implementation of post go live release(s) Final acceptance of post-go-live release and business change management Continued communications, training programme and related documentation Planning and development for further post-go-live release(s)				Go-live 31 January 2022 Continued communications, training programme and related documentation First Annual Safety Report submitted in CTIS in June
Digital workspace (TRIP)	n/a	To use a Digital workspace for capturing, filtering and scientifically assessing HS signals by users from the Horizon Scanning team (TRS) and by Regulatory Observatory members (experts across the Agency, and	~~2022~~ Q1 2023	~~2022~~ Q3 2023	Provision of data sources for the Digital workspace (internal and - external sources), regularly updated, enable data analytics activities Provide the user facing workspace and underlying system for manual curation of horizon scanning signals and topics				not started

		eventually the EMRN)			Provide automatically updated topic insights Prepare for additional automated signal assessment				
Shortages (new mandate)	Regulation (EU) 2022/123	EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand	2021	2025	Monitoring supply and demand for critical medicines list and critical medical devices lists Reception of shortages notifications and supply data from MAHs for critical medicines and from industry bodies for critical medical devices Reception of demand data from EU SPOC for critical lists Matching /analyse supply and demand data to mitigate shortages Aggregated data analysis and reporting capabilities on forecasts of demand in combination with epidemiological data from ECDC				Regulation (EU) 2022/123 adopted 25 January 2022 iSPOC registration tool go-live in June 2022 *Transferred to Agile governance, under ESMP epic in Monitoring Value Stream*

					Contact management for MAHs iSPOC contact data for all medicinal products portfolio and for industry bodies contact data for all medical devices portfolio Monitoring of events that can lead to shortages reported by EU SPOC Case management capabilities Provide analysis capabilities to evaluate the impact of the event on the supply and availability of medicines Streamline the various channels that shortages are reported				
ePI pilot	n/a	This e-PI pilot project for human medicines (CAPs and NAPs) will provide the initial building blocks towards creation of electronic product information (summary of product characteristics, package leaflet and labelling) for	2022	2023	Delivery and implementation of electronic Product Information (ePI) pilot				ePI set-up project closed in Q1 2022 ePI pilot launched in Q2 2022 *Transferred to Agile governance, under ePI epic in Product Lifecycle Management Value Stream*

		EU medicines. Product information is currently only provided in PDF format							
European Medicines web portal	- Regulation (EC) 726/2004 - Regulation (EC) 1235/2010, art.26	Providing a unified and harmonised web-portal giving access to information on medicinal products	2022	2023	There are common elements with the Union Product Database project from the VMP-Reg programme supporting some of the future developments, as well interdependencies with SPM&S and e-PI projects				*not started but being assesed under the Product Lifecycle Management Value stream how and when to restart this epic*
Replacement of Document Management System (DREAM replacement)	n/a	The objective is to replace the Agency Document Management System, which is at end of lifecycle with a modern, flexible, collaborative	2021	2023	Develop the functional and technical design of the future solution Plan the migration process				Functional and technical design completed Migration process planned Staff training started
Data Centre 2.0	n/a	Impact assessment of moving the Agency data centre to a cloud system	2022	2023	Plan and impact assessment on how to move to a cloud-based data centre solution				Project delivered and closed in Q4 2022
Security Awareness Integration of Critical Systems Identity Management PKI Infrastructure Data Sharing	n/a	Reinforce the Information security of the Agency IT systems	Q4 2022	2025	Implementation of Security Awareness program Multifactor Authentication on Critical Systems Implement portal-based solution for data sharing Implementation of Zero Trust architecture				Contracts/procurement process ongoing

