EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Annual activity report 2020

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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 2020. The EMA annual activity report 2020 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 2020 comprises five main parts and annexes, as follows:

Part I: Key achievements in 2020. 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 2020 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 2020; 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 2020 work programme of the Agency, adopted by the Management Board at its meeting in December 2019,
- having regard to the annual report 2020 of the Agency adopted by the Management Board via written procedure on 30 April 2021,
- having regard to the annual activity report 2020 of the Agency presented to the Management Board at its meeting of 17 June 2021,

1. Recognises that due to the global Covid-19 pandemic, 2020 has been yet another extremely challenging year for EMA, requiring a shift in its priorities and extreme agility and resilience to maintain the high level of Agency's activities and to successfully support global efforts to combat the pandemic in a new and challenging environment;
2. Is pleased that the Agency successfully maintained the quality and continuity of its operations whilst completing the relocation to its final premises in Amsterdam;
3. Acknowledges the results presented in the annual activity report 2020 and recognises that the Agency has successfully adjusted to the new environment (e.g. meetings involving external participants held virtually) and remote working conditions and continued delivering its core tasks.
4. Is pleased with the fact that the Agency's work is well aligned with the European policy agenda and its mission, namely to protect human and animal health in the EU, and to ensure access to medicines that are safe, effective and of good quality, supporting also the innovation, availability and accessibility of medicines.
5. Praises Guido Rasi's excellent leadership and cooperation with the Management Board during his 9-year mandate and applauds his achievements as Executive Director of the Agency; among others, the proactive publication of clinical data, the EU Innovation Offices Network initiative, EMA's PRIority MEdicines (PRIME) scheme and the contribution to the tackle Antimicrobial Resistance (AMR).
6. Welcomes Emer Cooke as the new EMA Executive Director and wishes her luck and success with her new role in the Agency.
7. Welcomes the European Commission proposal to extend the Agency's mandate and looks forward to the roadmap the Agency will prepare to analyse the potential effects linked to the implementation of the EC proposal, once adopted. Yet, expects these new tasks to be supported by a corresponding increase in staff and resources.

COVID-19 PANDEMIC

8. Commends the achievements by the Agency, its staff, scientific committees' members and experts in dealing with the COVID-19 pandemic with minimal impact on output and productivity. Praises that health and wellbeing of staff was constantly addressed as a priority throughout the year.

9. Praises the Agency's resilience and responsiveness in managing the activities addressing the COVID-19 pandemic and mitigating its impact on the supply of medicines; appreciates the rapid deployment of the EMA Pandemic Task Force and is pleased with the waiving of Scientific Advice fees for the developers of COVID-19-related therapeutics or vaccines.

10. Acknowledges the efforts made by CHMP which led, already by the end of 2020, to granting a conditional marketing authorisation for the first vaccine to prevent the SARS-CoV-2 infection.

11. Welcomes the establishment of the EU Executive Steering Group on shortages of medicines caused by major events, to prevent and mitigate supply disruptions within the EU during the pandemic;

12. Congratulates the Agency's effort to contribute to the management of the crisis on behalf of the whole network and the EU Executive Steering Group in particular, by publishing the business continuity plan of the network and the regulatory flexibilities Q&A among other supportive documents.

13. Acknowledges the effort made regarding transparency and publication of information in lay language to explain the regulatory process to increase trust, in particular in vaccines.

RELOCATION TO AMSTERDAM

14. Appreciates the completion of EMA relocation to its permanent premises and praises the support provided by the Dutch government for the fully fitted and furnished, tailor-made building for the Agency's operations.

15. Appreciates the continued support provided to the staff and experts by the Agency to facilitate smooth relocation and settling in the Netherlands.

16. Acknowledges the efforts to address the situation of EMA's previous premises in London, while safeguarding the Agency's financial interests. Is still deeply concerned with the Agency being forced to act as a landlord for a property in a third country, and the ensuing financial, operational and reputational risks and implications.

17. Regrets once again the significant additional expenditure the Agency has incurred in 2020 in relation to relocation and Brexit, amounting to EUR 56.23 million, including the costs related to staff relocation to the Netherlands, and to the Agency's buildings.

ACTIVITIES

18. Appreciates the extended cooperation with the institutions of the European Union. Praises the work done with the European Commission and ECDC on vaccines and, in particular, on the European Vaccination Information Portal.

19. Is pleased with the Agency's scientific support given in 2020 to the European Commission, with regard to the preparation of the Pharmaceutical Strategy for Europe and the EU Beating Cancer Plan. Acknowledges EMA contribution to foster wider patient access to innovative medicines via its collaboration with the European Network for Health Technology Assessment.

20. Is pleased with the work done in collaboration with the European regulatory network in supporting companies marketing human and veterinary medicines, to mitigate the impact of UK withdrawal

from the EU after the end of the transition period on 31 December 2020, and to minimise the consequences on the supply of medicines.

21. Appreciates the work on marketing authorisations via the centralised procedure, both in human and veterinary medicines, which resulted in 2020 in EMA recommending for marketing authorisation 97 new human medicines, including 39 new active substances, and 20 new veterinary medicines, including 13 new active substances.

22. Is pleased to see that many of the approved human medicines represent a significant advance in treatments for children, rare diseases, and advanced therapies, such as the first vaccine to prevent infection from SARS-CoV-2, or the new vaccine for the active immunisation against the Ebola virus. In the veterinary field, the medicines approved included ten vaccines, eight of which were biotechnological vaccines; notes with satisfaction also the marketing authorisation granted to two new monoclonal antibodies.

23. Welcomes the Agency's decision to further encourage the development of treatments for rare diseases, by waiving all fees for scientific advice for academia developing orphan medicines.

24. Reiterates the importance of the Court of Justice opinion on two access-to-documents cases appealed before the Court of Justice in March 2018, whereby the Court of Justice upheld the Agency's approach to transparency and providing public access to documents relating to clinical study and toxicology data.

25. Looks forward for the Agency to restart its full-scale operations once the COVID-19 pandemic is under control.

26. Is pleased with EMA's continuous efforts to support SMEs, and recognises the importance of the work done by SMEs, especially on the occasion of the 15th anniversary of the implementation of the SME regulation.

27. Commends the Agency for continuing to ensure EU standards in medicine development and manufacturing, in particular by providing recommendations to marketing authorisation holders to avoid/mitigate risk of presence of nitrosamine impurities in medicines.

28. Recognises the work undertaken by the Agency to unlock the potential of big data for medicines regulation in the EU and is pleased with the publication of the final report of the HMA/EMA Joint Big Data Task Force. Welcomes the start of a veterinary big data strategy and the launch in May 2020 of the Analytics Centre of Excellence (ACE) for experimentation, with and development of new analytics-related technologies.

29. Applauds the full launch, in April 2020, of the industry Single Point of Contact (i-SPOC) system allowing regulators to detect and monitor common issues across Member States, spot patterns in medicines supply, and anticipate future supply disruptions.

30. Praises the work and achievements in the global fight against antimicrobial resistance, and especially the Agency's efforts in supporting the development of four new antimicrobial agents, collecting data on consumption of veterinary antimicrobials, and encouraging and advising on responsible use of antimicrobials.

31. Congratulates the Agency on the adoption and publication of the new 'EMA Regulatory Science Strategy to 2025' and of the new 'European Medicines Agencies Network Strategy to 2025'. Is pleased with the extensive collaboration with a wide range of public health stakeholders and experts in achieving these two landmark documents and looks forward to working together with EMA on these two new strategies.

32. Recognises the efforts made by the Agency, via the 'future-proofing' exercise, to make best use of the resources at its disposal. Acknowledges the beneficial impact it could have on EMA's ability to perform important new activities together with the Network and tackle important challenges ahead, such as big data, digitalisation and new scientific methods and technologies.

33. Welcomes the Agency's change management projects and the review of existing processes. Is pleased with the introduction of tools to support and embed the Agency's transformation towards a more agile, flexible, modern and responsive organisation.

34. Appreciates the Agency's swift reply to the cyberattack of December 2020 and acknowledges the strengthening of its defensive capabilities to protect EMA from future attacks.

TELEMATICS

35. Notes that several Telematics projects (e.g., substances and products management services, European medicines web portal, etc.) are still postponed or reduced due to lack of resources, staff and knowledge. Regrets that some projects are over time or over budget.

36. Praises the integration of Scientific Advice processes for human and veterinary medicines into the IRIS platform and the delivery of the first version in production of the Veterinary Union Product and Pharmacovigilance Database.

37. Acknowledges the notable progresses made towards a fully functional Clinical Trial Information System (CTIS). Is pleased with the positive outcome of the audit held in November 2020 and looks forward to the go-live version to be prepared for end of January 2022.

38. Welcomes the launch of two new projects: the ePI project, providing the foundations for the creation of electronic product information for EU medicines (human CAPs and NAPs), and DADI project (Digital Application Dataset Integration), replacing the PDF-based application form for initial applications.

LEGISLATION

39. Recognises the significant progress made on the preparation for the implementation of the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), which will become applicable on 28 January 2022.

40. Acknowledges the European Commission proposal for a new role in the Agency in the medical devices area: monitoring and management of shortages of critical medical devices and the management of expert panels responsible for conducting the clinical evaluation of and providing advice with respect to high-risk medical devices and in vitro diagnostics.

FINANCES AND HUMAN RESOURCES

41. Is pleased that the European Parliament has granted, on 28 April 2021, the discharge regarding the implementation of the budget of the Agency for the financial year 2019.

42. Notes that the Agency's final budget for 2020 amounted to EUR 369,749,000; that 84.22% of its revenue derived from the evaluation of medicines and other business-related activities; 15.65% from the European Union budget to fund various public health and harmonisation activities.

43. Notes the financial outturn, a surplus of approx. EUR 4.37 million, representing 1.18% of the final budget, was caused mainly by higher than budgeted fee-related income being collected at the end of the year.

44. Notes the 2020 provisional accounts and looks forward to giving an opinion on the EMA 2020 final accounts, following the receipt of the European Court of Auditors' observations on the provisional accounts.

45. Is pleased that the Agency managed to reach 100% occupancy rate for temporary agents, and notes that during 2020 the total number of staff joining EMA amounted to 164, while the total number of staff leaving the Agency during the same year amounted to 89.

AUDITS AND INTERNAL CONTROLS

46. Notes the results of the audit of the European Court of Auditors, confirming the reliability of the 2019 accounts and the legality and regularity of the transaction underlying the accounts of the Agency.

47. Is satisfied that no recommendations stemming from audits carried out by the Internal Audit Service of the Commission were open as of 31 December 2020.

48. Notes the positive result of the activities carried out by the Agency's internal audit capability, where no critical recommendations where open and only 3 very important recommendations remained under implementation as of 31 December 2020.

49. Understands that, among the audits planned for 2020, only the audit on Dutch incentives was rescheduled due to COVID-19 pandemic crisis and looks forward to having its result as planned by the end of 2021.

50. 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.

51. Notes with satisfaction that the ex-post controls carried out highlighted no significant weaknesses of the processes analysed; that only two areas with potential for improvement were identified and that these are being addressed by specific improvement action plans.

52. Is pleased to join the Agency and its staff in the celebration of EMA 25th anniversary since its creation on 26 January 1995.

DECLARATION OF ASSURANCE

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

54. Reiterates the concerns regarding the adequacy of the Agency's staffing levels in light of the continuously increasing workload, the significant responsibilities assigned to the Agency over the last years, and the possible new tasks stemming from the European Commission's proposal on EMA's new mandate.

55. Calls for an EU action at a political level to resolve the current unsustainable situation with the EMA premises in London.

56. Thanks again the scientific committees' members, experts, and patient representatives, as well as all NCAs and EMA staff for their exceptional commitment, especially in these extraordinary

circumstances due to the COVID-19 pandemic and appreciates the good collaboration in the network.

Amsterdam, 17 June 2021

[signature on file]

Christa Wirthumer-Hoche
Management Board Chair

Executive summary

European Medicines Agency in brief

The European Medicines Agency is a decentralised agency of the European Union (EU), created in 1995. As a result of the UK's decision to leave the EU, after 24 years, the Agency left its premises in London on 1 March 2019 and started operating from Amsterdam on 11 March 2019.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 the EMA. In this context, EMA delivers, maintains and provides data services, IT systems and infrastructure to Member States.

[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

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 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 – widely recognised by its stakeholders and partners, including at international level – 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, and, therefore, plays a key role in the protection of human and animal health in the EU.

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.

2020 in brief

In 2020, despite the difficulties caused by the global pandemic, 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 in protecting public and animal health and in allowing the European biomedical industry to innovate and create jobs and growth. It also contributes to achieving 'an economy that works for people'. Key achievements are detailed in section 1 here below, whereas major developments are reported in section 2.2. The full set of key quantitative data of the reporting year can be found in section 1 and section 2.

Key conclusions

Following the successful relocation to Amsterdam in 2019, EMA planned to gradually resume its full-scale operations in 2020; however, the outbreak of COVID-19 forced the Agency to re-prioritise its activities to tackle the global pandemic. The Agency successfully adjusted to the new environment and working conditions and continued delivering its core tasks.

Despite 2020 being another challenging year, with increased complexity in accounting and financial matters, EMA 2020 budget has been fully implemented, with a surplus of €4M which will be returned to European Commission. The Agency’s strong financial position and a comfortable cashflow is denoted by its net assets (€182 millions).

Based on all the facts presented in the report, including the management of the control system, and in light of 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. It has to be noted, though, that the adequacy of staff

and resources available to the Agency, as well as the uncertainty linked to the lease agreement for EMA's previous premises in London, further increased the pressure on the Agency at an already critical time.

1. Achievements of the year

2020 at a glance

HUMAN MEDICINES

In 2020, EMA recommended 97 medicines for **marketing authorisation**[2]. Of these, 39 had a new active substance which had never been authorised in the European Union before. The Agency also recommended 83 **extensions of indication** of medicines already authorised for marketing in the EU, offering new treatment opportunities for patients.

Six 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); 13 medicines received a recommendation for a **conditional marketing authorisation**, one of the possibilities in the EU to give patients early access to new medicines - and this was particularly important in the response to a public health emergency such as COVID-19; 5 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 May 2020, EMA's human medicines committee (CHMP) recommended granting a marketing authorisation in the European Union for a **new Ebola vaccine** that provides active immunisation to prevent Ebola virus disease. The recommendation to grant a marketing authorisation for the new vaccine follows the approval of the first Ebola vaccine in November 2019.

In the context of the **PRIME scheme**, which aims at helping patients to benefit as early as possible from promising medicines that target an unmet medical need, eight PRIME-designated medicines were recommended for approval. In addition to this, the Agency confirmed 22 **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.

As of 19 June 2020, to further encourage the development of treatments for **rare diseases,** EMA decided to **waive all fees for scientific advice for academia developing orphan medicines**.

Eligible applicants include public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations, on the condition that these entities are not financed or managed by private for-profit organisations in the pharmaceutical sector, nor have concluded any agreement with pharmaceutical companies concerning their sponsorship or participation in a specific research project for which a fee exemption is sought.

COVID-19

The Agency's activities in the context of the **SARS-CoV-2 outbreak** began already in December 2019, with a minimum level of activities including monitoring of the situation and liaising with relevant stakeholders, as per the Agency's health threat plan. As the outbreak continued to worsen, more actions were initiated in January 2020, including the creation of a dedicated mailbox for companies to submit information about their COVID-19 product development to seek regulatory and scientific advice from the Agency. A system was set up to triage all queries, respond to companies and, later on, in case of promising products, organise a teleconference with the EMA Pandemic Task Force (ETF) for

[2] The full overview of the 2020 human medicines highlights is available here https://www.ema.europa.eu/en/news/human-medicines-highlights-2020

direct discussion with developers. The mailbox and related processes started functioning at the end of January 2020 and have been in operation ever since.

The EMA Pandemic Task Force was activated upon the WHO's declaration of the pandemic on 11 March 2020, as per level 4 (crisis) of the health threat plan, and its mandate was modified to fit the situation. An inventory of all rapid procedures already available and those already used during the past pandemic and outbreaks was performed, and such procedures have been adjusted to the situation as needed, informing all stakeholders.

Additionally, to support and accelerate the development of vaccines and treatments **for the novel coronavirus disease (COVID-19)**, EMA has waived all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines as of 13 March 2020. The rapid scientific advice procedure put in place for potential COVID-19 treatments and vaccines reduces the review time to a maximum of 20 days (from 40-70 days), with no pre-specified submission deadlines. In addition, flexibility can be agreed, on a case-by-case basis, on the type and extent of the briefing dossier. Based on the experience gathered during the 2009 (H1N1) influenza pandemic, the best way to speed up authorisation of medicines during a pandemic is by initiating data assessment before a full dossier is complete and ready for submission. This means allowing developers to submit the data as they become available, so they can be assessed in a rolling fashion – the so-called '**rolling review procedure**'.

In June 2020, via the rolling review, EMA's human medicines committee (CHMP) recommended granting a conditional marketing authorisation to Veklury (remdesivir) for the **treatment of COVID-19** in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen. Through the same procedure, in December 2020, CHMP recommended granting a conditional marketing authorisation for the **vaccine** Comirnaty, developed by BioNTech and Pfizer, to prevent COVID-19 in people from 16 years of age. By the end of the year, the Committee was already reviewing the formal marketing authorisation application for another vaccine (Moderna's mRNA-1273 COVID-19 vaccine) and rolling reviews of two additional vaccines were also ongoing – one for the vaccine being developed by AstraZeneca with the University of Oxford and one for the vaccine from Janssen Cilag.

ENSURING MEDICINES AVAILABILITY DURING THE PANDEMIC

The rapid spread of COVID-19 led to swift and severe measures and restrictions implemented by governments all across Europe and the world, including lockdowns and bans on virtually any cross-border traffic. Such restrictions and their short notice period caused challenges for the medicines supply chain and, effectively, medicines' shortages.

To help address these issues, EMA initiated a number of activities:

- **EU Executive Steering Group on shortages of medicines caused by major events** was established to ensure urgent and coordinated action to prevent and mitigate supply disruptions within the EU during the pandemic.
- EMA launched the pharmaceutical **industry Single Point of Contact** (i-SPOC) **system** in April 2020, a fast-track monitoring system helping prevent and mitigate supply issues. The monitoring allows regulators to detect and monitor common issues across Member States; spot patterns in medicines supply; anticipate future supply disruptions early, and identify EU/EEA-wide measures to address disruption issues.
- The **EU Single point of contact** (SPOC) **network** also continues to be used for sharing information between Member States, EMA and the European Commission on critical medicine shortages.

- A **common framework for forecasting demand data** in the EU/EEA was developed to further enable identifying and preventing potential shortages from occurring.
- **Guidance** for medicine developers and companies **on adaptations to the regulatory framework** (for both human and veterinary medicines) to address challenges arising from the COVID-19 pandemic was first published in April 2020, for considering when deciding on mitigation measures for shortages. It is regularly updated to reflect the latest guidance.

Although the supply situation of some medicines improved in the course of 2020, global supply challenges remain.

ENSURING EU STANDARDS IN CLINICAL TRIALS AND MEDICINES MANUFACTURING

Throughout the year, EMA contributed to ensuring EU standards in medicine development and manufacturing. In particular, the Agency undertook several reviews to provide recommendations to marketing authorisation holders to avoid/mitigate risk of presence of **nitrosamine impurities** in medicines.

For medicines containing ranitidine, EMA recommended in April 2020 the suspension of the authorisations, due to the presence of NDMA (N-Nitrosodimethylamine) and concerns over potential endogenous formation of this nitrosamine from ranitidine in the body.

In June 2020, EMA finalised its review of nitrosamine impurities in human medicines and recommended companies to review their manufacturing processes and, where necessary, take measures to limit the presence of nitrosamines in human medicines to ensure that nitrosamines are either not present or are present below levels identified to protect public health.

In November 2020, CHMP aligned recommendations for limiting nitrosamine impurities in sartan medicines with previous recommendations it issued for other classes of medicines. This led to an amendment of the previous conclusions requiring companies to now carry out risk assessments, establish control strategies and carry out testing for nitrosamines at the level of the finished products.

With regards to ensuring manufacturing standards, applications for three centralised marketing authorisations and one type II variation were withdrawn due to non-compliance with **good clinical practice (GCP)**. The CHMP adopted one negative opinion (refusing the granting of the marketing authorisation) for a medicine for which there were GCP-related non-compliance issues in the clinical study submitted by the applicant.

VETERINARY MEDICINES

In 2020, EMA continued to authorise new medicines[3] to benefit **animal health in Europe**. Specifically, the Agency recommended **20 veterinary medicines for marketing authorisation**; 13 of these contain a new active substance (i.e. one that had not previously been authorised in the EU). Among the 20 medicines recommended for marketing authorisation, ten were vaccines - more than double the number of vaccines authorised in 2019. Of these, eight were biotechnological vaccines.

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) also recommended the granting of a marketing authorisation for two immunological products that were developed through biotechnological processes: the first monoclonal antibody to manage osteoarthritis in cats and a new canine monoclonal antibody for alleviation of pain associated with osteoarthritis in dogs.

EMA also recommended the establishment of **maximum residue limits (MRLs)** for two active substances and continued to monitor the quality and benefit-risk balance of the authorised medicines.

[3] The full overview of the 2020 veterinary medicines highlights is available here https://www.ema.europa.eu/en/news/veterinary-medicines-highlights-2020

ANTIMICROBIAL RESISTANCE

EMA and the European Medicine Regulatory Network played a pivotal role in tackling **Antimicrobial resistance** (AMR), a serious global public health threat, affecting both human and veterinary medicines. The global challenge is to develop new treatments and tests while using the existing therapies wisely and responsibly. In 2020, EMA supported the global fight against AMR by promoting the development of four new antimicrobial agents in the human field; collecting data on sales veterinary antimicrobials (the 10th ESVAC annual report was published in October 2020); encouraging and advising on responsible use of antimicrobials in animals by publishing, in January 2020, the updated scientific advice on the categorisation of antibiotics.

EMA also continued to support the implementation of the **European One Health Action Plan** against Antimicrobial Resistance. In 2020, EMA contributed by reviewing all available information on the benefits and risks of older antimicrobial agents and focused such review on human medicines containing fosfomycin. EMA also provided scientific inputs to the European Commission in preparing implementing legislation to limit the preventive use of veterinary antimicrobials.

VETERINARY REGULATION

Significant progress has been made on the preparation for the implementation of the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), which will become applicable on 28 January 2022.

Six scientific and technical recommendations on the content of the associated delegated and implementing acts have been sent to the EC in 2020, while the introduction of changes to scientific guidelines, regulatory advice, website and processes have notably advanced.