External User Journey	n/a	Facilitate the external users to get access to Agency systems in a secure way	Q4 2021	2022	Redesign the Agency's Identity and Access Management (IAM) platform to improve self-registration of external users				Project delivered and closed Q4 2022
SPM&S Substances and products management services EU SRS	- Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials reg. 536/2014, art.8193) - Pharmacovig. fees reg. 658/2014, art.7 Art.4 of Guideline on eprescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	Implementation of ISO Identification of Medicinal Products standards to apply interoperability and consistency to the information shared across the regulatory authorities within the EU and internationally and hand over of the European Substance Registration System to the Agency I-DIV	2017	2024	Art 57 migration Product Management Services (PMS) Application Programming Interface SIAMED & Art 57 integration/feedback loop EU scientific substance information system (EU SRS) handover				Development of interface and data migration to support IRIS EU SRS handover to the Agency done in Q4 2022 Has been moved to Agile value stream: PMS in Product Lifecycle Management SMS in Research and Development
Optimisation of the Administration supporting tools	n/a	Providing modern digital tools to support administration processes, increasing efficiency of processes, staff (as customers) satisfaction with improved services and reducing manual work	2021	2024	New fee regulation Intranet Risk Management Procure2Pay Onboarding V2.0				Intranet: technical configuration completed and will be launch in Q1 2023 Risk Management: pilot running in the Agency decision to come in 2023 how to move forward
SAP Finance	n/a	Replacement of the Agency financial IT system due to its end of life	2021	2025	Solution analysis and selection of replacement for SAP Finance				Options are being assessed for replacing old SAP Finance

Annex 14. Pharmacovigilance Fee Regulation: Key Performance Indicators and performance information for the calendar year 2022

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 2022, 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	2022 actual
Number of PSURs and PSUSAs procedures started	864
Number of imposed PASS protocol procedures started	5
Number of imposed PASS report procedures started	2
Number of pharmacovigilance referral procedures started	4

Number of pharmacovigilance annual fee chargeable units invoiced	145,579		
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	* 2022 estimated	2022 actual	2022 actual %
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **CAPs only**:		600	
· Micro sized enterprises	2.25%	3	0.50%
· Small and medium sized enterprises	7.50%	40	6.67%
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **NAPs or CAPs/NAPs**:		4,879	
· Micro sized enterprises	2.50%	37	0.76%
· Small and medium sized enterprises	7.50%	184	3.77%
MAHs invoiced for **Imposed PASS protocol** 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 protocol** procedures started for **NAPs or CAPs/NAPs**:		0	
· Micro sized enterprises	2.50%	0	#DIV/0!
· Small and medium sized enterprises	7.50%	0	#DIV/0!
MAHs invoiced for **Imposed PASS report** procedures started for **CAPs only**:		4	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%

MAHs invoiced for **Imposed PASS report** procedures started for **NAPs or CAPs/NAPs**:		0	
· Micro sized enterprises	2.5	0	#DIV/0!
· Small and medium sized enterprises	7.50%	0	#DIV/0!
MAHs invoiced for Pharmacovigilance **referral** procedures started for **CAPs only:**		4	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%
MAHs invoiced for Pharmacovigilance **referral** procedures started for **NAPs or CAPs/NAPs:**		142	
· Micro sized enterprises	2.50%	1	0.70%
· Small and medium sized enterprises	7.50%	4	2.82%

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	* 2022 estimated	2022 actual	2022 percentage
Eligible for pharmacovigilance **annual fee** chargeable units invoiced		145,579	
· Micro sized enterprises	2.5%	1,073	0.74%
· Small and medium sized enterprises	7.5%	8,846	6.08%
· Generics (non-SME)	36.0%	63,284	43.47%
· Authorised homeopathic, authorised herbal, and well-established use product	0%	24,978	17.16%

Target: the estimated percentages

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	[56] Invoiced in 2022	Cash collected in 2022	[57] Percentage	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	16,199	15,798	98% (87% in 2021)	10,918
Income recovered for imposed PASS protocol procedures started	73	73	100% (66% in 2021)	39
Income recovered for imposed PASS report procedures started	110	110	100% (100% in 2021)	47
Income recovered for pharmacovigilance referral procedures started	1,070	1,058	99% (100% in 2021)	716
Income recovered for pharmacovigilance annual fee chargeable units invoiced	8,796	8,745	99% (99% in 2020)	n/a

[56] 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 2022 and processed in 2023, whereas the amounts shown in the tables below show only the value of the invoices related to the applications started between January and December 2022. In addition, some of the applications received at the end of the year were processed in the financial system in January 2023.
[57] Invoices are issued with 30 days credit which means that the payment of the invoices issued in November and December 2022 were paid for in 2023. The final 2022 cash recovery rate as of April 2022 is 99.9% for PSURs and PSUSAs and 99.7% 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 2022

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 2022 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	**9**
Post-authorisation safety studies	**1**
Referrals initiated as a result of the evaluation of pharmacovigilance data	**2**
TOTAL	**12**

	2022		
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	147,875 (144,883 in 2021)	3,119
	Number of 'master' reports generated based on duplicated data	41,728 (81,360 in 2021)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded	147,054 (1,068,728 in 2021)	
	Number of adverse reaction reports recoded:	13,619 (959,665 in 2021)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review	32 (119 in 2021)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected	131,436 (131,963 in 2021)	
[58] Monitoring of substance groups and selected medical literature	Number of literature references screened and reviewed	487,635 (487,635 in 2021)	1,304
	Number of individual case safety reports (ICSRs) entered into Eudravigilance database and made available to National Competent Authorities and Marketing Authorisation Holders.	8,278 (9,190 in 2021)	

[58] 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.