The dedicated webpage (Veterinary Medicines Regulation | European Medicines Agency (europa.eu)) was continuously updated and included the launch of a quarterly newsletter in 2020 to provide details about the Agency's VMP-Reg programme.

In 2020, the programme definition, the vision and the change management strategy were agreed for the Veterinary Medicinal Products – Regulation Programme (VMP-Reg). The Union Product Database project (UPD) kicked off in January, and a first version of the repository went live on 24 September; a draft implementation guide for the Union Product Database was released for public consultation. In addition, a revised scope of the EV Vet3 project for the January 2022 go-live and subsequent functionality was agreed.

The antimicrobials sales and use data collection (ASU) project and the Manufacturers and Wholesale Distributors Database (MWD) project have both been initiated in November 2020 and the project governance has been established with Member States representations.

TELEMATICS STRATEGY IMPLEMENTATION

During 2020, EMA continued to implement the Telematics strategy on behalf of the Network. The progress of the development of the **Clinical Trial Information System (CTIS)**, its supplier performance and quality continued to be closely monitored by the EMA Management Board. The target go-live date for the system is January 2022, with several additional post go-live releases expected. The Clinical Trials Regulation requires an independent audit of the CTIS before the EMA Management Board and then European Commission determine that it meets the functional specifications adopted and is fully functional. The EMA Management Board endorsed the audit methodology which enabled the process for the selection of the supplier for the audit of the system to commence. The first audit visit took place in Q4 2020.

The **CESSP Phase 1 project** to replace the PDF-based application form for initial applications with a web-based solution called 'CESP Dataset Module' was put on hold at the end of March 2020 and a new project, the Digital Application Dataset Integration project **(DADI),** was established.

The governance for the Electronic Product Information **(ePI)** was established and the Steering Group began to meet. This is a new Telematics project for human medicines (CAPs and NAPs) which will provide the foundations for the creation of electronic product information (summary of product characteristics, package leaflet and labelling) for all human EU medicines.

A Proof of Concept for the **European Substance Registration System (EU-SRS)** was completed successfully and the results and a proposal for next steps was presented to the Telematics Governance during 2020.

The EU Telematics strategy and implementation roadmap to cover the period 2019-2020 was extended to cover the period up to the end of 2020. The extended roadmap is designed to guide the ongoing Telematics developments until the new EU Telematics strategy 2020-2025 is published.

BIG DATA

In January 2020, the **final report of the HMA/EMA Joint Big Data Task Force** (titled 'Evolving Data-Driven Regulation') was published, presenting top priority recommendations for action for the EU Regulatory Network to leverage big data for better medicines regulation and public health. The recommendations will be taken forward by a new HMA/EMA Big Data Steering Group, established in May 2020, and within EMA the coordination will be led by the Data Analytics and Methods Task Force. The Big Data Steering Group work-plan for 2020-2021 was adopted on 27 July, and outlines actions to accelerate the transformation of EMA to become a modern data-driven organisation.

In May 2020, the EMA Digital Business Transformation Taskforce launched the **Analytics Centre of Excellence** (ACE) – a cross-Agency collaboration hub for experimentation with and development of new analytics-related technologies. ACE will explore ways to implement new technologies, including AI and machine learning, to improve EMA process design, automation, information and knowledge-management. The multi-disciplinary cross-Agency ACE team consists of business, analytics and IT experts who run a number of projects in parallel.

SCIENTIFIC ADVICE PROCESSES TRANSFERRED TO IRIS

On 19 October 2020, scientific advice processes for human and veterinary medicines went live on IRIS, the platform that developers of human and veterinary medicines should use to request scientific advice. Received requests will now be processed by the EMA scientific advice teams using the customer relationship management component of the IRIS platform. The Scientific Advice Working Parties will also use the platform to access information and collaborate on documents to coordinate the provision of scientific advice, which is then submitted for adoption by the CHMP and CVMP respectively.

Scientific advice is the fourth business process to be integrated into the IRIS platform, in addition to orphan designation, parallel distribution and Innovation Task Force processes. The next development in IRIS will focus on onboarding the marketing status reporting onto the platform. The go-live for scientific-advice processes coincides with the launch of the newly revamped IRIS website and introduction of a quarterly newsletter to keep its current and future users up to date with the latest information concerning the platform.

EU INCIDENT MANAGEMENT PLAN 10-YEAR ANALYSIS

A 10-year analysis of the European Union incident management plan (EU-IMP) was published in the 'Pharmacoepidemiology and Drug Safety' journal in September 2020, showing that the EU medicines

network is supported by a robust regulatory framework with defined processes and clear responsibilities in place to handle public health incidents.

EU-IMP was established in 2009, in collaboration between EMA, HMA and the EC, to enable rapid and effective actions across the EU in case of an event or new information on authorised medicines with a potential serious impact on public health. Such incidents can affect the safety, quality, efficacy or availability of a medicinal product and causes may include the product's safety profile, manufacturing compliance or supply chain issues.

ELECTRONIC CERTIFICATES FOR MEDICINES

As of 30 March 2020, EMA no longer provides printed certificates for human and veterinary medicines, but only electronically signed and authenticated certificates, in order to maintain EMA's ability to provide these documents during the COVID-19 pandemic.

Initially, electronic certificates are only being issued as a measure to ensure business continuity during the COVID-19 crisis. Based on this experience it will be assessed whether the shift to electronic certificates should become a permanent solution in the future, in line with the Agency's efforts to digitalise its administrative processes for all documents requiring signature.

REGULATORY SCIENCE STRATEGY TO 2025

Other significant achievements of 2020 concerned the preparations to ensure that EMA was fit to tackle future scientific and technological challenges and able to deal with new responsibilities. In March 2020, EMA published its regulatory science strategy[4]. Developed over two years in consultation with a wide range of stakeholders, including healthcare professionals, patients, pharmaceutical industry, academia, and regulatory bodies, the strategy aims at advancing regulatory science over the next five years, covering both human and veterinary medicines. The strategy sets out key areas where new or enhanced engagement of the EU network is essential and where advances in regulatory science are necessary. It identifies strategic goals for engagement for human and veterinary medicines and includes core recommendations and underlying actions to support these.

Deliverables of the Regulatory Science Strategy continue to be embedded in EMA's multiannual work programmes and implementation plans of EMA's scientific committees, working parties and other groups involved in medicine evaluation.

One of the first concrete outcomes of the Regulatory Science Strategy was the implementation of a new, more agile organisational structure to ensure that the Agency operates as efficiently as possible to deliver high-quality outputs for public and animal health. The changes were implemented in March 2020 and took into account the rapidly evolving landscape for pharmaceutical research and development that requires regulators to keep up with advances in science and technology and prepare for future challenges at an ever-accelerating pace. They were also driven by the need to recalibrate to a reduced workforce following the relocation of the Agency to Amsterdam in 2019, while also dealing with an increased workload due to the pandemic and the implementation of various new pieces of legislation extending the scope of EMA's activities.

EUROPEAN MEDICINES AGENCIES' NETWORK STRATEGY TO 2025

Another fundament achievement of 2020 was the overarching **European Medicines Agencies' Network Strategy to 2025[5],** which was developed together with the Heads of Medicines Agencies

[4] The Regulatory Science to 2025 strategy is a plan for advancing EMA's engagement with regulatory science over the next five years, covering both human and veterinary medicines. The strategy aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.
[5] The European Medicines Agencies Network strategy to 2025 identifies shared challenges, goals and priorities, to give strategic direction to the work of the European medicines regulatory network.

(HMA), and in consultation with the European Commission and stakeholders to guide the work carried out by the European Medicines Regulatory Network in the coming years.

The European Medicines Agencies Network Strategy to 2025 outlines six priority areas for the network: availability and accessibility of medicines; data analytics, digital tools and digital transformation; innovation; antimicrobial resistance and other emerging health threats; supply chain challenges; and sustainability of the network and operational excellence.

The strategy was published in December 2020, following its adoption by the EMA Management Board and HMA. The strategy details how the network can continue to enable the supply of safe and effective medicines that meet patients' needs in the face of challenges posed by ever-accelerating developments in science, medicine, digital technologies, globalisation, as well as emerging health threats, such as the COVID-19 pandemic.

AGENCY REORGANISATION

To help the Agency make best use of the reduced resources at its disposal and be prepared for future scientific and technological challenges, EMA initiated an in-depth review of its organisation in 2019. This 'future-proofing' exercise is aimed at helping EMA strengthen its ability to perform important new activities together with the Network and tackle important challenges ahead, such as big data, digitalisation, and new scientific methods and technologies.

In this context, the Agency's organisational structure was changed significantly as of March 2020. Operations in the area of human medicines were integrated into **a single human medicines division** to allow the strengthening of the therapeutic focus along a medicine's lifecycle, with the ultimate aim of assuring the quality of scientific opinions and further improving support to EMA's scientific committees.

Four mission-critical task forces were established to support the human and veterinary medicines divisions, bringing together expertise to drive transformational change in the following high-priority areas: *Digital Business Transformation*; *Data Analytics and Methods* *Regulatory Science and Innovation* and *Clinical Studies and Manufacturing*.

Additionally, revision of the Information Management Division has been aiming to become more customer-focused, agile, integrated and innovative, and to provide all stakeholders with the right information-management tools, technologies and services to facilitate the delivery of quality medicines to the public.

TRANSFORMATION AND CHANGE PROJECTS ONGOING

In addition to the organisational changes, the Agency is also reviewing and changing a number of existing processes and introducing new processes and tools to support and embed the Agency's transformation and move towards a more agile, flexible, modern and responsive organisation.

A new change-management framework was launched in March to support the 'people' side of change at EMA. To successfully embed the framework within the Agency's processes, it is also integrated into the Agency's P3i methodology and training is being provided. A Change Management Centre of Expertise has also been established to develop change management capabilities across the Agency.

Furthermore, the administration transformation programme is ongoing, covering changes to processes, technology, organisation and ways of working in the areas of strategy and resource planning, workforce management, finance, travel and meetings management, process improvement and automation.

In 2020, the focus of the programme has been on finalising implementation of the new e-recruitment and learning management systems, introducing new tools and digitalising HR-related processes (such as onboarding and performance development and appraisal) and procurement processes.

EMA's 25th ANNIVERSARY

In 2020, EMA celebrated also its **25th anniversary** since its creation on 26 January 1995.This coincided with anniversaries in a number of key policy areas of EMA, such as the 20th anniversary of the Orphan Regulation; the 15th anniversary of the implementation of the SME regulation and 10 years of the MUMS/limited market policy.

CONTRIBUTING TO EU PRIORITIES

COLLABORATION WITH EU INSTITUTIONS

EMA continued to **collaborate with the ECDC and the European Commission** on the implementation of the actions announced in the Commission's communication and the 'Council recommendation on strengthening cooperation against vaccine preventable diseases' adopted in 2018. EMA developed communication content about the benefits and risks of vaccines, as well as their regulation in the EU to be included in the European Vaccination Information Portal (https://vaccination-info.eu), which was officially launched by ECDC in April 2020. The European Vaccination Information Portal is an online platform, available in all EU official languages, which aims to provide the public with a single EU repository of accurate, objective, up-to-date and easy-to-read information on vaccines and vaccination in general. It is one of the main tools at the EU level to address misinformation about vaccines in general and, since the start of the pandemic, it has been updated to include specific sections about COVID-19 vaccines.

EUROPEAN GREEN DEAL

In 2020, EMA continued the implementation of actions within its remit under the EU Strategic Approach on pharmaceuticals in the environment, which was adopted by the European Commission in early 2019. This strategy 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. This strategy is a key part of the **European Green Deal**, which aims to achieve a toxic-free environment and a zero-pollution economy for Europe.

PHARMACEUTICAL STRATEGY FOR EUROPE AND THE EU BEATING CANCER PLAN

In 2020, EMA provided scientific support to the European Commission with regards to the preparation of the **Pharmaceutical Strategy for Europe and the EU Beating Cancer Plan**. The Pharmaceutical Strategy for Europe was published in November 2020 and proposes several legislative and policy activities to achieve four main objectives: promoting accessibility and affordability of human medicines in the EU, supporting innovation, enhancing resilience, and ensuring a strong EU voice globally. EMA also provided support to ensure synergies and complementarities between the EC strategy and the European medicines agencies network strategy to 2025.

EUnetHTA

EMA also 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** (EUnetHTA), which spans across many aspects of scientific collaboration between different decisions makers along the lifecycle of medicines. EMA-EUnetHTA 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.

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.

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 2020 forecast/target
	Results within +/- 10% of the 2020 forecast/target
	Results 10%~25% below the 2020 forecast/target
	Results more than 25% below 2020 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.

In cases where absolute numerical change results in disproportionate variation, discretion should be used to reflect more accurately the significance of the change. For example, a number of applications falling from 3 to 2 (or rising from 2 to 3) can be marked green rather than red (blue), if this is in line with regular variations.

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

In line with the BCP implemented at the Agency, delivery of some of the activities in the adopted work programme was delayed or postponed. The status of the activities is indicated in the report as *maintained*, *reduced* or *suspended*, and *reactivated* according to the decisions taken on these activities. Traffic lights are also attached to the status indication (green, orange and red), to allow for a quicker, more visual assessment of the BCP impact on Agency's activities. Of note, *this traffic light is not linked to the results delivered in 2020*, but only reflects the BCP status of a given activity. No

traffic light or BCP status is provided for the activities that have been completed previously (e.g., in 2019) or those that were not included in the work programme at the time of adoption by the MB in December 2019.

1.1. Evaluation activities for human medicines

1.1.1. Pre-authorisation activities

Workload indicators

Procedure		2017 result	2018 result	2019 result	2020 forecast	2020 result
	Scientific advice/protocol assistance pre-submission meetings	118	97	90	102	91
	Scientific advice and protocol assistance requests, of which:	630	634	674	674	784
	Parallel scientific advice with international regulators	3	2	2	5	6
	Joint scientific advice with HTA bodies	29	27	20	23	2
	Scientific advice for PRIME products	28	36	26	29	37
	Protocol assistance requests	168	159	137	155	143
	Novel technologies qualification advice/opinions	19	9	16	18	15
	PRIME eligibility requests	81	57	60	55	69
	Scientific advice finalised	490	444	530	535	669
	Protocol assistance finalised	156	170	137	150	124
	Orphan medicines applications	260	236	233	280	235
	Submitted applications on the amendment of an existing orphan designation	2	1	1	5	0
	Oral explanations for orphan designation	80	86	68	85	60
	Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	630	669	671	500	735
	Finalised procedures for compliance check on PIPs	67	96	94	70	97
	Annual reports on paediatric deferred measures processed	197	270	242	170	253
	EMA paediatric decisions processed	402	407	433	350	517
	Requests for classification of ATMPs	46	55	70	50	74
	Innovation Task Force briefing/meeting requests	33	22	29	25	27
	Innovation Task Force Art 57 CHMP opinion requests	0	5	4	1	0

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	100%	100%	100%	100.00%
	PRIME eligibility requests assessed within regulatory timeframe	100%	100%	100%	100%	100.00%
	Orphan designation opinions delivered within the legal timeframe	100%	96%	100%	100%	100%
	PDCO opinions sent to applicants within legal timelines	99.75%	99.9%	99.5%	100%	99.81%
	Increase in scientific advice requests	8%	0.6%	6.5%	7%	16.3%
	SME requests for scientific advice (% of total scientific advice requests)	31%	31%	28%	30%	25%

[1] New indicator introduced in 2017 work programme.
[2] Slight delays incurred due to re-examination (1 opinion in 2014, 1 opinion in 2015, and 2 opinions in 2016).

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Facilitate research and development of new medicines	1.3-5		100%	REDUCED The activity is limited to high level presence in Innovative Medicines Initiative (IMI) scientific committee with no proactive identification of topics. Support has been given to the Scientific Committee of IMI and the Research and Innovation workstream has engaged in support to COVID-19 activities and EU calls for research. In particular, contacts were established on two projects (Orchestra and Uncover) resulting in participation to Orchestra.
		Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation		SUSPENDED The activity is planned to restart in Q1 2021
		Based on the horizon-scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, involving also NCAs, to address specific		SUSPENDED The activity is planned to restart in 2021.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		areas for innovation		
	1.3-8	Reinforce collaboration via EU Innovation Network with academia and research hospitals that could benefit most of the innovation offices regulatory support		SUSPENDED The activity is planned to restart in 2021.
	3.1-1	Use business forecasting and analysis tools to better inform the EU Network about past and prospective development and improve regulatory preparedness	50%	SUSPENDED due to COVID-19 BCP The activity is planned to restart Q1 2021. In Q1/Q2 2020 special focus has been on COVID-19 topics as support from business pipeline to COVID-ETF forecasting exercise.
	3.2-2	Establish a platform for project-specific engagement with developers, to optimise activities during the development phase		SUSPENDED The activity is planned to restart in 2021.
Ensure needs of specific populations are met, including elderly, children, patients with rare diseases and others	1.1-6	Identify specific actions for EMA and PDCO that allow implementation of the European Commission/EMA action plan following the EC 10-year report on the Paediatric Regulation	50%	REDUCED The activity is limited to addressing public health needs and operational improvements. Preparation of multi-stakeholder meetings hosted at EMA (virtual): Paediatric Oncology: Paediatric Forums (ACCELERATE) on epigenetic modifiers (Jan 2020) and follow-up forum on BET inhibitors (July 2020). Neonatology: Virtual International Neonatal Consortium (INC) workshop held in October 2020. Paediatric action plan: interim outcome report published on EMA and EC website (Dec 2020) Operational: ongoing revision of Paediatric investigation plan (PIP) summary report and opinion template. Delays for further activities due to COVID-19 BCP.
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders		SUSPENDED due to COVID-19 BCP

Objective	MAWP initiative	Activity	% complete	Achievements/results
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle	1.2-3	Coordinate delivery of actions under the EMA/EUnetHTA work plan, in conjunction with Joint Action 3	80%	MAINTAINED Review of the delivery of the EMA/EUnetHTA work plan at bilaterals; major deviation: suspension of the parallel consultation platform from EUnetHTA's side; other topics progressing; however, impacted by EUnetHTA capacity; additional items: preparation for engagement with HTAs on DARWIN; exchange of information in relation to COVID-19. Important note: the workplan was extended to 2021 in line with the prolongation of EUnetHTA JA3, hence the end of the activity is moved to 2021
Increase involvement of stakeholders in relevant regulatory activities	1.2-6	Capture and incorporate patients' values and preferences into the scientific review process, in particular in benefit-risk evaluation	30%	REDUCED a) carried out one pilot preference focus group and the analysis to be presented to CHMP; b) Introduced a new process (applicable as of January 2021) for early CHMP dialogue with patients groups; c) Started research into potential focus group methodology for EMA use; d) Started drafting a reflection paper on the generation of patient (experience) data in support of benefit-risk assessment.
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-6	Analyse experience with legislative provisions, identify gaps in regulatory framework and provide technical support to the EC and the Network in relation to optimising existing regulatory framework, including development and/or implementation of new or amended laws and regulations	100%	Completed. Analysis provided to the EC to support a potential review of the variation regulation.
		Prepare for implementation of Medical Devices and In vitro Diagnostics Legislation, in relation to the implementation of the new consultation procedures involving the Agency, i.e., consultation on borderline products, on products that may be	70%	MAINTAINED Successfully completed virtual workshop to support implementation of Article 117 of the MDR on drug-device combinations. - Visibility and competence of EMA in the area of medical devices (particularly combination products) and companion diagnostics increased through participation as speakers, panellists and

Objective	MAWP initiative	Activity	% complete	Achievements/results
		systemically absorbed by the human body, and on companion diagnostics		chairs at various conferences (DIA, TOPRA and RAPS). - Continuous support to ITF, Scientific advice, MAAs in relation to medical devices and companion diagnostics. - The Guideline on Quality Considerations of Drug-Device Combination Products and revised Q&As have not been published yet due to EC's limited resources and priority resulting in delayed comments and the establishment of a new task force on Art 117 only in October 2020.
Ensure and run highly effective and efficient processes to deliver pre-authorisation activities	3.2-2	Review and implement optimised operations for all functions supporting medicines' development, including knowledge management	100%	MAINTAINED - Implementation of the Assisted Validation System for the registration of Type IA, IB and II in the finance department and for the validation of Type IA and Type IB in the procedures service of the Committees and Quality Assurance Department. - The Personal Data Redaction (PeDaR tool) tool has been tested during the year with different type of documents to be ready for deployment of the solution in production. - Automatisation of the registration process of initials electronic application forms (eAF) in SIAMED for variations; - Experts Database - API to convert CV information from experts in xml to PDF to be published on the EMA website; - Procurement to Pay (phase 1) - Streamlined and simplified process for procurement and contracts - Manufacturers Data Quality - Identification of incorrect manufacturing site details in SIAMED - A roadmap and portfolio of projects for 2021-22 has been created.
Prepare EU to prevent or manage an Opioid misuse in Europe	1.1-21	Establish a Task force and a Steering group to prevent opioid misuse in Europe: opioid abuse, misuse and dependence crisis in US and Canada ongoing.	100%	MAINTAINED The Steering committee and the Task Force were established with adopted mandate and rules of procedure, having monthly Steering committee meetings and quarterly Task Force meetings. Four workstreams (WS) are established:

Objective	MAWP initiative	Activity	% complete	Achievements/results
				WS1 - review of best practice/mitigation measures; WS2 - Evaluation of data landscape; WS3 - Data collection and generation; WS4 - Collaboration with international stakeholders. The lead of WS1 completed and presented a report on the dedicated objectives of the workstream. Workstream 2 initiated its activity, based on the findings of the report.

1.1.2. Initial evaluation activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Number of MAA pre-submission meetings	63	71	72	70	70
Initial evaluation applications, of which:	90	84	103	114	116
New non-orphan medicinal products	32	31	33	36	43
New orphan medicinal products	19	17	27	27	28
Similar biological products	17	9	13	14	12
Generic products, hybrid and abridged applications	15	23	29	34	24
Scientific opinions for non-EU markets (Art. 58)	1	1	0	2	0
Paediatric-use marketing authorisations	2	0	0	1	0
Number of granted requests for accelerated assessment	10	11	13	8	12
Number of consultations of SAGs/ad-hoc expert groups in the context of MAAs	14	13	15	24	18
Reviews on the maintenance of the orphan designation criteria at MAA stage	24	45	40	60	35

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Applications evaluated within legal timeframes[1]	100%	100%	100%	100%	100%
Average assessment time for new active substances and biosimilars (days)	175.7	205.3	192.8	205	192
Average clock-stop for new active substances and biosimilars (days)	136.9	195.2	178.1	180	166

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	MAAs initiated under accelerated assessment that have been completed as accelerated assessment	58%	44%	43%	75%	50%
	Initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	69%	68%	68%	80%	70%
	Labelling review of the English product information annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	95%	96%	98%	90%	95%
	Therapeutic guidelines progressed to the next step or finalised (percentage vs planned)	60%	70%	80%	70%	60%
	Early background summaries drafted and sent to assessment teams (percentage vs planned)	100%	100%	100%	100%	100%
	Percentage of outcomes/results of workshops on therapeutic objectives published on EMA corporate website	90%	100%	n/a	100%	0%[3]

[1] Includes marketing authorisation and plasma master file applications
[2] New indicator introduced in the 2017 work programme
[3] Due to COVID-19 BCP no workshop was held

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality, robust, scientifically sound and consistent product information	3.3-6	Implement EMA action plan on EC's report to improve Product Information with regards to ePI	15%	SUSPENDED Key principles for ePI in the EU were adopted and published by HMA and EMA MB. However, all other actions from EMA action plan are on hold until further resources are made available.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	1.3-4	Support activities stemming from Joint Action 3/work package 4, by providing relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments	100%	MAINTAINED Product-specific exchanges for all applications subject to joint relative effectiveness assessment (REA) production by WP4; in accordance with operational guidance between EMA and EUnetHTA. The workplan has been extended to 2021 in line with the prolongation of EUnetHTA JA3, hence the end of the activity is foreseen by that date.

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: increase patients' involvement in assessment work and support the IMI PREFER project		SUSPENDED
		Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: explain the rationale for single-arm trials-based approvals to the public and explore the need for wider discussion of such approvals		MAINTAINED In the first part of 2020, an oncology paper has been completed and a second overarching paper was submitted by the Biostatistics working party to the CHMP in June 2020. A multi-disciplinary drafting group was formed in October 2020 to update the overarching paper.
Contributing to the global regulatory environment	4.1-xx	Develop position paper on trial integrity in the presence of interim results in on-going clinical trials and handling of its confidentiality		SUSPENDED due to COVID-19 BCP
		Review the experience gained from patient level data (PLD) analysis by the EMA committees and formulation of a plan for a targeted pilot	100%	REACTIVATED A presentation on the review of experience on individual patient data in clinical trials was presented at the CHMP Strategic Review and Learning Meeting on 22 September 2020. In Q3 2020, CHMP agreed to start with a pre-pilot on individual patient data, based on one marketing authorisation application. A plan for a pilot will be prepared and shared with CHMP in 2021.

1.1.3. Post-authorisation activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Variation applications, of which:	6,267	6,716	7,434	6,506	7,938
Type IA variations	3,080	3,433	3,886	3,154	3,989
Type IB variations	2,054	2,164	2,425	2,200	2,675
Type II variations	1,133	1,119	1,123	1,152	1,274
Line extensions of marketing authorisations	21	20	27	19	35
PASS scientific advice through SAWP	0	3	3	2	1

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	15	13	10	12	10
Renewal applications	94	90	107	81	99
Annual reassessment applications	19	22	25	27	24
Transfer of marketing authorisation applications	47	377	63	50	36
Article 61(3) applications	234	258	286	220	211
Post-authorisation measure data submissions	795	812	776	900	990
Plasma master file annual update and variation applications	22	19	17	38	28

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Post-authorisation applications evaluated within legal timeframes	99%	99%	99%	99%	99%
Average assessment time for variations that include an extension of indication	162	157	165	180	167
Average clock-stop for variations that include an extension of indication	67	66	76	90	84
Percentage of submitted risk-management plans, peer-reviewed by the Agency as part of the extension of indication and line extensions	100%	100%	100%	100%	100%

1.1.4. Referrals

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Pharmacovigilance referrals started	7	2	8	8	2
Non-pharmacovigilance referrals started	3	15	7	8	6

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and run highly effective and efficient processes to assess referrals	3.2-1	Development of a common understanding with the Network on the best use of referrals	70%	MAINTAINED - Report including analysis and recommendations has been finalised in Q1 2020 on the CHMP referrals based on efficacy. - An analysis and drafting of a report on temporary measures has been circulated to Pharmacovigilance Risk Assessment Committee (PRAC) subgroup. - Provision of training and delivery of the module on temporary measures for safety referrals.
Reliance		Review of nitrosamines impurities in medicinal products	continuous	MAINTAINED The review of nitrosamines impurities has been ongoing since the publication of the guidance to MAHs in September 2019. The implementation phase is ongoing.

1.1.5. Pharmacovigilance and epidemiology activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Number of signals peer-reviewed by EMA	2,062	2,204	1,806	1,800	1,888
Number of signals validated by EMA (assessed by PRAC)	82	74	50	40	39
PSURs (standalone CAPs only) started	551	554	554	572	525
PSUSAs started	372	327	246	332	304
Number of imposed PASS protocol procedures started	6	17	12	15	4
Number of imposed PASS result procedures started	6	8	3	8	4
Number of emerging safety issues received	21	8	5	10	4
Number of notifications of withdrawn products received	302	413	462	400	510
Cumulative number of products on the list of products to be subject to additional monitoring	336	351	342	350	343
Number of products included in the list of additional monitoring[6]	n/a	76	55	60	59
Number of products removed from the list	n/a	60	60	60	57

[6] Indicator introduced in Work Programme 2018

Procedure		2017 result	2018 result	2019 result	2020 forecast	2020 result
	of additional monitoring[2]					
	Number of incident management plans triggered	4	11	3	7	6
	Number of non-urgent information or rapid alert notifications submitted through EPITT	61	44	43	55	15
	Number of external requests for EV analyses	32	17	13	15	15
	Number of MLM ICSRs created	14,193	13,275	9,676	14,000	9,950

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%	100%	100%
	Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	100%	100%	100%	95%	95%
	Protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%	100%
	Percentage of reaction monitoring reports supplied to the lead Member State monthly	97%	95%	99%	94%	97%
	PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	1.2-4	Coordinate data collection and analysis to measure pharmacovigilance impact as feedback to improve processes	continuous	MAINTAINED Guidance on concept and methods for RMM effectiveness/impact evaluation incorporated in Revision 3 of GVP XVI (chapter B.5 and new Addendum II) will be launched for public consultation in Q1 2021; two EMA-funded impact studies launched (fluoroquinolone, ranitidine), two finalised (valproate, retinoid awareness studies), one collaborative study (alternatives to codeine) finalised; revised process for prioritising impact research topics implemented; review of effectiveness PASS evaluated by PRAC

Objective	MAWP initiative	Activity	% complete	Achievements/results
				2016-2019 finalised (project report under preparation); review of PRAC engagement 2015-2019 performed; development of PtC for PRAC engagement started.
	1.4-1	Finalise (2019) GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in Q1 2019	30%	MAINTAINED Following Brexit BCP suspension, the activity was resumed in March 2020. Compilation and review of comments (public consultation ended 28 Feb 2020). Some activities planned for 2020 have been delayed/postponed because of COVID-19-related priorities
		Prepare for public consultation (2020) and finalise (2021) GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators	GVP M XVI: 100% GVP M XVI Add II: 100% GVP M XVI Add III (PPP): 40%	MAINTAINED Following Brexit BCP suspension, the activity was resumed in October 2019. - Draft Good pharmacovigilance practice (GVP) XVI Rev.3 on RMM tools and Addendum II on effectiveness evaluation finalised for public consultation, to be launched on 3 February 2021 (on target with workplan). - Draft Addendum III on pregnancy prevention programme (PPP) ongoing with public consultation targeted for Q2 2021 (currently delayed by one quarter justified by COVID-19 priorities).
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through use of high-quality data, information and knowledge	1.2-4	Build and maintain capacity for EU Network analysis of epidemiological data	100%	REACTIVATED The Big Data Steering Group adopted its workplan in July 2020, setting its priorities for 2020 and 2021. In 2020, the BDSG met 7 times virtually and held the Big Data Stakeholder Implementation Workshop in December 2020. A project to deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real-World Interrogation Network – DARWIN EU) was established in November 2020. Through EMA framework contracts for epidemiological studies, the EU Network capacity for COVID-19 safety and effectiveness studies was increased.

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Notably, the ACCESS project created a network for COVID-19 studies and protocols so vaccines safety and effectiveness studies can start in 2021.
		Continue to develop and maintain inventory to facilitate access to data on real-world data in line with recommendations of the Big Data Taskforce	continuous	REDUCED The activity is reduced to maintenance activities and is planned to fully restart in 2021. The ENCePP database of resources (inventory) is continuously updated to include descriptions of disease registries and other real-world data sources used for regulatory decision-making. At the end of 2020, 198 centres, 31 networks and 153 data sources were included in the inventory.
		Conduct of a pilot of rapid analytics of Electronic Health Records to support committee decision-making including increasing the EU healthcare data accessible for analysis. Initiate at least eight in 2020 and twelve in 2021 EMA studies on real world evidence data	100%	MAINTAINED In 2020, nine studies were initiated in the EMA in-house databases (HPV vaccines, tolperisone, vedolizumab, ifosfamide, cladribine, hydroxychloroquine, docetaxel and COX-2 inhibitors, ceftriaxone, tofacitinib and other JAK inhibitors). Eight EMA-funded studies have been launched (including six COVID-19 related studies) and two other studies were procured but no tenderer applied. A rapid pilot with the PRAC was completed in 2020 and the final report will be presented in Q2 2021.
	1.2-5	Provide increased support to the use of registries for targeted products on the EU market from learnings including finalised guidance in 2020	continuous	MAINTAINED The guideline on use of registries for regulatory purposes was released for a 3-month public consultation in September 2020. As part of the consultation process, EMA hosted a virtual workshop in October 2020 to present the draft guideline to key stakeholders. EMA intends to publish the final document in 2021. An outline of a business process for real-world evidence input into scientific advice, PRIME and re-submission meetings has been drafted and is being tested.
	1.4-13.2-3	Based on the analysis of the pilot of MAH signal detection in EudraVigilance, implement the		REDUCED Activity reduced to pilot phase. The pilot was extended by EC until December 2021

Objective	MAWP initiative	Activity	% complete	Achievements/results
		decision of the European Commission on extension beyond the pilot phase, including new business process for MAH signals.		and it is currently ongoing (6 notifications in 2020, including 2 valid but not confirmed). Business process for MAH signals delivered in November 2019 (post-EC Internal Audit Service audit action).
		Deliver a training curriculum on methodology and Big Data, including specific training for assessors on real-world data in committee assessment	75%	MAINTAINED The Pharmacoepidemiology training curriculum and Biostatistics training curriculum were adopted in Q2 2020. The Big Data Training signpost document was launched on 30 June 2020. Material for the development of the first module of the Pharmacoepidemiology training curriculum has been assembled, but the module has not been developed yet due to the workload associated with COVID-19.
		Agree on a work plan for the development of guidelines on data, methods and evidence.	50%	REDUCED A review of three-year rolling plans for Working Parties that deal with the methodological or quantitative aspects was conducted in Q3 2020 by the review group on working parties to inform the design and priorities of the future methodology working party. The agreement of the workplan for the development of guidelines on data, methods and evidence is delayed until the review of activities of the Working Parties is complete.

1.1.6. Other specialised areas and activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Herbal monographs, new[1]	4	4	0	5	3
Herbal monographs, reviewed	n/a	7	13	12	14
Herbal monographs, revised	8	15	2	7	8
List entries	0	0	0	1	1

[1] Where assessment does not lead to the establishment of a monograph, a public statement is prepared.

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 forecast	2020 result
n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Promote application of harmonised international standards	3.2-15	Provide technical and scientific contribution to the development of ICH guidelines (Carcinogenicity assessment document evaluation for ICH S1)		SUSPENDED The activity should restart in Q3 2021. Despite activity being suspended, international regulators have completed their review of the prospective study evaluating the degree of concordance between the carcinogenicity assessment documents based on a weight of evidence approach with the data provided by sponsors from the 2-year rat carcinogenicity studies and a regulatory approach proposed. The final Step 1 (Consensus building - Technical Document) is being finalised before entering Step 2A (ICH Parties consensus on Technical Document) and subsequently Step 2B (Draft Guideline adoption by Regulators).
Effectively manage risks to the environment arising from the use of human medicines	4.2-6	Collaborate with the EC on the roadmap 'Strategic approach to pharmaceuticals in the environment' and update the EMA guideline on environmental risk assessment (ERA). Participate in EC cross-service group on medicines in the environment		SUSPENDED The activity should restart in Q1 2021 Despite this activity being SUSPENDED, EMA continued to contribute to several aspects of the EU Green Deal implementation and strategic approach for Pharmaceuticals in the Environment (PIE), including the guideline revision and the Ad hoc group on PIE (EMA + MS) whose action plan was endorsed by the Pharmaceutical Committee in Q4 2020.
Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective	1.1-1	Establish and run cross-Agency Task Force on antimicrobial resistance. Provide proposals and implement them for EMA activities to address antimicrobial resistance		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
Enhance ability to respond quickly to public-health emergencies	1.1-9	Collaborate with international stakeholders on the clinical study design and emergency use of medicines in case of a public health emergency and interact with medicines developers in the early stages of the development to facilitate early introduction of appropriate treatments or preventive measures	60%	MAINTAINED – COVID-ETF deliberations and approval of the COVID-19 vaccines (Comirnaty [Pfizer-Biontech], Moderna, AZ vaccine) – COVID-ETF deliberations on the regulatory guidance on the requirements on vaccine approval and approval of therapeutic products (RRs) – International coalition of medicines regulatory authorities (ICMRA) workshops on vaccines and therapeutics (include dates) – Continuous interaction with NITAG on the clinical study design (ACTIV-3 (2, 3b)
Contribute to European and international initiatives and collaborations in the area of AMR	1.1-2	To implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	10%	REACTIVATED Activity restarted with 3 panel meetings held in Q3-Q4 2020, focused on collaboration related to the intersection between COVID-19 and AMR (minimal input to the work of the WPs within).
	1.1-3	Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and the World Organisation for Animal Health (OIE) strategy	30%	MAINTAINED Contribution to the drafting of EMA/HMA network strategy to 2025; ICMRA statement, communication; Drug Information Association (DIA) presentation.
Enhance ability to respond quickly to public-health emergencies	1.1-9	Contribute to Joint Action on Vaccines and EC vaccines task force on vaccines (action the plan from the Council Recommendations on vaccination). This includes activities related to support R&D of vaccines including dialogue with NITAGs; discussion with EC and ECDC on platform for benefit/risk monitoring of vaccines *Expected to be resumed in 2020 (subject to resource availability)*	60%	MAINTAINED – COVID-ETF ativities in contribution to the EC pandemic management – Approval of COVID-19 vaccines Comirnaty (Pfizer-Biontech), Moderna vaccine. – EMA ECDC platform for vaccinies surveilance including established of the joint board
Update guidelines and	1.3-2	Finalise the new and revised guidelines related to the		SUSPENDED due to COVID-19 BCP

Objective	MAWP initiative	Activity	% complete	Achievements/results
inspection related procedures in accordance to the new legal requirements		implementation of the Clinical Trials Regulation, considering as applicable the comments received during public consultation		
		Development of vaccine outreach strategy	100%	Completed. Strategy finalised in 2020 and implementation initiated with priority on COVID-19 related activities.
		Collaboration with ECDC on European Vaccine Information portal	100%	MAINTAINED Website updated with information on COVID-19 disease and vaccines. Collaboration agreement between ECDC, EMA and DG SANTE on the management and development of the website drafted.
Develop Agency approach to implementation of GDPR in relation clinical trial participants/patient data received from 3rd parties		Prepare a paper guiding the Agency approach and where appropriate Q&A or guidance for the Agency and stakeholders	100%	MAINTAINED Draft Q&A was submitted on 1 July to the European Commission for comments (document titled 'Questions and Answers (Q&As) on data protection and the secondary use of personal data for medicines development and public health purposes').
Strategy on GMP evolution in light of new technologies and medicines and on supply chain challenges		Develop strategy paper on GMP evolution and supply chain challenges	5%	SUSPENDED due to COVID-19 BCP The activity is planned to restart in Q2 2021.
Implementation of the EU-DPR		Initial implementation of the EU-DPR	100%	MAINTAINED The implementation of the EU DPR continued in 2020, focusing in particular on the further update or creation of privacy statements, the systematic review of data protection clauses in all procurement contracts, the interactions with international regulators and the daily advice to all operational functions on data protection matters. On 4 May 2020, an all-staff training and awareness session was organised (followed by more than 350 staff members). The initiative was congratuled by the EDPS. Following the notification in the second half of 2020 by the EDPS of an enforcement order further to the 'Schrems II judgment', a huge Agency-wide mapping exercise on

Objective	MAWP initiative	Activity	% complete	Achievements/results
				existing international data transfers was organised. As a result, a final report (focusing on the interactions with private third parties/contractual partners outside the European Economic Area) was prepared and sent to the EDPS within the assigned deadline. In addition to this, reports on a limited number of personal data breaches that occurred at the Agency were prepared and stored in the Agency's central registers, and notifications sent to the EDPS when necessary. Regular contacts with the EDPS, DG JUSTICE and DG SANTE's Data Protection Coordinator were intensified in the second half of the year in respect of topics such as secondary uses of health data, use of real-world data in regulatory activities and use of cloud-based platforms and software.
Further development of the implementation of the EU-DPR		Full implementation of the EU-DPR and monitoring of compliance *Expected to continue in 2020 (subject to resource availability)*	continuous	MAINTAINED Despite the current resource constraints, the implementation of the Regulation pursued by the DPO/Assistant DPO in all areas of the Agency continues. Data protection support and continuous consultation is provided in relation to all initiatives and activities involving the processing of personal data. Amongst the more time-consuming activities, we can quote the interplay of the EUDPR with the Agency's cloud strategy and workplace digitalisation, the development of Data Protection impact assessment (DPIA) concerning high-risk processing activities, the development of privacy statements and records, the data protection checks within procurement procedures (review and drafting of documentation, technical advice for selection, review of vendor compliance).
		Impact assessment, planning and follow-up of the implementation of the recommendations of the report on sartans.	100%	MAINTAINED Lessons learned report published in June 2020, implementation plan was agreed by HMA & EMA management board and published on 27 October 2020. The

Objective	MAWP initiative	Activity	% complete	Achievements/results
				implementation of the recommendations is an ongoing process.

In addition to the above, EMA responded ad hoc to EC queries on ERA, and contributed to inter-service group on request of EC SANTE.

1.2. Evaluation activities for veterinary medicines

1.2.1. Pre-authorisation activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 target	2020 result
Innovation Task Force briefing requests	7	5	6	5	5
Scientific advice requests received	17	25	21	17	31
Requests for classification as MUMS/limited market, of which	25	32	34	25	29
Reclassification requests	8	5	9	5	4

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Scientific advice procedures completed within set timeframes	100%	96%	95%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide support and incentives to development of new medicines for MUMS/limited markets	2.1-1	Publish annual report on MUMS/limited market activities	100%	MAINTAINED The MUMS report was published in March 2020.
		Revise existing MUMS guidance in line with new veterinary legislation provisions	75%	MAINTAINED Review of the MUMS data requirements guidelines is ongoing and drafts for consultations are foreseen to be published in Q1 2021. A reflection paper was drafted for establishing the criteria for eligibility for applications under Art.23 of the Regulation (EU) 2019/6, to be published for consultation in Q1 2021.
Promote innovation and use of new	2.1-5	Promote access to the Agency's Innovation Task Force through presentations to industry, and		SUSPENDED due to COVID-19 BCP The activity is planned to restart in 2021.

Objective	MAWP initiative	Activity	% complete	Achievements/results
approaches in development of veterinary medicines		as part of existing pre-authorisation procedures		
	2.1-6	Develop regulatory guidance and strategy for technologies that are innovative to veterinary medicine	100%	MAINTAINED The ad hoc expert group on veterinary novel therapies (ADVENT) met once in the first half of the year to progress and finalise the Q&A document on target animal safety for stem cell products, the Q&A were adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) at its July 2020 meeting and published on the EMA website.
		Finalise a reflection paper including an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials to control infectious disease in animals	75%	MAINTAINED The consultation period for the reflection paper ended on 30 April 2020, comments are under revision and the final document is expected by Q2 2021.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	2.1-5	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice	100%	REDUCED Promotion of parallel scientific advice in pre-submission phase is an on-going activity. Specific additional activities to increase awareness of this option have been suspended due to BCP.
Support development and availability of veterinary medicines	2.1-2	Review recommendations from the CVMP ad hoc group on veterinary vaccine availability (CADVVA) and agree on CVMP and working parties' actions		SUSPENDED
		Develop a reflection paper on promoting availability of veterinary vaccines in emergency situations		SUSPENDED This activity was not restarted in 2020 due to de-prioritization in favour of tasks related to Reg. (EU) 2019/6.
		Field efficacy trials guidance to be developed as follow up of recommendations from the Field efficacy trials focus group held in 2017	20%	REACTIVATED The activity re-started in Q4 2020. A concept paper for the revision of the guidance on veterinary field trials and on indications for veterinary vaccines has been released for consultation. The CVMP Immunologcal working party is currently working on the revision of the guidance.

Objective	MAWP initiative	Activity	% complete	Achievements/results
	2.1-4	Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities	100%	MAINTAINED Following Brexit BCP suspension, the activity has been resumed in Q1 2020. There were no requests received in the first part of 2020.
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.
		Finalise revision of note for guidance on DNA vaccines non amplifiable in eukaryotic cells for veterinary use		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.
		Finalise concept paper and start revision of SmPC guideline for anthelmintic		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.

1.2.2. Initial evaluation activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Initial evaluation applications	17	15	23	18	15
New MRL applications	3	3	3	3	1
MRL extension and modification applications	3	2	4	1	1
MRL extrapolations	0	0	0	0	0
Art. 10, Biocides	0	0	0	0	0
Review of draft Codex MRLs	0	5	0	5	3

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Procedures completed within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality and consistent scientific outputs of the EMA	2.2-7	Evaluate training material on revised guideline, procedures and templates for CVMP assessment reports and provide training on these with emphasis on benefit-risk		SUSPENDED This activity is now superseded by training needs arising from the new veterinary regulation implementation.
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	2.1-8	Finalise, in collaboration with ECHA and the EC, the procedure for the establishment of MRLs of biocidal substances used in animal husbandry, included in the 10-year review programme (long-used substances)		MAINTAINED The European Commission is leading reflections/discussions on the procedure for the establishment of MRLs for biocides, with particular focus on the workshare between EMA and European Chemicals Agency (ECHA) within the procedure. The reflections/discussions continue at EC level. The Agency will only progress on this once the EC has concluded on the issue.
	2.1-8	Cooperate with ECHA and EFSA to harmonise assessment methodologies for MRLs (including consideration of international approaches) WP2020	40%	MAINTAINED The dedicated expert group had seven teleconferences from January to November 2020, to compare the models used by CVMP, EFSA for feed additives, and Joint FAO/WHO Expert Committee of Food Additives (JECFA). An intermediate feedback was provided to CVMP in July 2020. The report of the expert group was circulated to CVMP in December 2020. In July 2020, the Agency received also an official request from EC to produce a joint report with larger scope by July 2022 (then amended to November 2022). An enlarged expert group with larger EFSA representation was established in December 2020 to continue the work under the EC mandate.