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	1,282	11,480
Cost for assessment of post-authorisation safety studies	197	171
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	207	806
Annual cost for information technology systems and literature monitoring		7,941
Overall pharmacovigilance costs	**22,084**	

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 (€)
864	n/a	1,666	n/a	40,339	303	4,918	148	1	31	0	17,461,418

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 (€)
5	n/a	5	5	0	0		1	0	0	0	84,318
2	n/a	4	4	3	3	3	0	0	0	0	54,960

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 (€)
4	146	451	4	0	1	0	879,975

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	226	2
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	8	0
Annual fee for information technology systems and literature monitoring	419	1

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	40	0
Fee for assessment of post-authorisation safety studies	0	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	2	0
Annual fee for information technology systems and literature monitoring	160	4

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2022
Generic application (Article 10(1) of Directive No 2001/83/EC)	1,834
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,768
Authorised homeopathic medicinal product	81
Authorised herbal medicinal product	227

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 (€)
3,426	145,579	419	1	160	4	68,335	24,348	2,829	1,681	8,802,824	60.47

10) Atrribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	**PASS**	**Referral**
Austria	44		
Belgium	45	3	
Bulgaria	1		
Croatia	29		1
Czech Republic	25		
Denmark	55		1
Estonia	12		
Finland	42		
France	47		
Germany (BfArM)	63		
Germany (PEI)	57	1	
Greece	2		
Hungary	16		
Ireland	38	1	
Italy	34		
Latvia	10		
Lithuania	11		
Malta	1		
Netherlands	115		
Norway	14		
Poland	36	1	
Portugal	38	3	
Romania			
Slovakia	11		
Slovenia	4		
Spain	31		
Sweden	83		2
Total	**864**	**9**	**4**

	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	29	1,563	54				
Belgium	39	5,378	138	3	264		
Croatia	40	2,011	50			3	463
Denmark	53	8,165	154			1	343
Estonia	9	330	37				
Finland	41	2,868	70				
France	51	4,828	95				
Germany - BfArM	60	7,294	122			1	518
Germany - PEI	35	2,360	67	2	128		
Hungary	10	1,370	137				
Iceland	1	46	46				
Ireland	31	2,489	80				
Italy	33	2,576	78				
Latvia	5	455	91				
Lithuania	2	444	222				
Netherlands	99	4,460	45				
Norway	10	440	44				
Poland - URPL	9	559	62				
Poland - GIF	3	138	46				
Portugal	42	1,750	42				
Slovakia	10	1,082	108				
Slovenia	5	519	104				
Spain	35	3,038	87				
Sweden	91	5,853	64				
Grand Total	**743**	**60,016**	**81**	**5**	**392**	**5**	**1,324**

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 2022.

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
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
AE	Adverse event
AER	Adverse event report
AFS	Anti-Fraud Strategy
Agency	European Medicines Agency
AGP	Antimicrobials for Growth Promotion
AHEG	Ad Hoc Expert Group
AI	Artificial intelligence
ALIMS	Medicines and Medical Devices Agency of Serbia
AMR	Antimicrobial resistance
AMRC	African medicine regulators conference
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France) - French National Agency for Medicines and Health Products Safety
API	Active pharmaceutical ingredient
Art	Article
AST	Assistant category post
AST/SC	Secretarial and clerical category post
ASU	Antimicrobial sales and use
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AVS	Assisted Validation System
BCP	Business continuity plan and public health threat plan
BDSG	Big data steering group
BfR	German Federal Institute for Risk Assessment
BI@Admin	Business Intelligence for Administration
BoT	breach of trust
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
CA	Contract agent
CA	Commitment appropriation
CAMD	Competent Authorities for Medical Devices
CAP	Centrally authorised product
CAPA	corrective and preventive actions
CAT	Committee for Advanced Therapies
CBER FDA	U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research