1.2.3. Post-authorisation activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Variations applications, of which:	454	560	568	401	637
Type IA variations	238	331	356	206	380

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Type IB variations	130	137	139	135	195
Type II variations	86	92	73	60	62
Line extensions of marketing authorisations	5	1	2	3	2
Transfers of marketing authorisations	3	17	24	5	9

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Post-authorisation applications evaluated within legal timeframes	100%	99.9%	100%	100%	100%

1.2.4. Referrals

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Arbitrations and Community referral procedures initiated[1]	1	5	9	6	3

[1] A significant proportion of referrals provided substantial complexity and related to a large number of products (>100 products).

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	100%

1.2.5. Pharmacovigilance activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Periodic safety-update reports (PSURs)	161	158	159	160	160
Total adverse-event reports, of which:	50,885[1]	66,844[1]	70,392	70,000	66,901
Adverse-event reports (AERs) for CAPs	26,671	35,835	33,656	35,000	30,297
Adverse-event reports (AERs) for NAPs	24,214	31,009	36,736	35,000	36,604

[1] As in 2017, there has been a significant increase (30%) in the number of AERs received in EudraVigilance. An organic year-on-year growth is expected due to the increased number of centrally authorised VMPs. In addition, during the last two years, an increase of voluntary submission by MAHs of non-serious reports is noted and, particularly in 2018, voluntary electronic reporting of non-serious adverse events from some non-EU countries (50%) was determined by MAHs implementing the CVMP revised recommendation for the basic surveillance of EVVet data for CAPs.

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	PSURs evaluated within the established timelines	98%	99%	96%	90%	98%
	Adverse event reports for CAPs monitored within the established timelines	98%	98%	95%	95%	97%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	2.2-5	Organise dedicated focus groups with specialised veterinarians/healthcare professionals to obtain further detailed insight on key aspects to improve pharmacovigilance reporting, and feedback for further development		SUSPENDED The activity has been postponed to 2021 due to the need to redeploy resources to the new veterinary regulation tasks.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	100%	MAINTAINED The Veterinary pharmacovigilance bulletin was published in May 2020.

1.2.6. Other specialised areas and activities

Workload indicators

Procedure		2017 result	2018 result	2019 result	2020 forecast	2020 result
	n/a					

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Plan for and implement the revised veterinary legislation	2.2-2	Revise business processes to fit the new veterinary legislation provisions	20%	MAINTAINED Preparatory discussions are ongoing, the main part of the activity will be developed in 2021.
		Develop new guidance and revised existing one to support new procedures and processes for the new veterinary legislation	30%	MAINTAINED Coordination activities to distribute the tasks are ongoing and priorities have been assigned.
		Develop and implement new IT systems required by the new veterinary legislation	60%	MAINTAINED The projects concerning the Union Product Database and the Union Pharmacovigilance Database have been initiated including establishment of the governance structure and are progressing on time and on scope using agile development methodology.
	2.2-9	Provide technical support to the European Commission in drafting delegated and implementing acts specified in the new veterinary legislation	85%	MAINTAINED The following recommendations were submitted to the European Commission in 2020: - Format for collection of data on antimicrobial medicinal products used in animals; - Implementing measures on veterinary medicinal products regarding Good Pharmacovigilance Practice; - Format and content of Pharmacovigilance System Master File and its summary; - Measures on Good Distribution Practice for veterinary medicinal products; - Measures on Good Distribution Practice for active substances used as starting materials in veterinary medicinal products. - Scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed. Responses to two additional requests for scientific advice in relation to AMR will only be finalised after the publication of a related delegated act, on request of the

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Commission.
Support increased availability of veterinary medicines	2.1-3	Consider regulatory tools to implement recommendations of pilot project on the harmonisation of old veterinary antimicrobials (PPHOVA)	100%	REACTIVATED The activity restarted in Q3 2020. The reflection paper on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics (SmPC) harmonisation was published in July 2018 for public consultation ending in January 2019, comments were received from 5 stakeholders. After a period of suspension due to redeployment of resources to priority matters, the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) authors have finalised the reflection paper which has adopted by CVMP at its December 2020 meeting.
	2.1-11	Finalise a reflection paper on resistance in ectoparasites		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	80%	MAINTAINED EU comments on the draft guidelines were provided in March 2020. A second round of comments was requested in November 2020, these updated comments are expected to be finalised in January 2021
		Follow up on recommendations of the reflection paper on anthelmintics resistance		SUSPENDED This activity has not been restarted in 2020 due to de-prioritisation in favour of tasks related to Reg. (EU) 2019/6.2020.
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	100%	MAINTAINED The task force met five times in 2020 to supervise and progress the actions of the thematic working groups.
	2.4-9	Contribute to the considerations of the proposals for the joint HMA task force on availability at the European Surveillance Strategy group for the perspective of CAPs, as part of developing systems to facilitate	35%	MAINTAINED The preparation of the Terms of Reference of the pilot for the implementation of the guidance for MAHs on product shortage detection and notification and the preparation of the Terms of Reference of the pilot for NCAs

Objective	MAWP initiative	Activity	% complete	Achievements/results
		management of shortages and ensure the adequate supply of essential veterinary medicines		for the use of product shortage metrics were put on hold due to the COVID-19 outbreak. A report following a survey on withdrawal notifications was finalised in 2020. The second phase of the pilot on the SPOC system for products availability has been currently delayed due to the COVID-19 outbreak; however, the newly created SPOC network was activated by the COVID-19 crisis.
Provide high-quality and consistent scientific outputs	3.2-15	Finalise revision of guideline on summary of product characteristics for antimicrobials	80%	REACTIVATED The activity restarted in Q4 2020, the finalisation of the guideline is expected for Q2 2021.
	2.2-7	Revise training needs of the veterinary network and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity	60%	MAINTAINED The veterinary training coordination group met in July and December 2020. The training needs were assessed and a plan for training courses for 2021 was developed. The curriculum leads continued their work on the development and preparation of training courses for 2021 and 2022. Due to the COVID-19 crisis, all veterinary face-to-face training courses in 2020 have been postponed. A series of 5 webinars on quality was delivered in October 2020. It was decided to run the other planned courses in 2021 (a conversion to online webinars may be required) and in 2022.
Promote uptake of harmonised standards at international level	4.2-6	Contribute to training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	100%	MAINTAINED EMA developed and delivered two training presentations on registration of antimicrobial products and the use of VICH GL27, as well as contributing to the review of training slides on VICH GL39 and a training document on setting withdrawal periods. All training sessions are available on the VICH website.
	4.2-5	Continue dialogue with international risk assessment bodies with a view to increasing harmonisation of scientific approaches and methodologies for the establishment of MRLs		MAINTAINED No further topics for discussion were identified for this year.
Contribute to	2.4-4	Finalise the reflection paper on	90%	REACTIVATED

Objective	MAWP initiative	Activity	% complete	Achievements/results
minimising the risk to man and animals from the use of antibiotics in veterinary medicine		extended-spectrum penicillins		The activity was resumed in Q2 2020. The reflection paper was discussed by the CVMP Antimicrobial working party in four meetings and is expected to be finalised by Q1 2021
	2.4-3	Finalise report on stratification of sales data per species as part of the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals	75%	REACTIVATED The activity re-started in Q4 2020. The first draft of the report was prepared in the first half of 2020 and available data from this project have been used for the validation of technical estimates of AMR sales for pigs and poultry as used in the JIACRA third report. The final report, subject to availability of resources, will be finalised in Q1 2021
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	100%	MAINTAINED The 'Reflection paper on the harmonisation of the reporting of consumption of antimicrobials' is carried over for delivery under the draft Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) strategic plan for 2021-2025 and is to be finalised in 2021. The Agency organised three TATFAR meetings in 2020 in relation to this reflection paper and participated in two TATFAR plenary meetings.
	1.1-3	Contribute to implementation of the next phase of the EC action plan on antimicrobial resistance, the WHO global action plan, OIE strategy and other action plans (such as the G8)	100%	MAINTAINED The One Health Network meeting, scheduled for March 2020, was cancelled due to COVID-19 crisis and no virtual alternative was organised. EMA participated virtually in three meetings of the OIE AMR working group, which met in April, June and October 2020, and its subgroup on poultry in June and October 2020, which delivered a poultry-specific review of the OIE list of antimicrobials of veterinary importance. EMA also attended the One Health EJP Stakeholder Committee meeting that met virtually in May 2020. Virtual meetings were held with the OIE to support the development of an OIE database on antimicrobial use.
	2.4-2	Refine and continue data collection on the consumption	100%	MAINTAINED Data for 2018 were submitted and

Objective	MAWP initiative	Activity	% complete	Achievements/results
		of antimicrobials in veterinary medicine and publish the outcome in the ESVAC annual report		validate by June 2020. The 10th ESVAC report was drafted and MS consulted in July 2020. The report was published in October 2020.
	2.4-5	Finalise, in cooperation with EFSA and ECDC, the third report on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals	80%	MAINTAINED The JIACRA group met several times virtually in 2020 to progress the work on its third report. Due to the ongoing COVID-19 crisis and its impact on resources, ECDC, EMA and EFSA requested to the EC an extension of 6 months of the original deadline for the submission of the report. The report is foreseen to be published in June 2021.
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	Finalise reflection paper on higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome	10%	REACTIVATED The activity re-started in Q4 2020 and the reflection paper is foreseen to be published in July 2021.
		Draft a concept paper as starting point for a guideline development on the potential risks associated with the use of veterinary medicinal products in aquaculture		SUSPENDED The activity is scheduled to re-start in March 2021. The finalisation of the concept paper is foreseen for December 2021.
	2.4-6	Reflect on a methodology that could be used to better characterise the exposure to the environment following the use of veterinary medicinal products containing PBTs		SUSPENDED
	2.4-8	Provide advice to the European Commission to assist the implementation of their strategy on managing pharmaceuticals in environment	100%	MAINTAINED Advice to EC is provided as needed.

1.3. Horizontal activities and other areas

1.3.1. Committees and working parties

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Number of reimbursed meetings	529	408	321	488	52
Committee meetings[1]	76	76	76	76	75
Training	30	29	29	14	4
Workshops	32	35	4[2]	15	2
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	396	273	212	388	112
Number of virtual meetings (audio-, video- and web-conferences)	4,802	4,793	3,443	5,000	5,409
Number of reimbursed delegates	8,743	7,214	6,015	9,182	1,003
Number of non-reimbursed delegates	1,464	1,064	523	1,500	60

[1] Indicator updated to include Management Board meetings
[2] 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

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Percentage of delegate satisfaction with meeting support service	n/a[1]	n/a[1]	n/a[1]	85%	n/a[2]
Up-to-date electronic declarations of interests submitted by committee members and experts, prior to participating in a committee, SAG or other meeting	100%	99%	100%	99%	100%
First-stage evaluations of competing interests for committee members and experts completed prior to their participation in the first meeting after the submission of a new or updated declaration of interests	100%	100%	100%	100%	100%
Ex-ante verifications of declarations of interests for new experts completed within two weeks after upload of the DoI in the experts' database	99%	100%	100%	96%	100%

[1] As of 2017, delegate survey is being aligned with the annual delegate survey conducted by the Scientific Committees Service of the Agency. However, as this service did not conduct a survey in 2017, no delegate satisfaction survey was conducted in 2017.
[2] Due to the BCP situation giving rise to predominantly virtual meetings, the survey was not launched in 2020.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-1	Support the activities of the HMA Regulatory Optimisation Group (ROG) to simplify and optimise Regulatory operations		SUSPENDED The activity is planned to restart in 2021.
Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Finalise the regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines and translate to implementation phase	100%	Completed. The Regulatory Science Strategy has been translated into European Medicines Agencies Network Strategy and EMA Multi-annual work programme 2021-2024.

1.3.2. Inspections and compliance

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
GMP inspections	314	332	386	220	130
GLP inspections	0	1	0	1	0
GCP inspections	136	140	137	135	59
Pharmacovigilance inspections	15	20	9	14	16
PMF inspections	83	84	111	65	40
Notifications of suspected quality defects	161	147	175	200	170
Notifications of GMP non-compliances[2]	23	25	19	20	10
Number of medicinal products included in the sampling and testing programme	58	53	67	70	81
Standard certificate requests	4,023	3,703	2,565	3,500	3,115
Urgent certificate requests	531	1,069	2,399	1,500	1,647
Parallel distribution initial notifications received	2,639	2,304	2,468	2,300	3,172
Parallel distribution notifications of change received	1,975	2,184	2,103	2,100	[3]
Parallel distribution notifications of bulk change received	6	11	12	15	10
Parallel distribution annual updates received	3,798	5,245	4,270	5,500	11,624

[1] PMF inspections included in GMP inspections results.
[2] Previously: 'Other GMP inspections related notifications'
[3] Included under "Parallel distribution annual updates received".

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%
	Standard certificates issued within the established timelines	64.2%	0%[1]	28%	90%	80%
	Average days to issue standard certificate	10.3	27.3[1]	59.6[2]	10	23.6
	Urgent certificates issued within the established timelines	100%	99%	97%	100%	98%
	Parallel distribution notifications checked for compliance within the established timeline	96%	97%	37%	90%	90%
	Additional GCP inspections addressed through information exchange on inspections carried out by international partners	39%	38%	42%	35%	38%
	Outcome reports of the sampling and testing programme for centrally authorised products, followed up with the MAH within one month of receipt	100%	100%	100%	100%	100%

[1] Average processing time increased from 10 to over 60 days during the second half of 2018, creating a backlog due to increased shortage of staff through long-term leave and internal mobility to priority areas, together with an increase in requests on Brexit-related variations of the marketing authorisation.
[2] Average processing time remained significantly higher than the target in 2019 due to continuous staff shortages and backlog issues. Actions were taken during the year to remedy the issues and reduce processing time, which by November 2019 had reduced to 30 days on average.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	4.3-2	Strengthen collaboration with trusted international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan), on GCP and pharmacovigilance compliance and inspections activities in areas of interest	continuous	REDUCED The activity is limited to exchange on product specific issues. In the context of the pandemic and of the evaluation of COVID-19 products, collaboration with other regulators have increased. Routine exchanges have been strengthened with international partners: US-FDA, WHO, Canada and Japan; specific confidentiality agreements were signed in order to exchange Inspection Reports for Covid-19 products with Argentina, South Africa, Brazil, Peru and Mexico.
	4.1-5	Enhance cooperation with member states in co-ordinating third country inspections	continuous	MAINTAINED Cooperation with member states in co-ordinating third country inspections has been enhanced. Flexibilitites and distant assessment procedures have been put in

Objective	MAWP initiative	Activity	% complete	Achievements/results
				place to faciliate GMP verification of API and finished product manufacturers during the COVID-19 pandemic. Additionally, increased oversight of manufacturers has been fostered by participating in the API programme and the sterile finished product pilot programme, recently extended to cover manufacturers of vaccines.
Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-14	Provide regulatory support to the work of the EU Observatory, to facilitate the transition from high-enriched uranium to low-enriched uranium	continuous	REDUCED This activity is limited to exchange on product specific issues. Participation to the 22nd EU Observatory meeting (September 2020).
	1.1-20 1.1-12 1.1-11	Support and collaborate with the EMA/HMA task force on the availability of authorised human and veterinary medicines	continuous	MAINTAINED The EU Executive Steering Group on shortages caused by major events was established in March 2020 and there were a total of 24 meetings in 2020. The group met every week, also with industry associations, to provide strategic leadership for urgent and coordinated action to prevent and mitigate supply disruptions within the EU during the pandemic.
		Support the implementation of the agreed Work Plan of the EMA/HMA task force on the availability of authorised human and veterinary medicines and provide the secretariat for the task force	continuous	SUSPENDED due to COVID-19 BCP During the December 2019 meeting, HMA agreed to extend the mandate of the group for further 3 years. Workplan has been reviewed and the plan output has been postponed to Q1/Q2 2021 due to COVID-19 impact and lack of EMA resources. Some progress has been made on the review of the workplan and on the Good practice guidance for patients and healthcare professionals on the prevention of shortages.
		Support the operation of the Single Point of Contact system and provide the secretariat for the system	continuous	SUSPENDED due to COVID-19 BCP
Improve application of equivalent	4.2-1	Support training activities in India and China, including establish a panel of European		SUSPENDED The activity has not restarted in 2020 due to the pandemic.

Objective	MAWP initiative	Activity	% complete	Achievements/results
standards of good manufacturing and clinical practice throughout the world		inspectors available to participate in capacity-building workshops in these countries		
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors from international regulators		SUSPENDED The activity is currently suspended due to the COVID-19 pandemic implications.
Expand work-sharing and mutual-reliance initiatives	4.3-1	Coordination of Joint Audit Programme in support to the implementation and extension of the EU US MRA	Continuous	MAINTAINED The JAP activities continued but audits were significantly delayed due to COVID-19. The audit of the Romanian veterinary GMP inspectorate was performed in January 2020 as planned. Audits of the following human (h) and veterinary (v) GMP inspectorates were postponed to 2021/2022: Cyprus (v), Czech Republic (h), Germany (h+v), Greece (h+v), Hungary (h), Slovakia (v) and Slovakia (h). Also, the audits of the pre-accession countries Serbia and Montenegro had to be postponed due to the pandemic.

1.3.3. Partners and stakeholders

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Requests for SME qualification	582	487	536	597	518
SME status renewal requests	1,185	1,334	1,235	1,613	1,205
Number of cases of patient/consumer engagement[1] in EMA activities	950	493	769	550	594
Number of cases of healthcare professionals engagement[1] in EMA activities	450	212	212	200	176[2]
New scientific, regulatory and telematics curricula developed	8	2	2	2	2
Number of training events advertised to the EU Network	140	60	40	60	46
Number of reimbursed training events to the EU Network	25	8	12	15	1
Number of messages circulated via 'Early	380	440	411	440	612

Procedure		2017 result	2018 result	2019 result	2020 forecast	2020 result
	Notification System'					
	Number of EMA communications pro-actively sent to stakeholders	172	175	128	175	178
	Number of EPAR summaries and EPAR summaries updates published	283	343	286	300	297
	Number of summaries of orphan designation published	240	169	117	150	154
	Access to documents, requests received	823	822	783	900	597
	Access to documents, documents released	2,876	2,422	1,429	2,700	1,024[3]
	Requests for information	4,843	7,554	7,200	7,500	7,055[3]
	Number of documents published on the EMA corporate website	7,369	4,840	9,012	7,000	5,963
	Number of pages published and updated on the EMA corporate website	4,790	6,307	3,383	4,000	2,511
	Number of press releases and news items published	187	183	143	150	217
	Requests for interviews and comments by media representatives	2,149	1,517	1,476	1,000	1,770
	Number of reports, brochures and leaflets produced	25	85	206	30	357

[1] 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.
[2] Revised 2020 final figure
[3] 2020 figure updated from dataset completed in February 2021

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Satisfaction level of patient and consumer organisations	n/a	n/a[1]	n/a[1]	95%	90%
	Satisfaction level of healthcare professional organisations	n/a	n/a[1]	n/a[1]	95%	92%
	Satisfaction level of SMEs	93%	95%	n/a[1]	80%	89%
	Responses to ATD requests provided within set timelines	96%	96%	89%	92%	90%
	Responses to RFI requests provided within set timelines	98%	97%	96%	97%	82%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	81%	85%	84%	80%	83%
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	8	7	10	10	7
	Number of users registered to the EU NTC	3,583	4,424	5,121	5,100	5,290

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Learning Management System					
	Number of NCA experts registered to the EU NTC learning management system	2,668	3,480	3,143	4,100	4,297
	Satisfaction level of partners/stakeholders with EMA communications	82%	n/a	n/a	80%	78%
	Average rating of pages on corporate website during the year	3.3	3.1	3.4	3.3	3.4

[1] Due to BCP next survey expected in 2020

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Strengthen stakeholder relation focusing on patients and consumers, healthcare professionals, industry associations and academia	1.3-3 3.1-7	Implement a framework for collaboration with academia with respect to human medicines and consider the need for any specific adaptations to the framework with respect to veterinary medicines	75%	REACTIVATED Proposal for internal academia collaboration matrix presented to EXB and Academia collaboration first meeting held. Action plan to be developed and presented to EXB for endorsement in Q1 2021.
	3.4-6	Publish annual report on EMA interactions with industry associations	100%	REACTIVATED The 2018-2019 biennial report was presented to MB in Dec 2020.
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals and their organisations	100%	REACTIVATED The 2018-2019 stakeholders engagement biennial report was presented to MB in Dec 2020
	3.4-5	Participation in CIOMS Working Group XI-on patient involvement in clinical development and safe use of medicines	80%	MAINTAINED Draft Council for international Organisation of Medical Sciences (CIOMS) guidance was produced at the end of 2020. Work from the editorial review group is ongoing. Publication expected Q1/Q2 2021.
Further develop support to, and strengthen stakeholder relations with SMEs	1.3-8	Implement action plan arising from 10-year report on the implementation of the SME Regulation	100%	Completed.
Further strengthen Agency's transparency and	1.4-5	Plan the relaunch of clinical data publication		SUSPENDED The activity remains suspended in 2020, with the exception of the relaunch in Q4 2020 for products targeting COVID-19