CCI	commercially confidential information
CDC	U.S. Center for Disease Control and Prevention
CDP	Clinical Data Publication
CECP	clinical evaluation consultation procedure
CHMP	Committee for Medicinal Products for Human Use
CHMP SO	Committee for Medicinal Products for Human Use Scientific Opinion
CMA/MA	conditional marketing authorisation/marketing authorisation
CMC	Chemistry, Manufacturing and Controls
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CPS	New Certificates tool
CRM	Customer Relationship Management
CRP	Collaborative Registration Procedure
CTCG	Clinical Trials Coordination Group
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
DALT	Digital Acceleration Leadership Team
DARWIN EU	Data Analytics and Real World Interrogation Network
DCT	decentralised elements in clinical trials
DG INTPA	European Commission Directorate-General for International Partnerships
DGHM	German Society for Hygiene and Microbiology
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DIMSIS II	Development, implementation and maintenance support of information systems
DIVS	Document Identification Validation System
DoI	Declaration of interests
DPA	data processing agreement
DPC	Data Protection Coordinators
DPIA	Data Protection Impact Assessments
DPO	Data Protection Officer
DREAM	Document Records Electronic Archive Management) system
EAAD	European Antibiotic Awareness Day
EAC	East African Community Region
EATRIS	European Infrastructure for Translational Research
EC	European Commission
EC SUMMA	Financial Platform of the European Commission

ECA	European Court of Auditors
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
eCTD	Electronic common technical document
EDPS	European Data Protection Supervisor
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMRN	European medicines regulatory network
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
EORTC	European Organisation for Research and Treatment of Cancer
EP	European Parliament
EPAR	European public assessment report
ERA	Environmental risk assessment
eRMR	electronic Reaction Monitoring Reports
ESEC	European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESUAvet	European Sales and Use of Veterinary Antimicrobials Working Group
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	Emergency Task Force
EU	European Union
EU IN HS report on FMT	EU-Innovation Network Horizon Scanning Report Faecal Microbiota Transplantation
EU NTC	EU Network training centre
EU SPOC	single points of contact in NCAs for shortages
EU-DPR	Data protection Regulation for EU institutions and bodies
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EU-IN	EU innovation network
EU-M4all	Medicines for use outside the EU
EUMSD	European medicines supply database
EUnetHTA	European network for health technology assessment
EURD	European Union (EU) reference dates and frequency of submission of periodic safety update reports (PSURs)
Eurostat	statistical office of the European Union
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVDAS	EudraVigilance data analysis system
EVV	Union Pharmacovigilance Database

EVVet	veterinary EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EWG	Expert Working Group
EXB	EMA Executive Board
EXPAMED	Expert Panels on Medical Devices
FDA	United States Food and Drug Administration
FDA CBER	U.S. Food and Drug Administration's Center for Biologics Evaluation and Research
FG (I, II, III, IV)	Function group (for contract agent staff)
FHIR	Fast Healthcare Interoperability Resources
FMT	Faecal Microbiota Transplantation
FTE	Full-time equivalent
FVE	Federation of Veterinarians of Europe
GCP	Good clinical practice
GDP	good-distribution-practice
GDPR	General Data Protection Regulation
GFR	General Financial Regulation
GLP	Good laboratory practice
GMDP IWG	GMP/GDP inspectors working group
GMP	Good manufacturing practice
GVP	Good pharmacovigilance practice
GxP	Good practice (e.g., laboratory, clinical, manufacturing etc)
HCP	Healthcare professional
HCPWP	Healthcare Professionals Working Party
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority (Ireland)
HR	Human resources
HTA	Health technology assessment
IAC	Internal audit capability
IAS	Commission's Internal audit service
ICDRA	International Conference of Drug Regulatory Authorities
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
IIA	Institute of Internal Auditors
IPA	Instrument for Pre-accession Assistance
IPD	Individual patient data
IPRP	International Pharmaceutical Regulators Programme
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
ISO	International Organisation for Standardisation
iSPOC	single points of contact in industry for shortages