Objective	MAWP initiative	Activity	% complete	Achievements/results
open data commitments				pandemic. The first publication for COVID-19 product was at the end of October 2020 for Veklury (remdesivir).
		Hold regular discussions in the technical group on anonymisation of clinical data		SUSPENDED The activity remains suspended in 2020, subject to BCP.
	1.4-5 1.4-6 1.4-7	Agree draft principles of transparency		SUSPENDED The activity remains suspended in 2020, subject to BCP.
Ensure a more optimal organisation of the available expertise within the network for services provided to EMA	3.1-5	Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation	ongoing	MAINTAINED In the urgent timeline of the REMDESIVR assessment, CHMP used the MNAT approach for the quality part of the assessment. Furthermore, MNAT use continues to be monitored, in particular for COVID-19 products, to identify any necessary adjustments needed for more effective implementation.
	3.1-6	Implement the second phase (2020) and launch the third phase (2021) of the multinational assessment team approach post-authorisation		SUSPENDED due to COVID-19 BCP The second phase implementation is planned to restart after COVID-19 BCP, unless required earlier in context of COVID-19 assessment (situation is being monitored through COVID-19 WS3).
Ensure 'fit-for-purpose' scientific capability of the Network	3.1-1	Identify emerging topics and gaps in expertise which require action to increase capability of the EU Network		MAINTAINED No activity developed in 2020.
		Develop in collaboration with the Network, the EU Medicines Agencies Network Strategy to 2025	100%	Completed. The European Medicines Agencies Network (EMAN) Strategy to 2025 was finalised and published on both EMA and HMA website on 8 December 2020
		Develop the Regulatory science observatory with a collaborative methodology to contribute to the EU Medicines Agencies Network Strategy to 2025		SUSPENDED
	3.1-3	Work with the Network to prioritise training needs	80%	MAINTAINED During 2020, 46 new courses were made available in the EU NTC LMS, including 8 webinars and 37 online courses, across a wide variety of topics, including Quality, Pre-Clinical, Oncology,

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Pharmacovigilance, Regulatory, and Herbal areas. Discussions were also held in the context of the Veterinary Co-ordination Group, concerning training needs in the Veterinary area. A project was initiated for the development of e-learning on a key biostatistics guideline.
	3.1-2	Review and update existing curricula to ensure provision of up-to-date training	80%	MAINTAINED In the first half of 2020, work continued on the review of recommended areas of training in existing curricula to ensure that these reflect prioritised needs and with the Network to develop training in these areas, as well as instigating curricula in new areas to deal with emerging challenges from advances in science and technology. This included discussion on: i) the development of training in the GCP and Bioequivalence Inspections areas; ii) curricula in the area of Big Data (including Data Literacy and Biostatistics); iii) Regulatory Science Strategy topics; iv) involvement in clinical trials information systems (CTIS) training; v) Roadmap for Digital Academy. A meeting of EU NTC stakeholders, including Curriculum Steering Group leads, was held in November 2020, with Curriculum leads encouraged to review current curriculum frameworks and to identify upcoming training needs. This will be further progressed in 2021. Preliminary discussions also took place on the development of training curricula on Data literacy, Medical devices and Veterinary Environmental Assessment.
	1.3-8	Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency		REDUCED The activity is reduced to observer status.
		Foster the visibility and activities of the EU Innovation office network to ensure effective and harmonised		SUSPENDED The activity is planned to restart in 2021.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		support to early innovators at local and European level		
Increase awareness on the evolution of the regulatory framework	1.3-8	Identify in cooperation with the EU Innovation office network and the scientific committees priority areas (therapeutic areas, technologies, other) for which there is a need to develop communication tools, such as regulatory guidelines, white papers, publications in peer review journals etc.	100%	REACTIVATED Reports on Artificial intelligence and Genome editing finalised and delivered. Plan for publication of entire reports series developed.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency .work, outputs and medicinal products	3.3-10	Improve EMA's crisis communication by drafting and testing a crisis communication plan	80%	SUSPENDED Despite the activity being suspended in the context of the COVID-19 pandemic:- a crisis plan was developed and adjusted on an ongoing basis; - a document setting out the communications approach was prepared; - daily COVID-19 communications coordination meetings set up and held; - COVID-19 communication log established and used as the main planning tool; - streamlined and shortened approval processes; - regular review meetings are taking place to review crisis communication strategy; - regular contacts kept with ECDC, EC, NCA communication groups; - COVID-19 communications log established and used as the main planning tool; - streamlined and shortened approval processes.
	3.3-7	Carry out an EMA perception survey to better understand communication opportunities and challenges, and review the Agency's communication products and tools as per the results of the survey	80%	REACTIVATED Survey run and preliminary analysis of the findings carried out. The preliminary analysis will be presented in a summary form.
	3.3-3	Improve the corporate website by adding new tools and features, such as tools to improve search, search-engine	100%	Completed. Website accessibility and quality-management tool agreed and purchased

Objective	MAWP initiative	Activity	% complete	Achievements/results
		optimisation, accessibility, analytics and others		for an initial one-year trial period.
	3.3-1	Develop and implement a five-year EMA Communication Strategy	80%	REACTIVATED In Q1 2020, a plan for collection of necessary background information was developed and building blocks for the framework strategy were identified. Three cross-Agency workshops were carried out and overall goals were identified. The communication strategy is to be finalised in Q2 2021.
		Develop and implement an annual communication plan, in line with the framework strategy for external communication	100%	MAINTAINED The annual communication plan was developed and completed in 2020
	3.3-4	Continue development and implementation of a social media strategy, including consolidate social media channels and grow followership	50%	SUSPENDED The activity remains suspended in 2020, subject to BCP.
	3.3-5	Develop new digital and multimedia communication tools	75%	SUSPENDED The activity is planned to restart in 2021. Despite the activity being suspended: - Annual report 2020 was developed in a new digital format; - visuals for social media and sliders were systematically developed and published with at least 80% of news announcements; - a range of visuals to explain the development, evaluation, authorisation and post-authorisation monitoring of COVID-19 were developed and published; - work to strengthen visual identity to help streamline creation of visual content has begun.
	3.3	Support open access publication of relevant scientific articles	100%	MAINTAINED 19 articles provided as open access.

1.3.4. International activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
Interactions with FDA	654	584	454	700	644
Interactions with PMDA/MHLW	138	122	96	200	132
Interactions with Health Canada	91	175	125	700	224
Interactions with any other stakeholders	498	734	506	700	866
Number of information and/or document exchanges	929	920	461	900	988
Number of teleconferences organised	166	172	142	150	235
ICMRA executive committee and full membership TC	n/a	n/a	n/a	10	52
International stakeholders' visits (fellowships, experts, observers)	n/a	n/a	n/a	25	1
Organisation of International awareness sessions	n/a	n/a	n/a	2	0

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Reliance: Ensure best use of resources through promoting mutual reliance and work-sharing	4.2-3	Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators	100%	REDUCED Activity limited to product specific issues only. - WHO workshop (11 March 2020 , Geneva) on the European Union Article 58 procedure and the Swissmedic Procedure for Marketing Authorisation for Global Health Products (MAGHP). - Follow-up EU-M4all products (liaising with experts, WHO, applicants): Dapivirine vaginal ring, Dengue vaccine, Dolutegravir, Bivalent oral poliomyelitis vaccine and arpraziquantel (Scientific Advice). - Parallel application for EU-M4all (Article 58) opinion and centralised procedure Marketing Authorisation (in progress). - Interacting with WHO (e.g. in the process of expert/observer's nomination),

Objective	MAWP initiative	Activity	% complete	Achievements/results
				with concerned regulators from different National Regulatory Authorities and internally with EMA colleagues from other departments (e.g Product lead of EU-M4all medicinal products). - Promote parallel applications for EU-M4all scientific opinion and centralised marketing authorisation procedure. Public consultation on guidance for parallel application launched. First parallel application expected in March 2021. Training to WHO experts/NRA observers organised (to be delivered in Feb 2021).
Communication: Promote convergence of global standards and contribution to international fora	4.2-8	Provide assistance to candidate countries, to align their standards and practices with those established in the European Union, and to further foster their integration process. Active participation in international fora and communication to stakeholder, including but not limited to ICDRA, DIA, ICH, IPRP.	80%	REDUCED - ICDRA meeting has been postponed - Regular interactions with DIA - Collaboration ICMRA/ICH on quality management - Nitrosamines M7 discussion ongoing
		Support ICH GCP Renovation process by participation in ICH E8 and ICH E6 revisions as Regulatory chair	80%	MAINTAINED ICH E8 expected to be finalised in Q2 2021, ICH E6 academic stakeholder engagement initiated, academic stakeholder representatives began meetings with the expert working group and commenting on shared text of the ICH E6 principles. Overall progress slightly slower due to lack of face to face expert working group meetings
		Establish platform for EU ICH governance	5%	SUSPENDED The activity is planned to restart in 2021
Collaboration/supply chain: Improve application of equivalent standards of good manufacturing and clinical practices	4.2-2	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	50%	REDUCED - EU and FDA compiling catalogue of GxP training involving or regarding India, including scientific and regulatory conferences. EMA reaching out to MS on events, priorities, also to Japan, WHO, European Directorate for the Quality of Medicines & HealthCare (EDQM) and Pharmaceutical Inspection Co-operation

Objective	MAWP initiative	Activity	% complete	Achievements/results
throughout the world				Scheme (PIC/S). BCP on hold. - GCP/PhV Inspections taking place outside the EU are announced to local regulators, giving the possibility to observe the inspections.
Collaboration/supply chain: Assure product supply chain and data integrity	4.1-1	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	90%	REDUCED The activity is limited to support the topic lead. The working group has finalised a draft document on technical recommendations to allow interoperability of Track&Trace systems globally, which was adopted and published on the ICMRA website in November 2020, for public consultation ending on 28 February 2021.
Collaboration/capacity building: Support training and capacity building of non-EU regulators	4.4-2	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		SUSPENDED
		A meeting/training related to IPA will be organised at EMA in November 2020.	100%	MAINTAINED The first 2-day virtual training for candidate countries and potential candidates (basic level) was successfully held on 17-18 October 2020. In addition to those countries (about 200 participants), staff from EU NCAs participated (about 100 participants). Programme for the second training (advanced) has been developed. It will be organised in Q1 2021, subject to availability of resources due to the persistence of the pandemic.
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	50%	REDUCED Training webpages with update
		In collaboration with WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO		Completed

Objective	MAWP initiative	Activity	% complete	Achievements/results
		training platform		
Collaboration/capacity building:		Re-start of the International awareness sessions for regulators; Organisation of the Veterinary awareness session in April 2020		SUSPENDED due to COVID-19 BCP The activity is planned to restart in 2021. Veterinary awareness session postponed to 2021, but preparatory work completed
		Collaborating with EC/EMA to develop a joint long-term strategy for targeted and effective training programs on pharmaceutical GMP/GCP in China and India.		SUSPENDED The activity is planned to restart in 2021
Communication:		ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA face to face meetings.	100%	MAINTAINED Regular activities: Executive Committee teleconference meetings held in 2020: 9 (including one with WHO Director-General) Plenary meetings in 2020: 1 COVID-19 dedicated ICMRA meetings: 1) ICMRA SARS-CoV-2 Vaccines workshop - 2 meetings 2) ICMRA COVID-19 Therapeutics workshop - 2 meetings 3) ICMRA COVID-19 Real Word Evidence workshop - 4 meetings; 4) ICMRA COVID-19 Policy Bi-weekly TCs - 18 meetings ICMRA COVID-19 Working Group - 16 meetings - Communication strategy agreed - Track & Trace interoperability recommendations issued for public consultation - Progress of the Innovation project (AI) - Multiple statements issued, including on vaccine confidence and AMR.
Core business:		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 and	100%	MAINTAINED - 8 guidance documents updated, including the International guidance for sharing documents and the one on Parallel Scientific Advice; - relaunch and publication of the 'International affairs highlights' newsletter, after the BCP period covering 18 months of AF-IA activities; - initial preparatory work for the

Objective	MAWP initiative	Activity	% complete	Achievements/results
		other international partners fellowships and expert visits		Veterinary awareness session planned to take place in April, but cancelled due to COVID-19 crisis; - work programme report on the overall 2019 activities; - organisation of 92 cluster meetings, teleconferences; - organisation of 6 missions (decrease due to COVID-19 crisis) - 67 documents redacted; - support to the organisation of all teleconferences involving the ICMRA secretariat, as well as other global teleconferences related to COVID-19
Reliance:		support EU and EU/MRA team meetings	100%	MAINTAINED upport extension of the MRA for veterinary products: - progress with capability assessments for single (veterinary only) Competent Authorities; - technical discussions with EU auditors and FDA CVM regarding EU audit of CVM/CAPA plan; - ongoing support to Member States, EMA MRA and FDA teams; - ongoing support to EC for establishment of a timeline/conditions for implementation of MRA for veterinary products. Support to MRA Human related activities: - preparatory work for recognition of third country inspections (surveys to MS and FDA completed; analysis ongoing); - preparatory work/discussions on pre-authorisation inspections - discussions on proposals for improvement of functioning of MRA Human (e.g. GMP compliance document). Support to organisation and follow-up of actions from Joint Sectoral Committee meeting in October 2020.
Collaboration/capacity building:		Collaboration in the establishment of the African Medicines Agency (AMA)	50%	MAINTAINED Participation in: 1) African Medicines Regulatory Harmonisation Partnership Platform Virtual

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Meeting i.a. on the AMA update (Feb.) and submission of B22 the proposal to further support harmonisation processes in Africa. 2) African Medicines Regulatory Harmonisation – Innovation in Regulatory Science – capacity building, the Role of National Regulatory Agencies in informing the African Union policy organs and update on AMA (June).

In 2020, activities were repurposed to support COVID-19 activities, among others, vaccines, shortages, paediatrics and pharmacovigilance, and to facilitate exchanges and ad hoc meetings for vaccines and therapeutics, in particular the development programme for remdesivir. In addition to the above, other activities carried out during the year related to facilitation of collaborative international activities (e.g. 'Open initiative' started in Q4 2020), the WHO Collaborative Registration, the WHO Prequalification Programme; the preparation to the CAPs ARs sharing with the South African Health Products Regulatory Authority; the international collaboration and contribution to the nitrosamines taskforce. Relevant exchanges were pursued with FDA concerning the COVID-19 pandemic, Parallel Scientific Advice for complex generics, BT/PRIME collaboration, pregnancy and breastfeeding.

1.3.5. Information management

Workload indicators

Procedure		2017 result	2018 result	2019 result	2020 forecast	2020 result
	Number of Telematics information services provided by EMA	23	25	25	25	25
	Number of ongoing Telematics IT projects where EMA is the delivery organisation	11	3[1]	3	3	5
	Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	6	5	8	8	8
	Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments		3	3	4	3

[1] The EudraCT Legacy project has been postponed due to the delays in the Clinical Trials programme, and the Safety reporting and the EU portal and clinical trials database projects have been merged into one project: Clinical Trial Information System, thus the number of ongoing Telematics IT projects have been reduced of 2 projects.

Performance indicators

Performance indicators related to core business		2017 result	2018 result	2019 result	2020 target	2020 result
	Satisfaction of EMA internal and external users (% satisfied or very satisfied)	94%	91.92%	80%	80.00%	93%
	Availability of corporate/Telematics IT systems and corporate website	100%	98.11%	98%	98%	98%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
n/a				

1.4. Support and governance activities

Workload indicators

Procedure	2017 result	2018 result	2019 result	2020 forecast	2020 result
n/a					

Performance indicators

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Posts on the Agency establishment plan filled	98%	98.3%	98.65%	98%	100%
Total TA staff recruited against vacant posts	15	29	36	24	51
Staff turnover rate (staff leaving against total no. of staff TA & CA)	4.1%	4.57%	7.25%	8%	4.81%
Time to fill position from vacancy notice to establishment of reserve list					
Standard procedure[1]	-[2]	-[2]	79% < 3 months	< 3 months	88% < 3 months
Medium procedure[1]	-[2]	-[22]	n/a	< 4 months	n/a[3]
Large procedure[1]	-[2]	-[2]	n/a	< 6 months	n/a[3]
Revenue appropriations implemented	96%	93.88%	96.29%	97%	104.30%
Expenditure appropriations implemented	93%	90.76%	98.56%	97%	98.83%
Payments against appropriations carried over from year N-1	89.9%	90.57%	94.94%	97%	95.49%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1	1%	1.23%	2.19 %	1%	4.62%
Title 2	11.8%	16.31%	10.79%	15%	20.71%
Title 3	28.1%	30.21%	29.16%	25%	31%
Payments made within 30 days' time	97.3%	97.04%	97.59%	98%	96%
Receivable overdue for more than 30 days (including provision for bad debts)	n/a	8.10%	7%	<10%	6%
Availability of Telematics/corporate IT systems and corporate website (% of time)	99.3%	98.11%	88.8%	98%	98%
Energy consumption (change in % per workstation)	-5%[4]	-3%[4]	n/a[5]	n/a[5]	n/a[5]
Water consumption (change in % per workstation)	+13%[4]	-7%[4]	n/a[5]	n/a[5]	n/a[5]
Paper consumption (change in % per workstation)	-13%[4]	-8%[4]	n/a[5]	n/a[5]	n/a[5]

Performance indicators related to core business	2017 result	2018 result	2019 result	2020 target	2020 result
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)	+13%[4]	-5%[4]	n/a[5]	n/a[5]	n/a[5]
Recyclable waste produced (change in % per workstation)	+10%[4]	-22%[4]	n/a[5]	n/a[5]	n/a[5]
Recycling rate (change in % per workstation)	-4%[4]	3%[4]	n/a[5]	n/a[5]	n/a[5]
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	n/a	-6%[4]	n/a[5]	n/a[5]	n/a[5]
Overall net CO2 emissions (per workstation)	n/a	-14%[4]	n/a[5]	n/a[5]	n/a[5]

[1] *Standard procedure*: for a specific post
Medium procedure: for more than one post but limited to one job profile
Large procedure: generic competitions across multiple divisions
[2] New indicator introduced in 2019 work programme.
[3] The distinction between medium and large procedure no longer applies
[4]Results only for premises at 30 Churchill Place in London, UK.
[5] Due to EMA relocation to Amsterdam (2019) and move from temporary to permanent premises (2019-2020), environmental performance indicators cannot be estimated. To provide meaningful environmental targets, at least one base year of gathering data with regular building occupancy is required and therefore it is envisaged that the new environmental indicators will be set up only for 2022.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	3.2-4	Develop and implement a framework for integrated planning and monitoring activities	65%	MAINTAINED The framework for integrated planning is developing together with its change management activities. The process started with the reshaping of the single programming document where activities have been divided in 3 pillars according to their nature. A first high level set of performance indicators focusing on output/outcomes has been identified. The next step in 2022 is to better review and refine the level of resources associated. The pilot project on Post-authorisation activities was successfully completed and will serve as the basis for the future time vs resources exercises in H division and possibly the rest of the Agency.
	3.2-5	Implement a competency management framework	80%	MAINTAINED Competency Framework, job grading, job titles have been reviewed; consultation with staff will follow in Q2 2021. Roll out of the competency framework and updated role descriptions will be in Q4 2021 as part of the Performance and

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Development programme.
		Digitalise HR-related processes (onboarding tool, appraisal, career development) and gradually replace the overall HR management system	100%	**Onboarding project:** - Business requirements signed off; - Onboarding tool was launched on 20th May for TA, CA and SNEs; - Onboarding tool was launched for interims and contractors on 1st June; - To-be processes completed; - Training guidance updated; - Onboarding portal published; - Cross-boarding analysis and configuration in staging finalised; - Onboarding for trainees was launch in July. Project completed: 100% **Performance and Development programme**: Digitalisation workstream was completed on 15 December. - Business requirements signed off; - Goals and Performance module was moved into production and went life 15 Dec; - Succession and Development module was moved into production and went life 15 Dec; - Change management and communication strategy have been signed off; - Training material was produced and delivered for phase 1 and planned and organised for phase 2 and 3. Project completed: 100% **E-signatures design project completed**: - stakeholder identification; - business requirements completed; - technology selection done; - POC launched for two final vendors and final solution has been chosen. to be implemented. Project completed: 100% **Urgent and massive notification system replacement**: Current massive notificaiton system was replaced at EMA after a technology selection and fast implementation of a new system allowing all EMA staff

Objective	MAWP initiative	Activity	% complete	Achievements/results
				mebers, contractors, interims and trainees to be notified when an urgent message needs to be communicated to everyone. Project completed: 100%
		Digitalise procurement and some reporting processes	100% for registration process and P2P 20% for Business Intelligence	MAINTAINED **Registration process** : Initial electronic application forms (eAF) registration in SIAMED has been automated for variations that represent 60% of appications in volume. 1 FTE could be redeployed. **Procurement to pay (P2P)**: The process has been reviewed, roles have been clarified and procudres drafted. Preliminary work for the selection of an appropriate tool has been done. This process will support the centralisation of procurement. **Business intelligence**: Business requirements have been gathered; the dashboard for procurement/contracts has been deisgned and BI technology put in place.
		Review project governance in line with Agile development approach	10%	REACTIVATED Work was reinitiated in Q4 2020 with Business Consultancy and Informantion Management Division. Workshops and steering committee to oversee the change will be impemented in Q1 2021.
		Implement improved delegate reimbursement, travel and accommodation booking process and tools		SUSPENDED The project was prematurely closed due to the selected technology proving inadequate to the Agency's needs and the challenges faced by the COVID-19 situation. The online booking tool, Cytric, developed through the travel agent was completed and, as soon as the COVID-19 restrictions allow, will be made accessible to the delegates.
Maintain high level of independence, integrity and transparency in all aspects of	3.1-8	Conduct the annual review of the Agency's handling of independence	100%	MAINTAINED Report 2018-2019 endorsed at MB meeting in March; implementation plan approved by MB in June; report published in June; all actions implemented; 3 policies revised (Experts, MB and staff);

Objective	MAWP initiative	Activity	% complete	Achievements/results
Agency's work				revised policy for experts and revised e-DOI form effective 1 Jan 2021.
		Implement the action plan of the anti-fraud strategy	100%	MAINTAINED The 2020 outstanding action on random checks to be performed at Division and Task Force level was performed by year-end. A brief summary of the results was reported to the Management Board at its December meeting, and the related reports will follow in Q1 2021. Each of the 9 random checks entailed a desk review of a specific, fraud-relevant process, as well as interviews with the responsible colleagues. The other actions for 2020 have a recurring nature (e.g. fraud risk assessment, continuous monitoring of effectiveness of the measures, etc.) and they were performed in the second half of 2020, as planned. No fraud concerns emerged from these actions; however, the AFO served one notification to OLAF in respect of the cybersecurity attack detected by EMA in December 2020. OLAF's decision-making process on this case is still ongoing.
Subletting arrangements of London premises		Manage subletting arrangements of London premises		MAINTAINED The Agency continued to manage the sub-let premises: - analysed and approved architectural modifications to the building - monitored construction and unrelease matters - managed VAT matters - managed procured contracts - one additional Licence to Alter was put in place for works on floors P, G and 1. - progress monitoring has been ongoing throughout the year Monitoring of sub-lessee payments in place. Negotiations to settle outstanding amount due to pandemic disturbance on-going per 31/12/20. Registration to HMRC in place and active as of 8 March 2020. One new specific contract, SC04, under FWC EMA/2015/48/IS put in place for tenant monitoring services. SC03

Objective	MAWP initiative	Activity	% complete	Achievements/results
				amended with an extension of construction monitoring to 31 August 2021 for continuity of services. New procurement of property advisory and consultancy services launched in December 2020

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.

Most significant issues discussed at the Management board in 2020 included:

- **COVID-19 pandemic and its implications:**
  - Revised Rules of Procedure of the EMA Management Board were adopted on 19 March to **enable meetings to be held virtually** and so that members could participate to the meeting through remote connection, so as to cope with situations of emergency, possibly coupled with the activation of the Agency's Business Continuity Plan (BCP) in compliance with internal guidelines. All virtual plenaries were successful and allowed the Board to take all the decisions necessary to the functioning of the Agency, including the nomination of the new EMA Executive Director by secret ballot, which took place by means of the EUSurvey platform provided by DG DIGIT.
  - The Management Board was informed and updated on the **COVID-19 Business Continuity Plan** aimed at safeguarding the Agency's core activities related to the evaluation and supervision of medicines during the pandemic and to ring-fence resources dealing with COVID-19.
  - EMA status reports on the **activities of the EMA COVID-19 Steering Group** (previously Taskforce) were given at each meeting, with the Board also informed of the first 'rolling review' of data on a **COVID-19 vaccine** in October.
- **Brexit:**
  - The Board received **updates on the EMA Business Continuity Plan for Brexit** (adopted in 2017) so providing an overview of the continuity of Agency's operations ahead of the UK's departure from the EU. Whilst still operating under the EMA's Business Continuity Plan for Brexit, the Agency invoked the COVID-19 Business Continuity Plan in response to the Agency's activities as a result of the COVID-19 pandemic.
  - The Board's concerns regarding the Agency's previous premises in London, continuously voiced in the past, were once again echoed in the 2019 Annual activity report as Emphasis of matter. The Board stressed its concern over the Agency, being an EU health agency, managing a commercial property in a third country diverting resources from its mission, including COVID-19 activities, and operating outside its remit.

Other significant items approved or decided by the Management Board in 2020 include:

- **Extraordinary Management Board meeting for nomination of the new Executive Director of the EMA**

The EMA Management Board nominated Emer Cooke as the new Executive Director of the Agency at an extraordinary virtual session on 25 June. The Board selected Emer Cooke from a shortlist of candidates created by the European Commission.

- **Final Management Board meeting of Guido Rasi at the helm of the EMA**

The October 2020 meeting of the Management Board was Guido Rasi's final Board meeting as EMA's Executive Director before the end of his mandate. The Chair of the Board, Dr Christa Wirthumer-Hoche, thanked Professor Rasi on behalf of the Board for his leadership of the Agency over the last nine years and for successfully charting the Agency's course through the challenges of the past few years. Guido Rasi's mandate as the Executive Director of the EMA ended on 15 November 2020.

- **Activities required by the Founding and Financial Regulations**

The Board's operational tasks include reporting on the use of the European Union contributions for the Agency's activities. In 2020, these activities involved:

  - adopting the assessment of the Executive Director's Annual activity report for 2019;
  - adopting the 2021-2023 Programming document, including the 2021 budget
  - adopting the EMA's annual report for 2019; and
  - delivering an opinion on the Agency's final accounts 2019.

- **Development of the Clinical Trials Information System for the EU Clinical Trials Regulation**

In March, the Board endorsed the Clinical Trials Information System (CTIS) audit methodology, enabling the process for the selection of the supplier for the audit of the system to commence. In June, the Board endorsed the methodology and next steps to further develop the CTIS 'go-live' plan.

Throughout the year, the Board was updated on the status of the ongoing development of the CTIS by means of monthly reports.

- **EU Telematics Management Board (EU TMB)**

A report on the activities of the EU Telematics is provided to the Board at each meeting by the EU TMB, a strategic governance body principally responsible for establishing the EU Telematics Strategy and providing strategic governance as to its implementation.

- **Internal audit and advisory activities at the European Medicines Agency**

In accordance with the Financial Regulation, and with the aim of ensuring effective co-ordination between various audit bodies, the Management Board received the strategic internal audit plan 2020-2022 by the Internal Audit Service in March.

In October, the Management Board adopted the revised Internal Audit Charter of the Audit Capability (Advisory Function-Audit) of the European Medicines Agency.

In December, the Management Board adopted the Audit Strategy 2021-2023 and the Annual Audit Plan for 2021.

- **Regulatory Science Strategy to 2025**

The Board endorsed in March the Regulatory Science Strategy to 2025, the plan for advancing engagement with regulatory science over the next few years. The strategy will be a key pillar of the

work of the Agency and the Network in the coming years and feeds into the development of the European medicines network strategy to 2025.

- **Tenth Annual Report: MUMS/limited market scheme for veterinary medicines**

The Board adopted the ten-year report on the MUMS/limited market scheme for veterinary medicines in March.

- **EMA 2018-2019 annual reports on independence**

In March, the Board endorsed the EMA 2018-2019 annual reports on independence followed by the adoption, in June, of a plan for implementing the recommendations set out in the said reports.

- **Updates on the presence of nitrosamine impurities in medicines**

At each meeting, the Board was updated on the exercise undertaken by EU authorities to determine what lessons can be learned from the presence of nitrosamines in medicines. In October, the Board endorsed a plan for the implementation of the recommended actions aimed at ensuring that regulators are better prepared to manage future cases of unexpected impurities in medicines.

- **Review of activities of EMA's working parties**

A set of high-level guiding principles and core recommendations for the review of activities of the Agency's working parties was adopted at its March 2020 meeting. At subsequent meetings, the Board was informed of steps taken to implement changes both in the veterinary and human areas.

- **Management Board Topic Co-ordinators Group on 30 Churchill Place**

Management Board representatives were nominated as Topic Coordinators for the Board to participate in a working group established between EMA, DG BUDGET and DG SANTE concerning the lease agreement of the EMA's former premises of the EMA in London, UK.

The board was kept updated on developments throughout the year, under conditions of strict confidentiality.

2.2. Major developments 2020

COVID-19 PANDEMIC

The outbreak of the COVID-19 global pandemic in early 2020 significantly changed not only the Agency's plans, but every aspect of life and business in general, shifting the global focus to safety, health and wellbeing on an unprecedented scale.

While it is impossible to foresee the full impact of this pandemic, it is clear it will be significant, multifaceted and long-lasting. Unlike Brexit, where the impact was mostly focused on maintaining seamless Agency operations during transition (i.e., executing the physical relocation and retaining staff to ensure Agency's ability to deliver its core activities), the COVID-19 crisis has changed the landscape in which the Agency operates. It affects not only the Agency, but also the whole European Medicines Regulatory Network (EMRN) – National Competent Authorities (NCA), the Commission, as well as the global health organizations and the world at large. Therefore, EMA has had to react to the impact of the pandemic in terms of the impact on the Agency, on the Network, and also on the international scale.

Business continuity management

Following the outbreak of COVID-19 global pandemic in the European Union in Q1 2020, the Agency invoked its business continuity plan (BCP) and public health threat plan in order to protect staff,

delegates and contractors' health and safety while continuing to deliver on its mandate. EMA priorities in the pandemic are:

- Ensuring health and safety of staff, delegates, contractors and community at large;
- Ensuring business continuity and undisrupted assessment and monitoring of medicines, so that patients in Europe continue to have access to high-quality, safe and effective medicines;
- Supporting and facilitating fast and safe development of effective and safe measures to treat and prevent the spread of COVID-19.

The Agency's BCP outlines key elements and measures with regard to each of these aspects.

Considering how the work of EMA is interlinked with that of the EU Regulatory Network, and to allow effectively addressing the impact of the COVID-19 pandemic on the regulatory activities across the EU, guiding principles for the prioritisation of COVID-19 related work and regulatory procedures were defined in a dedicated EMRN Business Continuity Plan, agreed with the whole EU Regulatory Network, and aligned with BCP measures set out by the Human and Veterinary Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh, CMDv). The Agency's COVID-19 BCP is part of the European Regulatory Network COVID-19 BCP and includes also additional aspects specific to the Agency.

To ensure quick and appropriate response to a highly dynamic and fast-changing situation, the Agency monitored closely developments along different dimensions of the pandemic impact. The decisions were made considering the actual situation and expected trends, as well as guidance and decisions made by the EC, Dutch government and health organizations such as ECDC and WHO.

COVID-19 Steering Group

A COVID-19 Steering Group, chaired by Deputy Executive Director, was set up to coordinate and manage the Agency's activities related to the coronavirus pandemic. The mandate of the Steering Group is to ensure EMA's preparedness for any possible scenario during the pandemic. The work of the Steering Group is organised in several work streams, each focusing on a specific aspect of the crisis:

- Work stream 1: therapeutic response;
- Work stream 2: supply chain;
- Work stream 3: business continuity and impact;
- Work stream 4: human resources;
- Policy/institutional group.

Staged approach to BCP

EMA COVID-19 BCP follows a staged implementation approach, and the first phase of the EMA COVID-19 BCP was invoked on 9 March 2020, reducing any physical presence in the EMA building to a minimum and maintaining the Agency operations virtually.

In terms of the Agency's activities, the initial BCP provisions implied status quo – no on-going activities were reduced or suspended, but also the previous plan to gradually resume activities suspended or reduced during Brexit BCP was put on hold.

Subsequent BCP phases would be triggered if the Agency was no longer able to continue operating at its present scope of activity and resources needed to be re-allocated due to, e.g., increasing workload

of COVID-19 related activities or unavailability of EMA staff for health or other reasons (e.g., child-mining when schools are closed).

BCP implementation is continuously tracked and monitored and decisions and actions are taken as and where needed. Flexibility is also ingrained in the application of the BCP to ensure most appropriate course of action is taken as the pandemic evolves. This also means that the Agency may decide to revert some of the measures already implemented while maintaining others.

Impact on the Agency's activities

In order to safeguard the delivery of its core activities and to ring-fence resources to deal with COVID-19, the Agency implemented prioritisation of activities based on their impact on public health and the Agency's ability to function. The starting point of the COVID-19 prioritisation was the Brexit BCP, adjusted to reflect the realities of COVID-19.

For the purposes of COVID-19 BCP, the Agency's activities have been categorised into 3 levels of priority:

- Category 1 activities – highest priority activities related to core business, legal obligations, and ensuring Agency operations, as well as all COVID-19 activities;
- Category 2 activities – strategic activities or other core activities not captured in category 1;
- Category 3 activities – lowest priority non-strategic activities such as governance and support activities, and transparency and information activities such as requests for information.

All COVID-19-related activities are given highest priority, in terms of

1) coordinating all activities of the scientific committees on scientific aspects of the crisis related to management of medicinal products,
2) liaising with developers to provide scientific contribution to new drugs/vaccines development,
3) coordinating the actions required to manage the risk of shortages of medicines, and
4) providing enhanced coordination of the EU Regulatory Network to ensure the least possible impact on time and quality of evaluation and supervision of medicines.

Implementing prioritisation measures has allowed the Agency to mobilise approximately 40 FTEs to work on addressing the challenges brought by the pandemic.

Cyberattack on the European Medicines Agency

In December 2020 EMA was the subject of a cyberattack attempting to unlawfully access Agency's documents and correspondence. EMA swiftly launched a full investigation, in close cooperation with law enforcement and other relevant entities and strengthened its defensive capabilities to protect the Agency from future attacks.

United Kingdom leaves European Union

On 31 January 2020, the United Kingdom left the European Union and became a third country to the EU. A transition period started on 1 February 2020 and ended on 31 December 2020.

The UK's withdrawal from the EU posed major challenges for the Agency, and considerable work had to be done, to ensure that the activities relating to the authorisation, supervision and maintenance of medicines are not disrupted and continue to be undertaken on time and to the same high level of

quality the Agency's stakeholders have come to expect, and that patients in Europe continue to have access to high quality, safe and effective medicines.

Over the last three years the Agency, together with the NCAs and the European Commission, worked relentlessly to help prepare the Network and the industry for the impact of the UK's withdrawal. Among other tasks, this included:

- re-distributing the UK portfolio of medicines: by 1 July 2019, the appointed rapporteurs and co-rapporteurs from the EU27 plus Iceland and Norway took over full responsibility for more than 370 centrally authorised products which previously had UK rapporteurs or co-rapporteurs;
- identifying any potential gaps in experience within the Network and implementing measures to address these;
- providing guidance for pharmaceutical companies to enable them to mitigate any detrimental impact of the UK's withdrawal, including updated EC and EMA guidance to stakeholders on the applicable rules in Northern Ireland after the end of the transition period on 31 December 2020;
- processing variations, changes to and transfers of marketing authorisations, products with qualified persons for pharmacovigilance (QPPVs) and pharmacovigilance master files (PMFs) based in the UK;
- analysing the impact of the Withdrawal agreement on the networks, information systems or databases established on the basis of Union law within the pharmaceutical field, to assist the European Commission in preparing its decision (dated 16 October 2020) granting the United Kingdom acting in respect of Northern Ireland access to networks, information systems or databases established on the basis of Union law;
- providing continuous and proactive communication and guidance to stakeholders throughout this period.

In addition to business-related challenges, EMA also successfully tackled the challenges stemming from the requirement to relocate to its new host country:

- working closely with Dutch authorities to set out specific aspects and conditions of the relationship between the Agency and its new host country, including signing the seat agreement on 1 July 2018, providing relocation support to EMA staff, and construction of the new permanent EMA premises in Amsterdam Zuidas;
- subletting its former premises in London to a subtenant (WeWork) from July 2019 for the full period until the expiry of EMA's lease in June 2039;
- implementing a number of exceptional measures to support staff relocation and ensure a smooth transfer of several hundreds of households;
- undertaking recruitment efforts to replace the staff who decided not to move with the Agency;
- relocating the Agency's data centres and running procurement procedures to ensure the necessary contracts for goods and services are in place at the time of the Agency's move to the Netherlands.

REVISED MANDATE FOR EMA

In 2020, EMA welcomed the European Health Union package proposed by the European Commission to strengthen the EU's preparedness for crisis situations and response. The proposals included a possible extension of EMA's mandate.

The Commission's proposal for an extended EMA mandate reflects and strengthens several of the structures and processes that the Agency had voluntarily and proactively established to respond to the

COVID-19 crisis, for example the coordination of the monitoring of shortages of critical medicines and the creation of a scientific Emergency Task Force which can swiftly advise clinical trial sponsors and medicine developers during public health emergencies. The proposal acknowledged that the work done so far by the Agency, together with the national medicines authorities, has been effective.

The Commission also proposed a new role for EMA in the medical devices area, including two very specific tasks building on EMA's experience in setting up systems for the monitoring of medicines and working with scientific experts in various clinical areas, as well as EMA's important role within the network in the implementation of the medical device legislation. These new tasks include monitoring and management of shortages of critical medical devices and the management of expert panels responsible for conducting the clinical evaluation and providing advice with respect to high-risk medical devices and in vitro diagnostics.

Finally, the Commission proposed to strengthen the mandate of EMA by providing an explicit legal basis to access and analyse real-world healthcare data and by establishing, jointly with ECDC, a vaccine safety and effectiveness monitoring platform.

An Extended Mandate Task Force (EMTF) was set up by the Agency's Executive Board in December 2020 to define the scope of the changes that EMA will have to introduce to implement the new legal mandate foreseen, to analyse the consequences of these changes and to draft a high-level roadmap for its implementation.

EC DIGITAL STRATEGY FOR EUROPE AND DATA STRATEGY

In parallel to EMA's activities in digitalisation and big data, the European Commission published in February a new five-year Digital Strategy for Europe, which focuses on promoting innovative technologies, a data-driven single market and a digitalised society for the EU. The Commission also published a Data Strategy outlining new actions for improving access to and management of data in the EU and announcing the development of a common EU health data space; and in this regard the EC will support big data projects promoted by the network of EU regulators in the area of public health. Finally, the EC also published a White Paper on Artificial Intelligence setting out the principles for a legislative framework for trustworthy AI.

EP CALLS FOR MORE EU ACTIONS ON MEDICINES SHORTAGES AND PHARMACEUTICALS IN THE ENVIRONMENT

On 17 September, the European Parliament (EP) adopted two political resolutions regarding pharmaceuticals in the environment and medicines shortages.

In the resolution on shortages of medicines, the EP welcomed the ongoing HMA/EMA activities and called for the Agency to be "designated as the regulatory authority tasked with preventing shortages of medicines at EU level during emergencies and beyond, with a correspondingly wider mandate and increased resources". EP also recommended "that the Commission, the Member States and the industry, under the leadership of the EMA, work together to introduce greater transparency in the medicine production and distribution chain and the creation of a European unit for preventing and managing shortages".

In the resolution on pharmaceuticals in the environment, the EP welcomed the Commission's strategy (adopted 11 March 2019) yet called for more tangible actions, including potentially a revision of EU legislation on GMP and ERA, together with concrete timelines for implementation. EP called on EMA to "make sure that MA applicants submit a completed environmental risk assessment by the time of the authorisation for marketing human medicinal products, so that adequate risk management measures can be established and published". Additionally, EP called on EMA for a timely implementation of the new Veterinary Regulation "with a view to reducing the use of antibiotics, including by evaluating the

feasibility of setting up an EU-wide active substance-based review system by 28 January 2022 and other potential alternatives for the environmental risk assessment".

Although these resolutions are not legally binding *per se*, they demonstrate the strong interest of the EP in these topics and the EP's expectations in these areas. These recommendations may also come up as EP priorities in the context of the EU pharmaceutical strategy and possible future revision of the EU pharmaceutical legislation.

COURT OF JUSTICE UPHOLDS EMA'S APPROACH TO TRANSPARENCY

In January 2020, the Court of Justice upheld EMA's approach to transparency confirming in clear and unambiguous terms the right of citizens for access to clinical study and toxicology reports submitted to EMA for the purpose of granting a marketing authorisation for human and veterinary medicinal products.

The Court of Justice dismissed in their entirety the two appellate cases (C-175/18 P and C-178/18 P) that concerned the application of the Transparency Regulation to requests for access to documents that have been drafted by third parties, are in the possession of EMA, and relate to human and veterinary medicinal products. In particular, the cases related to EMA's decisions to disclose toxicology and clinical study reports that had been submitted by companies to EMA as part of their applications for granting a centralised marketing authorisation.

The Court reiterated the principle of the widest possible public access to documents held by Union institutions, bodies, offices and agencies. An exception to that principle may be applied for the protection of commercial interests only if it is proven by the marketing authorisation holder/applicant that the disclosure of documents would pose the risk of a concrete harm to the commercial interests of the persons concerned. The Court of Justice agreed with EMA that such harm was not established in respect of the disclosure of the clinical study and toxicology reports at stake. The judges confirmed that transparency must be the rule and exceptions must be applied and construed narrowly.

2.3. Budgetary and financial management

2.3.1. Budget overview

The total 2020 budget (revenues and expenditure), as adopted by the EMA Management Board on 19 December 2019, amounted to €358,071,000, representing a 7.54% increase compared to the 2019 initial budget (€332,959,000). One amending budget was processed in 2020 in order to include revenue from the 2018 budgetary surplus to be claimed from the European Commission, increase expected revenue from scientific applications and decrease revenue from the 2020 EU contributions to match revised expectations. The resulting final budget amounted to EUR 369,749,000.

Despite the considerable and additional uncertainties, including the COVID-19 pandemic, 30 Churchill Place and Brexit, the final budget outturn of the Agency was close to the final budget (a surplus of approx. EUR 4.4 million (see detailed information on budget outturn in Annex II), representing 1.08% of total revenue).

2.3.2. 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 revenue entered in the accounts as at 31 December 2020 amounted to EUR 376,246,022.54 (2019: EUR 339,889,499.26).

Of total C1 income, 84.22% derived from the evaluation of medicines and other business-related activities, 15.65% from the European Union budget to fund various public health and harmonisation activities, including positive outturn of previous year, and 0.13% from various sources (2019: 89.15%/10.77%/0.09%).

Assigned revenue (external, R0, and internal, CL), which is handled outside the adopted budget, totalled EUR 27.46 million.

2.3.3. Expenditure (commitments and payments)

Of the adopted budget, i.e. fund source C1, commitments totalled EUR 365,433,231.93, or 98.83% of final appropriations (2019: 98.56%). Payments totalled EUR 290,132,295.87, or 79.39% of commitments (2019: 84.26%).

2.3.4. Appropriations carried forward from 2020 to 2021

Automatic carry-forward

Automatic carry-forward to financial year 2021, C1 to C8, totalled EUR 75,300,936.06 or 20.61% of appropriations (total carried forward from 2019 to 2020: EUR 53,790,023.71 or 15.74%).

2.3.5. Implementation of appropriations carried forward from 2019 to 2020

Automatic carry-forward from financial year 2019 to 2020, i.e., fund source C8, totalled EUR 53,790,023.71. Payments against these appropriations equalled EUR 51,366,115.00 (95.49%) of appropriations (2019: 94.94%) and EUR 2,423,908.71 were cancelled.

2.3.6. Appropriations from external and internal assigned revenue

External assigned revenue (R0) stems from inducements related to the Agency's new headquarters in Amsterdam. In 2020, EUR 14.26 million were received and EUR 14.23 million consumed.

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 2020, EUR 13.20 million were received, with another EUR 6.80 million invoiced. CL expenditure amounted to EUR 18.31 million consumed.

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

The Agency's available appropriations in 2020 included assigned revenue. In accordance with the Financial Regulation, this revenue, matched by expenditure appropriations, is managed outside the adopted budget and under separate fund sources, i.e. R0 for external assigned revenue, and CL for internal assigned revenue.

The vast majority of the assigned revenue relates to the Agency's office buildings, with the remainder, approx. EUR 349,000, related to grants received from the EU budget to fund projects within the IMI and IPA programmes.

2.3.7. Budget transfers

In line with Article 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 indicator of deficiencies in financial 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, change in expenditure due to exchange rate fluctuation, etc.

During 2020, a total of 14 transfers were made, 13 of which involved expenditure appropriations. Five of the transfers made involved a transfer between titles, and none of these exceeded the 10% ceiling set for transfer between titles.

The transferred expenditure appropriations were primarily needed to cover additional commitments for rapporteur payments and scientific studies, due to the increase in the number of scientific applications and the COVID-19 pandemic, as well as IT project development, as approved by the EXB.

2.3.8. 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, means that the level of cancelled expenditure appropriations does not indicate delays in the implementation of the work programme but should rather be considered the result of stringent monitoring of actual revenue and adjustments to the expenditure.

Of the adopted budget, expenditure appropriations totalling EUR 4,315,768.07 remained unused, corresponding to 1.17% of final appropriations (2019: EUR 4,993,011.64, 1.44%).