IT	Information technology
IVMAB	Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JCA	Joint Controllership Agreement
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
JRC	European Commission's Joint Research Centre
JSC	Joint Scientific Consultations
KPI	Key performance indicator
LMS	EU Network Training Centre Learning Management System
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
MB	Management Board
MD	Medical devices
MD/IVD	medical devices/in vitro diagnostic medical devices
MDCG	Medical Device Coordination Group
MDSSG	Medical Devices Shortages Steering Group
MEDEV	Medicine Evaluation Committee
Member State (MS)	Member State of the European Union
MERS	Middle East respiratory syndrome
MFDS	Ministry of Drug and Food Safety (South Korea)
MHLW	Ministry of Health, Labour and Welfare, Japan
MLS	macrolides, lincosamides and streptogramins
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MSSG WG	Medicines Shortages Steering Group Working Group
MTG	Main Therapeutic Groups
MUMS	Minor use, minor species
MVP	minimum viable product
MWD	Union Manufacturers and Wholesale Distributors Database
NAP	Nationally authorised product
NB	Notified Body
NCA	National competent authority
Network	European medicines regulatory network
NICTAC	Network ICT Advisory Committee
NISG	Nitrosamines International Steering Group
NITAGs	National immunization technical advisory groups of WHO
NTWP	Novel Therapies and Technologies Working Party
OIE	World Organisation for Animal Health
OLAF	European Anti-Fraud Office
OMS	Organisation Management Service
ONCWP	Oncology Working Party
One Health EJP	One Health European Joint Programme

OPEN	Opening our Procedures at EMA to Non-EU authorities
PA	Payment appropriation
Parliament	European Parliament
PASS	Post-authorisation safety study
PAVM	EMA-Partnerships for African Vaccine Manufacturing
PBT	Persistent bioaccumulative and toxic substance
PCWP	Patient and consumer working party
PDCO	Paediatric Committee
PECP	performance evaluation consultation procedure
PEDAR	Personal Data Recognition
PHE	public health emergencies
PHEIC	Public Health Emergency of International Concern
PhRMA	Pharmaceutical Research and Manufacturers of America
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance working party
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PKI	Public Key Infrastructure
PLM	Product Lifecycle Management Value Stream
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
PMO	Office for administration and payment of individual entitlements
PMS	Product Management Services
PO	Product Owners
POC	Point of Contact
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROM	CHMP's preparatory and organisational matters meeting
P-SMEG	Pilot Signal Management Expert Group
PSUR	Periodic safety-update report
PSUSA	PSUR single assessment
PV	Pharmacovigilance
Q (1, 2, 3, 4)	Quarter (1, 2, 3, 4)
Q&A	Questions and answers
QAT	quality control, assurance and acceptance testing
QIG	Quality Innovation Group
QIS	quality information summaries
QPPV	Qualified Person for Pharmacovigilance
R&D	Research and development
RAPS	Regulatory Affairs Professionals Society
RFI	Request for information
RKI	Robert Koch Institute
RPA	Robotic Process Automation

RSS	Regulatory Science Strategy
RWD	Real world data
RWE	Real-world evidence
SA	Scientific advice
SAFe	Scaled Agile Framework
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SCC	Standard Contractual Clauses
SCG	Scientific Coordination Group
SciCoBo	Scientific Coordination Board
SCORE	Strategic Communication Review Group
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SMS	Substances Management Services
SNE	Seconded national expert
SPD	Single Programming Document
SPM&S	Substances and product management services
SPOR	Substances, Products, Organisations, Referentials
STARS	Coordination and Support Action on Strengthening Training of Academia in Regulatory Science
SUSAR	Serious unexpected suspected adverse reaction
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TBD	To be decided
TCIP	Technology Capability Investment Plan
TCS	EMA Clinical Studies and Manufacturing task force
TDT	EMA Digital Business Transformation task force
TEI MAV+	Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+)
TF	Task force
TFAAM	Task Force on Availability of Medicines
TGA	Therapeutic Goods Administration, Australia
TIAs	Transfer Impact Assessments
TRIP	Topic Relations Information Perspective
TRS	EMA Regulatory Science and Innovation Task Force
TW	Teleworking
TWG1	thematic working group
UI	User interface
UK	United Kingdom
UPD	Union product database
UPhV	Veterinary Union pharmacovigilance
US	United States of America
VAERS	U.S. Vaccine Adverse Event Reporting System
VAMF	vaccine antigen master files
VAR	Variation

VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform
vPTMF	vaccine platform technology master file
VR	Virtual Reality
VSIAG	Veterinary System Improvement Advisory Group
WAAW	World Antibiotic Awareness Week
WHO	World Health Organization
WLA	WHO listed authorities