The underuse of commitment appropriations is within the acceptable range, and around 1%-3% for each title

2.3.9. Payment of interest on late payments

In compliance with the Agency's standard contract, established in accordance with Art. 77 of the Financial Regulation, the terms of payment are 30 days upon receipt of a valid invoice. If these terms are not respected, from day 31 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 8%[7]. 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.

In 2020, 1,332 payments out of a total of 30,615, i.e. 4.35% of all payments, were made later than 30 days after receipt of a valid invoice (2019: 2.41% of all payments). This resulted in default interest of EUR 12,638.45 being paid to suppliers and contractors (2019: EUR 7,706.95).

2.3.10. Brexit-related expenditure

The financial consequences of Brexit, i.e., the Agency's departure from the UK and move to the Netherlands, were still felt in 2020, with the financial planning for 2020 including Brexit-related expenditure of €73.8 million. Key expenditure items include cost related to incentives on 30 Churchill Place, fitting-out of the EMA building in Amsterdam and staff members' transfer to the Netherlands.

Planning for 2020 also included an estimated 10 FTEs dedicated to Brexit-related activities. The actual hours recorded for the year amounted to 8.5 FTEs.

Final expenditure is estimated at EUR 56.23 million of which EUR 27.1 million were covered by assigned revenue.

[7] in accordance with Article 116 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council

2.3.11. COVID-19 budget impact

In regard to the revenues, the main impact was felt through a drop in inspections, as these had to be slowed down and rescheduled due to the travel restrictions imposed in response to the pandemic. In 2020, the recovery orders issued were €385.6 million, 4.3% above the expected estimate.

In order to facilitate development of vaccines and treatments for COVID-19, as of 16 March 2020 EMA waived fees for scientific advice for pharmaceutical industry developing COVID-19 treatments and vaccines. This, however, did not impact revenue estimates, as these were not part of the initial budget estimates. Moreover, post-authorisation applications, e.g., variations and extensions to cover COVID-19 aspects, are expected to result in a net increase of fee income.

The impact of the pandemic can also be seen on meeting expenditure, expenditure on duty travel for staff, recruitment, staff training and IT contractors, where travel restrictions have resulted in expenditure below initial budget estimates.

2.3.12. Grants, contribution and service level agreements

In late 2019, HMA and EMA Management Board adopted the final report of the HMA-EMA joint Big Data Task Force. The first recommendation of that task force was for the EU Network to establish a platform to access and analyse real world healthcare data (referred to as Data Analytics and Real World Interrogation Network – 'DARWIN EU'). The final report indicated that the project costs to establish DARWIN EU would be of the order of €30-50 million over approximately three years and the annual operating costs should come from a change to the EMA fee regulation, to ensure sustainability.

At the time of drafting this report, discussions with the Commission are ongoing regarding project funding.

In addition to this, EMA received grants for the amount of €349,000 from the EU budget to fund projects within the IMI and IPA programmes.

2.3.13. Procurement

Over the last few years the Agency has experienced significant changes in its internal and external working environment – including the Agency's final move to its new office base in Amsterdam, substantial internal reorganisation and the current COVID-19 crisis, all of which have required additional procurement of goods, services and works. As a result, the last three years have continuously seen a substantial number of procedures run in parallel.

A decrease of the total number of on-going procurements was foreseen in January 2021 as compared to December 2020, but the Procurement and Purchase Standards service was facing an exceptionally high number of procurements ongoing (39) in parallel, 22 of which were foreseen to be closed – and the resulting contracts for which were foreseen to be awarded and signed still before the end 2020.

The procurement plan overview shows that as of the end of February 2021, EMA had a total of 93 procurement procedures ongoing (41) or planned (52). Of these, 35 procedures were run as inter-institutional procurements, with EMA as a lead for 8 of them and other EU Agencies / institutions leading 30 of these. Another 58 planned or ongoing procurements were EMA-only procurement procedures.

Procurement procedures	Closed in 2020	Ongoing	Planned for				Total planned
			2020	2021	2022	beyond	
EMA-only procedures	40	22		25	8	3	36
Interinstitutional	15	19		9	1	6	16
EMA-led	*1*	*4*		*4*	*0*	*0*	*4*
Non-EMA led	*14*	*15*		*8*	*1*	*6*	*15*
Total	**55**	**41**	**0**	**34**	**9**	**9**	**52**

40 procurement procedures were closed in 2020 by signing a contract and 23 were cancelled or closed without awarding the contract.

Despite a forecasted reduction in the number of procurement activities to be run, a significant number of unplanned activities had reached PPS, thus resulting in stretched resources. In January 2021, 3 PPS FTEs left the service. Replacements are ongoing with effective dates for onboarding planned in April-June window period.

With regard to the type of procurement procedure used in EMA-led procedures (including interinstitutional ones), negotiated procurement procedures were used in 29% of cases, open procedures were used in 39% and re-opening of completion has been the case for 28% of procurement procedures. Only one procurement was closed in 2020 as Direct award based on exception, and only procedure currently ongoing has been amended. The type for 4 planned procurement procedure is still to be determined.

Procedure type (EMA-led procurements)	Closed in 2020		Ongoing		Planned		Total	
Negotiated 1-15k	13	24%	2	5%	2	4%	17	11%
Negotiated >15-60k	1	2%	1	2%	0	0%	2	1%
Negotiated >60-139k	6	11%	3	7%	8	15%	17	11%
Negotiated without contract notice	4	7%	3	7%	0	0%	7	5%
Negotiated subtotal	*24*	*44%*	*9*	*22%*	*10*	*19%*	*43*	***29%***
Open procedure	15	27%	23	56%	20	38%	58	**39%**
Re-opening of competition	15	27%	8	20%	18	35%	41	**28%**
to be decided	1	2%	1	2%	4	8%	6	**4%**
Total	**55**		**41**		**52**		**148**	

A total of 34 procurement procedures are currently planned to be launched during 2021.

2.3.14. Cost and benefits of controls

In 2020, EMA allocated approximately 10 FTEs for control activities (amounting to 1.3 M euros or 0.35% of the Agency's 2020 total 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 authorising officer by delegation is required to send an annual management report to the Executive Director. This report 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.

This year the Executive Director, in view of the ongoing COVID-19 crisis, has agreed that in order to meet the requirements of article 3.9 of the charter, the Authorising Officers' Declarations of Assurance will suffice to provide her with guarantee that the resources made available have been used for their intended purpose, in accordance with the principles of sound financial management and that the controls put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

The Authorising Officers by Delegation, Noel Wathion, Deputy Executive Director; Alexis Nolte, Head of Human Medicines Division, and Nerimantas Steikunas, Head of Administration and Corporate Management Division, provided their Declarations of Assurance to the Executive Director, no reservations were reported.

2.5. Human resources management

In 2020, the key developments in regard to staff and human resources management included:

- **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 2020 included:

  - Go-live of the new onboarding system on 20 May 2020. This new SuccessFactors tool bridges the selection procedure (that uses the recruitment tool), the contract preparation, and the first day at the Agency. It aims to facilitate the arrival of future colleagues to the Agency, as well as the cross-boarding of existing staff, and digitalise the numerous administrative forms which a newly-hired person needs to complete and sign;
  - Strengthening of the 'Careers' portal, launching a new section dedicated to onboarding questions and work-life balance at the EMA;
  - Work to review the related processes, to complement the newly introduced tools with up-to-date, efficient and effective HR processes;
  - Launch of the Performance and Development programme that aims to change the approach towards performance management, as well as foster career path opportunities. With more clear and informed decisions, it is expected to become a powerful process facilitated by a tool to support colleagues across the organisation to grow professionally. Some of the deliverables include a new methodology for cascading objectives, a new competency development

framework and a new appraisal process and tool, which will enable continuous evaluation approach with flexible feedback and smart goals-setting.

- **Establishment of the new Rules, Procedures and Partnerships Service**

  A new Rules, Procedures and Partnerships Service has been created in the Staff Relations and Support Department. Among other tasks, this service is now in charge of HR policy and implementation of the EU staff regulations, Article 90 complaints, litigation related to the Staff Regulations, performance management, implementation of staff privileges and cooperation with external partners relevant to staff matters, such us the Ministry of Foreign Affairs, the European Schools and other stakeholders.

A number of HR implementing rules were adopted in 2020. The list of these can be found in Annex IV.

During 2020, the Agency recruited 82 statutory members of staff (51 TA and 31 CA). 15 national experts were seconded to the Agency, 31 trainees and 36 new interim assignments provided services to the Agency. The total number of staff joining EMA therefore amounted to 164. During the same year, 59 statutory staff members (26 TA, 33 CA) and 13 SNEs left the Agency. 17 interim assignments were also terminated. The total number of leavers was 89.

The rate of resignations amongst statutory staff decreased in 2020 following several years of increase (mainly triggered by the Agency's relocation) and an all-time-high in 2019, when 82% of staff who left, left by resignation The rate of resignations for 2020 was 53%, with a turnover rate for TA and CA of 4.81%.

The occupancy rate amongst temporary agent staff was 100.0%.

2.6. Strategy for efficiency gains

Despite the increase of activities over the last 5 years and the impact of the COVID-19 pandemic, increasing the pressure on a number of staff mostly involved in scientific activities, EMA demonstrated significant productivity gains and more efficient ways of working.

During the year, the Agency developed its efficiency gains strategy mainly following two dimensions - process improvement and digitalisation.

Process improvement: Following the future-proofing exercise drivers, in 2020 the Agency started the process review to complete the integration of the Human Medicines division activities. The objective of the exercise was two-fold; first, further efficiency improvement and, second, preparing the digitalisation of processes by transferring them into the IRIS platform.

Digitalisation: In 2020, EMA started its Digital Transformation. In the context of the future-proofing exercise, a Digital Business Transformation task force was created, with the mandate to develop and execute a digitalisation strategy for the Agency. This work encompassed several activities, key to digitalisation of EMA services:

- Creation of the Analytics Centre of Excellence (ACE), a cross-Agency initiative with the aim of exploring how analytics - including artificial intelligence, machine learning and robotics – can be used to build pragmatic solutions for existing EMA business needs.
- Establishment of a Digital Change Workstream, to drive complex digital change initiatives that impact on EMA's strategy, operational structure and operations in relation to the European medicines regulatory network, its partners and stakeholders.
- Continuation of EMA core business process digitalisation via IRIS – a modern and secure online platform to handle knowledge and regulatory and scientific procedures.

- Driving the development of digital skills and change management expertise across the Agency to enable digital transformation and support organisational change.

Additionally, the Administration Division ran a specific programme targeting the revamping and streamlining of HR procedures and, in parallel, the enhancement of the financial and reporting systems.

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

2.7.1. Internal Audit Service (IAS)

According to the risk assessment carried out by IAS in 2019, the main risk factors relating to the Agency's activities were based around the quality of the work delivered and the security of information gathered, dependence on the knowledge of highly specialised staff, and the importance of having a solid IT framework to support the medicines' evaluation, supervision and pharmacovigilance processes. Well-managed scientific committees and working groups were also key to the functioning of the Agency and its collaboration with the different stakeholders.

With these risk factors in mind, the IAS has selected 'HR and ethics', 'IT governance and portfolio management' and 'the management of meetings for EMA's committees, working parties and other groups' as the three main audit topics for the coming years.

The Human resources and ethics audit, planned to take place in 2020, was postponed to 2021 at the Agency's request, due to the COVID-19 pandemic crisis management.

2.7.2. Internal audit capability (IAC)

Due to the COVID-19 pandemic crisis, the following **internal audits** were rescheduled to take place during the second half of the year: Information Security Management; Management of the IT Outsourcing, Management of PRIority MEdicines (PRIME) scheme, while the audit on Dutch incentives was postponed to 2021.

Based on the results of the 2020 audits, follow-ups, consultancy activities and analyses, the Head of Audit Advisory Function believes that the internal control systems put in place by the Agency, in the period subsequent to the move of the Agency from London to Amsterdam, and marked by the COVID-19 crisis, provide reasonable assurance regarding the achievement of the business objectives in line with BCP arrangements, notwithstanding the exceptions described in the relevant findings included in the audit reports issued during 2020, for which management has prepared improvement action plans and monitors the implementation continuously.

2.7.3. European Court of Auditors

The European Court of Auditors (ECA) adopted its 'Annual report on EU agencies for the financial year 2019'[8] on 22 September 2020.

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

[8] https://www.eca.europa.eu/lists/ecadocuments/agencies_2019/agencies_2019_en.pdf

Whereas there are no critical findings, the report includes an emphasis of matter drawing attention to the uncertainty with the lease agreement for the Agency's previous premises in London, an observation on the legality and regularity of transactions and three observations on sound financial management.

The report includes also a follow up of six previous years' observations, of which three have been completed, one is ongoing and two are outstanding, one of which is not under the Agency's control. With regard to the corrective action concerning e-invoicing observation, in 2020 the Agency is proposing full digital solutions to submit invoices and tenders on line.

Observation on the legality and regularity of transactions[9]	
Observation number	**Description**
18	At the time of our audit, there were 119 on-site consultants providing services at the EMA's premises. They were employed by a number of providers, some of them from other Member States (mostly from Belgium) and some based in the Netherlands. The Agency was unable to confirm to the auditors whether the temporary-work agency staff providing services on its premises qualified for posted worker status under the provisions of Netherlands law concerning the transposition of the Posting of Workers Directive (Directive 96/71/EC of the European Parliament and of the Council) and the Enforcement Directive (Directive 2014/67/EU of the European Parliament and of the Council). We consider that in the context of calls for tenders for acquisition of services, the EMA, as contracting authority, has the responsibility to verify the declarations of compliance with EU and national social and labour law made by contractors (including legislation concerning the posting of workers) as required by the Financial Regulation applicable to the general budget of the Union. By way of example, the EMA could have fulfilled this requirement by asking its contractor for a list of these workers and asking it to submit evidence that it complied with the national legislation in the host Member State (e.g. proof that the contractor had notified the host Member State about the posted workers). However, at the time of our audit, it had not done so. Nor had it taken any further such steps to ensure compliance with the requirements imposed by the Financial Regulation in this connection. The EMA also needs to be aware of its host Member State's national legislation concerning posted workers, and to comply with any obligation that this legislation imposes on the receiver of services (i.e. the EMA) provided by posted workers.
Observations on sound financial management	
Observation number	**Description**
19/20	When running a public procurement procedure, contracting authorities must divide contracts into lots, if appropriate, with due regard 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. In March 2019, the EMA launched a procurement procedure. The procedure covered two items: the supply of printers, and the management of the goods loading bay at the Agency's new premises in Amsterdam. These two items are completely unrelated. But they were nevertheless combined into a single same lot, with an estimated value of 6 200 000 euros over a maximum period of 6 years. Only two offers were received for this tender. By combining the procurement procedures for the supply of printers and the provision of loading bay management services, the Agency 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. The life span of the equipment in the contract and the significant amount which the contractor would have to invest to acquire the printers are not sufficient grounds for such an extension.
21	In October 2019, the EMA concluded a framework contract with three companies for the supply of temporary workers. The combined maximum value of the contract was 15 450 000 euros. According to the tender specifications, the price element had a weighting factor of 40 %. It was stipulated in those specifications that this element must include an all-inclusive hourly rate conversion factor applied to the gross hourly remuneration of the temporary workers in specific staff categories. Based on the offers received, especially in the categories FGII and FGIII, which had the highest weighting factor in the overall price element, the conversion factor ranged from 1.85 to 1.95. However, the EMA did not request an estimate of the gross staff cost for the interim

[9] Ibid, page 7-10

Observation on the legality and regularity of transactions[9]	
	workers in each requested staff category (e.g. employer's contributions, and other expenses covered by the employer according to Netherlands labour law). As a result, the EMA could have been in a better position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts
22	In March 2019, the EMA relocated from London to Amsterdam in preparation for the United Kingdom's withdrawal from the European Union. To facilitate the transition, the Agency granted an additional travel allowance to each member of staff who relocated to Amsterdam, and the members of their household. The amount of this additional allowance (1 227 euros for each person who received it) was calculated as a flat-rate amount according to the price of a business-class ticket instead of the economy-class fare as stated in the Staff Regulations. If the Agency had calculated the amount of this additional travel allowance on the basis of an economy-class fare, the normal class of travel for journeys made within the EU, it would have delivered the same result more economically. This applies even if the Agency had purchased additional luggage allowance for each person who received the allowance, to make it equivalent to the luggage allowance permitted in business class. We conclude that the EMA gave little consideration to the principle of economy in calculating the amount of the additional travel allowance. By 31 December 2019, the EMA had paid both the statutory and this exceptional travel allowance to 481 EMA staff members and 524 members of their households. The total amount disbursed by that date was 1 263 305 euros, instead of 30 562 euros in the case only the statutory allowance had been applied. Together with 245 000 euros reserved for further such payments, the amount expected to be spent on the exceptional travel allowance is 1 477 743 euros.

Follow-up of previous years' observations[10]		
Year	**Court's observations**	**Status of corrective action** (Completed / Ongoing / Outstanding / N/A)
2014	The Agency's fee regulation provides due dates for the collection of fees. These due dates were not respected for most of the transactions audited.	Completed
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.	Ongoing
2016	The founding Regulation requires an external evaluation of the Agency and its operations by the Commission only every ten years.	Outstanding (Not under the Agency's control)
2017	There is a need to strengthen the accounting officer's independence by making her directly responsible to the Agency's Director (administrative) and Management Board (functional).	Completed
2017	The Agency publishes vacancy notices on its website, but not on the website of the European Personnel Selection Office (EPSO).	Completed
2017	E-procurement: by the end of 2017, the Agency had introduced e-tendering for certain procedures, but not e-invoicing and e-submission.	E-submission: Completed E-invoicing: Outstanding

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

2.8.1. Internal Audit Service

No recommendations were open as of 31 December 2020.

[10] Ibid, page 11-12

2.8.2. Internal audit capability

The current state of play of the implementation of recommendations stemming from IAC audits includes no open c*ritica*l recommendations and 3 *very important* recommendations for which the implementation of improvement actions remains ongoing. The improvement action plans are still being implemented due to constraints brought upon by the Agency entering Business Continuity Contingency plans in response to the Agency relocation (from 2016 till January 2020) and the COVID-19 pandemic (as of March 2020) which impacted on the availability of human resources.

The open recommendations pertain to improvements in the areas of:

Request for Information from external parties: to introduce regular monitoring and reporting.

Risk Management Plans (RMP): to strengthen the efficiency of monitoring and reporting of activities in the RMP, which will help clarify roles and responsibilities and training plans supporting the management of collected RMP.

Capacity building activities for pharmacovigilance systems: to develop a joint approach for pharmacovigilance capacity-building activities for both human and veterinary medicines, to strengthen the monitoring, to increase the sharing of best practices; and to target a wider range of stakeholders involved in Pharmacovigilance tasks.

In 2020, 21 major recommendations were issued (0 critical and 21 very important) among three audits on Information Security management, IT outsourcing and PRIME.

- The Information Security Audit included 9 very important recommendations in the domains of security governance, risk management, IT infrastructure and security awareness among employees.
- For the engagement on IT outsourcing, the IAC issued 7 very important recommendations. These pertained to strengthening the process, monitoring providers' performance and introducing an IT risk management tool.
- Finally, the Prime Medicines scheme Audit led to 5 very important recommendations being issued, covering the need to develop a PRIME strategy/roadmap, to further develop training plans and to strengthen workload monitoring and reporting.

In 2020, the IAC closed 8 very important recommendations from previous internal audits. The implementation of these actions led to improvements in the performance of controls, including the enhancement of the Agency Eudralink's naming conventions. The Agency also strengthened information, communication and reporting controls, which is evidenced by the enhanced monitoring of the effectiveness of skills and knowledge acquisition across the EU Network. The Agency also improved its monitoring process over pharmacovigilance capacity-building activities by systematically collecting and analysing participants feedback and ensuring that these activities refer to set strategic objectives and goals.

2.8.3. Follow-up of recommendations issued following investigations by OLAF

No investigations were opened by OLAF in 2020 and no recommendations were issued as of 31 December 2020

2.9. Follow-up of observations from the discharge authority

As a follow-up to the discharge decision, EMA reported[11] on the measures taken in light of the observations made by the discharge authority for 2018 in its annual report under Article 110(2) of the Framework Financial Regulation. Controversial points and challenging topics raised in the recommendations made by the EP Rapporteur and other MEPs, included reliance on the fees from industry, the conflict of interests of experts, the 'revolving doors' phenomenon and the cooling-off period for staff joining the private sector after leaving the Agency, as well as the reliance on IT consultants.

On 28 April 2021, the European Parliament voted positively on the discharge for EMA's 2019 accounts. This is the final approval of the budget implementation for 2019, and the decision is based on a review of the annual accounts and the Court of Auditors' annual report.

2.10. Environment management

In 2020, the Agency continued its work on developing an Environmental Management System in line with the EMAS regulation.

Since April 2020, preparations for the Environmental Management activities were resumed and a 'Roadmap for Environmental Management 2020 to 2024', with a target for registration to EMAS within that period, will be put in place as of 14 January 2021. As a first action, the Environmental Policy will be reviewed and approved on 14 January 2021 and staff involvement will be secured through re-initiation of the EMA Green Group at the end of January 2021, in accordance with an updated mandate.

As of 2020, the Environmental Management System, EMS, is being updated with specifics of the Agency's new permanent premises.

EMA is also participating in the inter-institutional tender procedure for Green criteria in procurements of helpdesk services, launched in late 2020.

The European Union has within the Green Deal updated its target by setting a 55% net reduction of greenhouse gas emissions by the year 2030, compared with 1990.

Following temporary premises being occupied for the majority of 2019 (10 March until 31 December 2019), the compulsory teleworking due to the COVID-19 pandemic for the majority of 2020 (16 March to 30 September), and reduced office occupancy for the remainder of 2020, there is still fine-tuning to be expected in the EMA building also in 2021.

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 despite the events taking place in 2020, the Agency's way of working has not been greatly disrupted and we have managed to address the challenges COVID-19 has presented to us. EMA core business activities have continued at the same high level as in the past, even though we have had to redeploy resources from de-prioritised activities. The Agency is determined to explore in full the lessons and opportunities presented by such an unsettling year, in order to become even stronger and better in the future. Nonetheless, it is true that we have never worked in such conditions before and we cannot be complacent with our successful navigation so far, nor can we let our guard

[11] The report is publicly available on the website of the Budgetary Control Committee of the European Parliament.

down, as the current situation can change dramatically from one day to the next, and issues can occur unexpectedly.

2. (b) External evaluations

The latest external evaluation of the Agency took place in 2009, and resulted in a European Commission report that was published in January 2010. The Agency's follow-up to the recommendations from this report were described in detail in the Programming Document 2018-2020.

In 2017, the European Commission started preparing for the next evaluation, and in 2018 it selected Ernst & Young (EY) to perform a study on the operation of centralised procedure (CP) and decentralised and mutual recognition procedures (MRP/DCP) for the authorisation and monitoring of medicinal products for human use during the period 2009-2017.

The contractor delivered its analysis to the European Commission in March 2020, with publication scheduled for February 2021 in a general Commission report ('Commission report on the experience acquired with the MA procedures') to the European Parliament and to the Council. However, even though the period covered by the EY report pre-dates the pandemic, DG SANTE is now considering including wider consideration of the experience with COVID-19 in the Commission report, which would imply further postponement of the publication.

European Commission's evaluation of experience with the operation of the Orphan Regulation

In line with the Commission's commitment in the context of its Better Regulation agenda to keep existing laws under review, in March 2018 the European Commission started preparing an evaluation of the functioning of the orphan regulation EC No 141/2000 over the period 2006-2017. A study was commissioned to Technopolis Group and ECORYS, which was delivered to the Commission in late 2019 and published in August 2020, in order to analyse the impact of the incentives provided in the EU orphan legislation on innovation, availability and accessibility of orphan medicinal products. On the basis of this report, a roadmap for the revision of the paediatric and orphan regulation was published at the end of 2020.

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 and functioning of the 17 principles, a questionnaire was prepared, based on the catalogue of questions and indicators suggested by the European Commission. The questionnaire was then addressed to the managers and staff members in charge of specific principles or elements of the internal control framework. In addition, results of a staff survey questionnaire (conducted in November-December 2020) served as a cross-check of whether the principles' implementation was successful in practice, and were included - where deemed appropriate - to provide a more objective response to questions and aspects that cannot effectively be assessed based on a single opinion (such as questions on staff satisfaction with communication arrangements or perceptions of how the management is performing), and to support responses provided by the question/principle owners with a reflection of the broader sentiment of the Agency's staff.

The review shows that the internal control system, including 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.

Elements and principles affected by the COVID-19 BCP in place at the Agency were noted, and actions are suggested to be undertaken when the BCP status is lifted. Some areas for improvement were also identified, with regards to transparency in decision-making, talent management, resource planning and mobility, as well as mapping business processes and information flows, especially in light of the recent reorganisation.

3.1.2. Ex-ante control system and register of exceptions

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 two main principles of 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. In addition, the SAP financial system is an effective tool for mitigating financial risks associated with the payment processing.

In 2020, the overall rejection rate of transactions was 0.7% compared to 0.4% in 2019, as shown in the table below. No financial exception was registered during the reporting year.

Comparison between verified and rejected transactions	2019	2020
Number of transactions verified	84,806	61,233
Number of transactions rejected	361	437
• of which related to manual adjustments, technical rejections or interface issues following the decentralised verification	123 (34%)	106 (24%)
• of which other issues (incorrect currency, calculation errors, wrong allocation, etc.) or procedural issue (missing document, change of requirement, wrong cost centre, etc.)	238 (66%)	331 (76%)
Overall rejection rate	0.4%	0.7%

3.1.3. Ex-post control system

Ex-post controls are part of the management and internal control procedures; they are required under Article 45 of the Financial Regulation.

The purpose of 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 (Deputy Executive Director, 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.

In 2020, the Agency conducted six ex-post controls, two of which were financial and four non-financial. Financial ex-post controls were carried out on Annual Fees (Human and Veterinary Medicines) and Parallel Distribution activities.

Non-financial ex-post control were conducted for the Annual Travel Allowance 2020 calculations, access to documents activities, compliance with IT Change Management process and on the handling of declaration of interests of experts.

Overall, the ex-post controls highlighted no significant weaknesses of the processes analysed, although two areas with potential for improvement were identified: Parallel Distribution financial processes and Compliance with IT Change Management; these are being addressed by specific improvement action plans.

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 2020. This year's exercise had to take into consideration the impact and changes stemming from the future-proofing exercise that resulted in significant changes, either at organisational level and in scope and responsibilities of a number of roles at the Agency,

The functions considered sensitive were recorded in the Sensitive functions register 2020. 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 2020, the committee reviewed 8 cases and expressed 8 favourable opinions, without conditions.

3.1.6. Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2020, reconciliations for 100% of the data between the product- and procedure-tracking systems and SAP were carried out on a regular basis, except for data from the newly interfaced IRIS system. Findings were detected in the Pharmacovigilance PSUR area and rectified with a financial impact in terms of delays in fee recovery for some transactions related to the 2019 and 2020 financial year.

3.1.7. Data protection

EMA processes personal data in accordance with the rules laid down in Regulation (EU) 2018/1725 (EU DPR, in force since 11 December 2018) and is subject to the supervision of the European Data Protection Supervisor (EDPS).

The Acting Data Protection Officer and the Assistant DPO have continued to pursue the implementation of the EU DPR, focusing, in particular, on the further update or creation of privacy statements, the systematic review of data protection clauses in all procurement contracts, the interactions with international regulators. They provided training and daily advice on data protection matters to all operational functions. On 4 May 2020, an all-staff training and awareness session was organised by the Acting DPO and followed by more than 350 staff members, with congratulations for the initiative by the EDPS, who joined the session with a keynote speech.

On 20 July 2020, an Internal Guidance on Personal Data Protection was adopted, establishing the 'data protection governance system' of the Agency, i.e. the main rules and principles of processing personal data at EMA in accordance with applicable legislation, as well as the procedures to handle personal data breaches and data subject requests, to carry out data protection impact assessments, to evaluate contractors' compliance with data protection rules, including when cloud systems and/or technologies are involved.

Further to the 'Schrems II judgment' by the Court of Justice, the EDPS notified all EU institutions and agencies of an enforcement order. Consequently, an agency-wide mapping exercise on existing international data transfers was carried out and a final report (focusing on the interactions with private third parties/contractual partners outside the European Economic Area) was sent to the EDPS. Advice on data protection matters was regularly given on several cases involving interactions with public entities, such as peer regulators outside the European Economic Area and international organisations.

Moreover, reports on a limited number of personal data breaches that occurred at the Agency were prepared and stored in the Agency's central registers, and notifications were sent to the EDPS when necessary.

Regular contacts with the EDPS, DG JUSTICE and DG SANTE's Data Protection Coordinator were intensified in the second half of the year in respect of topics such as secondary uses of health data, use of real-world data in regulatory activities and use of cloud-based platforms and software.

The sophisticated cyberattack on EMA systems, detected in early December 2020, generated a huge workload related to the assessment of risks for the data subjects affected by this malicious breach, and the consequent need to notify data subjects as required.

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 standards of honesty, propriety 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 has adopted its Anti-Fraud Strategy (AFS) which has been in place since December 2014 and regularly reviewed. It is accompanied by a 3-year action plan and both the strategy and the action plan are updated every three years.

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

Prevention and awareness-raising are the most important objectives of the AFS since its first adoption back in 2014. This aspect has remained unchanged in 2020. An anti-fraud training is organised as part of the induction training for new staff members, as well as via a mandatory anti-fraud e-learning training that new staff members are required to take.

In 2020, no administrative enquires were opened, nor additional actions were deemed necessary based on the continuous monitoring of ethical behaviours.

Only one case of suspected fraud/irregularity has been reported by EMA to OLAF in 2020 which decided not to open an investigation.

Moreover, since March 2020, OLAF has been contacting EMA in the context of enquiries related to counterfeited medicinal products, personal protective equipment and diagnostic materials related to the COVID-19 outbreak.

3.1.9. 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.

3.1.9.1. Management Board

The policy on the handling of competing interests of the Management Board (policy 0058) was last revised in June 2020, with effect from 1 July 2020. The revision addressed provisions concerning the inclusion in the definition of financial interests of stock warrants, i.e. type of stock option, introduction

of a definition of partner, i.e. registered partnership certifying a stable non-marital partnership, and inclusion of reference to the new EU GDPR legislation.

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 industry or any other industry related to any declared personal interests), as well as the action requested from the Management Board.

Moreover, members are informed in writing and ahead of the meeting, of the perceived conflict of 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 minutes.

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

No breach of trust procedures were initiated for Management Board members in 2020.

3.1.9.2. 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 June 2020, with effect from 1 January 2021. The previous version of the policy, in effect during 2020, has been in force since 1 December 2016.

The new provisions concern for CAT members and alternates the introduction of interests to be declared in the biotechnology and medical device sectors as foreseen in art. 22 of Regulation 1394/2007 and for all experts the introduction of interests to be declared on their personal or organisation’s involvement in the repurposing of a medicinal product. There are now also restrictions for inspectors declaring close family interests and grants/funding to align with current practice in the majority of EU member states and at FDA. In addition, the same provisions as introduced in the policy for Management Board members and the decision on rules for Agency staff were incorporated, i.e. the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation.

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 authorisation, supervision and maintenance of medicinal products for human or veterinary use, needs to be restricted or excluded, due to interests in the pharmaceutical industry.

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 industry that could affect their impartiality. The Agency also requires the experts to submit an up-to-date electronic curriculum vitae (e-CV) when signing 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:

- non-involvement with a company or product throughout an expert's mandate will result from them having held an executive or lead role in the development of a medicine during previous employment with a pharmaceutical company.
- for the majority of declared interests, a three-year cooling-off period is foreseen, whereby restrictions to involvement decrease over time, and distinguish between interests that remain current and those within the last three years.
- there is no cooling-off period if certain types of interest are no longer present, such as financial interests.

Requirements for members of scientific committees are stricter than for experts participating in advisory bodies and ad-hoc expert groups, and hence more restrictions apply when the expert declares an interest. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than for the other committee members.

In Case T-594/18, *Pharma Mar v Commission*, the General Court annulled a Commission decision refusing the grant of a marketing authorisation for the medicinal product Aplidin on the basis that two experts from the SAG, which was consulted during the re-examination procedure, had alleged conflicts of interests. The Agency was not a party in the lawsuit and is of the view that the General Court interpreted incorrectly EMA’s policy on the handling of competing interests of scientific committee members and experts. The judgment is immediately binding on the European Commission and the re-examination procedure for the MA application for Aplidin needed to be restarted. The Agency took immediate minimum measures for the immediate implementation of the judgment, not only for the Aplidin case, but also for ongoing and planned regulatory procedures as from November 2020. For SAGs and AHEGs, experts that 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 adverse impact of the judgment on the Agency’s operations, but also on the NCAs’, is considered very significant in terms of finding the best specialist expertise, a trend that has already been observed and which may lead to decreasing the robustness of the scientific assessment and possible important delays in the assessment of MAAs. The Management Board, at its meeting in December 2020, endorsed continuation of the minimum implementation measures pending the outcome of an appeal that has been launched by member states in January 2021.

All members proposed for the Agency's scientific committees have their e-DoI screened before their formal nomination. 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 committee 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 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. In 2020, no breach-of-trust procedures were initiated.

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 2020, 6 delegates informed the Agency of such intention and the restriction was immediately applied. The imminent employment in a company did not constitute a conflict for any of the ongoing procedures.

In 2020, 617 e-DoIs were checked before new experts were uploaded in the EMA Experts database as an *ex-ante* control. In 16 cases, it was noted that the expert failed to declare previous employment in a pharmaceutical company as mentioned in their e-CV, requiring an update of the e-DoI. The 2020 ex-post control focused on SAG/AHEG and working party participants as a follow-up to findings from previous ex-post controls and in view of the decentralisation of the working party secretariats. Overall, the control showed that the system for handling declarations of interests for meeting participation works well. For the minor findings, corrective actions were proposed. No major problems with the e-DoI completion by the experts or the e-DoI evaluation by EMA staff were identified.

3.1.9.3. Agency staff

The 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.

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 was last revised and is in force from 1 October 2020. A previous revision of 2019 incorporated an additional question for staff to also declare patent applications or intellectual property rights held in the past 5 years. The latest revision served to incorporate a broader definition of 'pharmaceutical company', to be better aligned with policy 0044 for experts.

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.

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 2020 to 31 December 2020, staff made a total of 36 applications, resulting in 28 authorisations without restrictions, and 8 staff authorisations with restrictions. SNE cases had no 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 - 12 months.

A new Executive Director’s decision was signed in November 2020 to increase transparency, which implements the publication on EMA’s corporate website of 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 2020 is given in Annex 9.

3.1.9.4. External consultants and contractors

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

- The contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the contract. Such conflicts of interest or professional conflicting interest could arise, in particular, as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflicts

of interest or professional conflicting interest which could arise during performance of the contract, must be notified to the Agency in writing, without delay. In the event of any such conflict, the contractor shall immediately take all necessary steps to resolve it.

- The Agency reserves the right to verify that such measures are reasonable, and may require additional measures to be taken, if necessary, within a time limit which it shall set. The contractor shall ensure that the contractor's staff are not placed in a situation that could give rise to conflicts of interest. Without prejudice to section II.7 of the standard framework contract, the contractor shall replace, immediately and without compensation from the Agency, any member of the contractor's staff exposed to such a situation.
- The contractor shall abstain from entering into any contract likely to compromise its independence.
- The contractor declares:
  - that it has not made, and will not make, any offer or agreement with any third party of any type whatsoever, from which an advantage can be derived under the contract;
  - that it has not granted, and will not grant; has not sought, and will not seek; has not attempted, and will not attempt to obtain; and has not accepted, and will not accept any advantage, financial or in kind, to or from any third party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, in as much as it is an incentive or reward relating to performance of the contract.
- The contractor shall pass on all the relevant obligations in writing to the contractor's staff and to any natural person with the power to represent it or take decisions on its behalf, as well as to third parties involved in performance of the contract, including subcontractors. A copy of the instructions given, and the undertakings made in this respect, shall be sent to the Agency should it so request.

In addition, the Agency requests all IT consultants to sign individual declarations of interest and confidentiality undertaking at the beginning of their assignment, which are stored centrally by the Procurement and Purchase Standards Service.

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 2020, 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, 4 May 2021

[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 matters:

1. A set of significant new tasks such as the handling of medicines shortages and support to medicine development, implementation of the Veterinary Medicinal Products regulation, GDPR, Medical device regulation and Clinical trial regulation, has been assigned to the Agency over the last years virtually without any increase of staff. Furthermore, the Agency's fee-related workload has been constantly increasing (by 28% from 2014-2018, see also ECA report[12], and by 43% from 2014 to 2020) and only partially compensated by efficiency gains. The COVID-19 related workload has been addressed during the COVID-19 pandemic by granting 40 TAs for the years 2021 and 2022. It must be noted, however, that this evolution will entail long-term effects linked to the pharmacovigilance and post authorisation activities which are not addressed by the above-mentioned temporary additional posts. Additionally, the total CA posts will be impacted by the requirement to phase out short term 'Brexit' contract agent positions by 2023, resulting in approximately 12.9% reduction of contract agent positions from 2019, further reducing the available workforce. In conclusion, the high resource constraints combined with the predicted surge in COVID-19 related pharmacovigilance and post-authorisation workload is therefore putting EMA under significant additional pressure at a very critical time.
2. The lease agreement for EMA's previous premises in London sets a rental period until 2039 with no exit clause. The Agency's premises in the United Kingdom were not dealt with as part of 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 EMA lease agreement, the Agency sought contractual possibilities to dispose of the premises and mitigate the financial burden on the EU budget, subletting its premises from July 2019 for the full period until the expiry of EMA's lease in June 2039. However, it must be noted that EMA remains legally bound by the lease and is financially responsible for its former premises in the UK. As a result of this long-term liability, the Agency has to continuously divert some of its financial and 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

[12] ECA special report Future of EU agencies – Potential for more flexibility and cooperation p.23 (published on 22 October 2020)

EU have business use – an activity not foreseen in the Agency's founding regulation. The total estimated outstanding rent, associated service charges and landlord insurance to be paid by EMA for the period from 2021 until the end of the lease term is €377 million (£338 million). The EMA Management Board has stressed on numerous occasions unsustainability of this situation in the long term and requested EU institutions to resolve this matter at the highest political level. The current volatility of global – and UK – economies, caused by the pandemic, further highlights the urgency of a fast political-level resolution to allow the Agency to fully focus its resources on fighting this public health crisis.

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, 4 May 2021

[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 and cancellation of appropriations

Budget outturn	2016	2017	2018	2019	2020[1)]
Reserve from previous years' surplus (+)	€ 1,949,934.18	€ 12,766,679.69	€ 10,231,434.65	€ 14,468,000.00	€ 13,800,853.44
Revenue actually received (+)	€ 303,148,763.37	€ 304,593,745.61	€ 306,849,690.42	€ 325,421,499.26	€ 362,445,169.10
Payments made (-)	-€ 254,096,375.63	-€ 253,807,515.04	-€ 253,281,077.77	-€ 292,769,994.74	-€ 290,132,295.87
Carry-over of appropriations (-)	-€ 43,032,304.83	-€ 54,017,070.70	-€ 54,821,802.27	-€ 59,150,354.42	-€ 75,300,936.06
Cancellation of appropriations carried over (+)	€ 2,763,567.15	€ 4,350,907.86	€ 4,982,084.89	€ 2,744,268.82	€ 2,423,908.71
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00
Exchange rate differences (+/-)	-€ 502,149.59	€ 581,555.58	-€ 159,476.48	€ 1,003,466.80	-€ 585,264.08
Adjustment for negative balance from previous year (-)	€ 0.00	€ 0.00	€ 0.00	€ 0.00	-€ 8,283,114.28
Total	**€ 10,231,434.65**	**€ 14,468,303.00**	**€ 13,800,853.44**	**-€ 8,283,114.28**	**€ 4,368,320.96**

1) Data as per provisional 2020 accounts

The financial outturn, a surplus of approx. EUR 4.37 million, representing 1.18% of the final budget, was caused mainly by higher than budgeted fee-related income being collected at the end of the year.

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

Title I

- lower expenditure on salaries and allowances, staff training and duty travel; mainly due to lower recruitment and the effect of teleworking and lock-down (COVID-19 pandemic). These savings were partially offset by higher than budgeted expenditure on national experts (new commitment rules), trainees and employer’s social security payments;

Title II

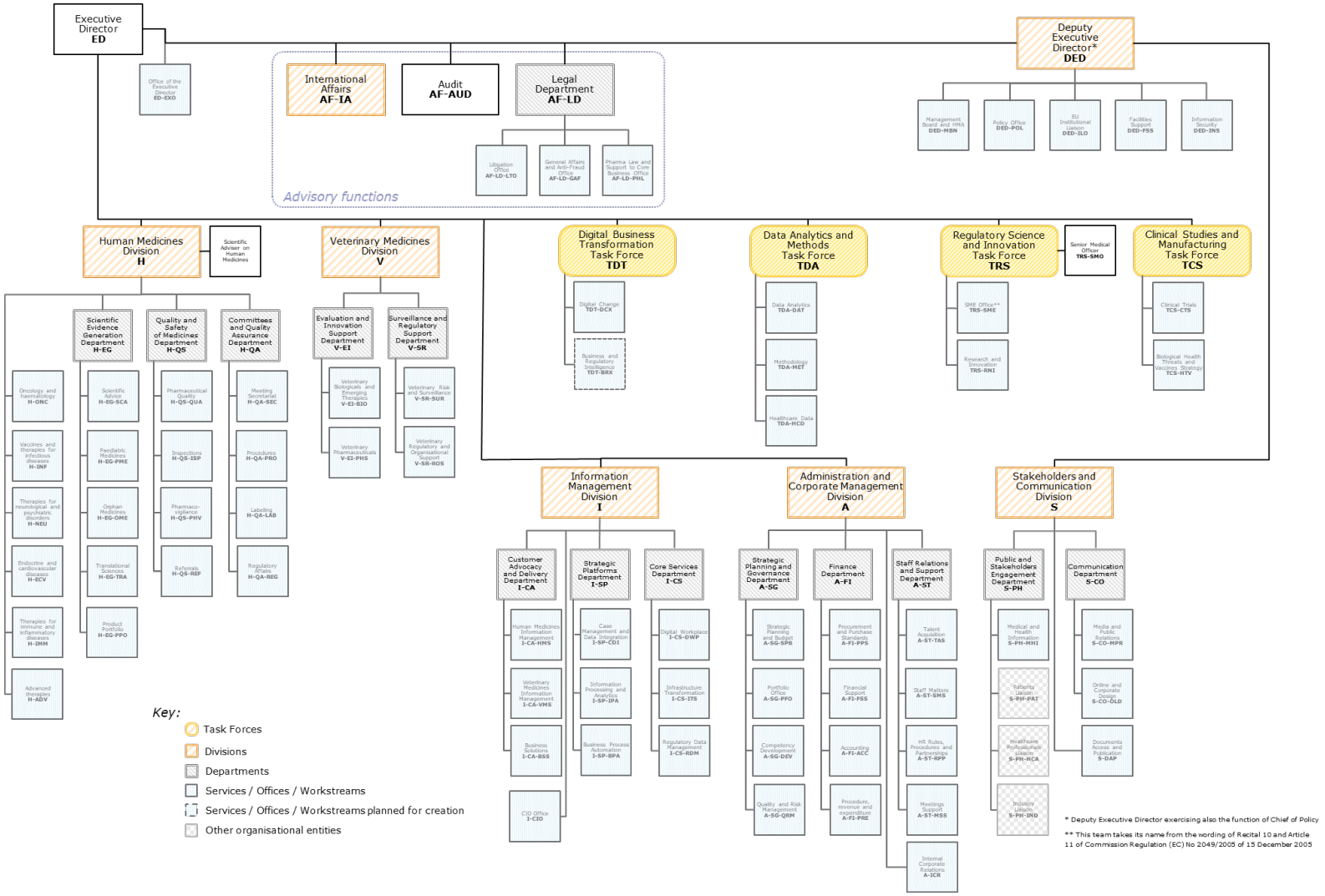
- lower than estimated costs related to the Agency’s former headquarters in London, in particular inducements, lower expenditure on cleaning, catering (COVID-19 pandemic);
- offset by higher expenditure on IT hardware, IT maintenance cost (caused by COVID-19 pandemic) and consultancy related to projects and initiatives.

Title III

- higher expenditure on business IT development, due to the launch of new projects, as approved by EXB; higher expenditure on rapporteurs, as a consequence of higher number of applications submitted, and on scientific studies (related to COVID-19).
- partly offset by lower meeting expenditure (due to COVID-19 pandemic).

The Agency achieved outcomes below or close to the guidance 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: 4.6%, title II: 20.7%, title III: 31.5%.

Annex 3. Organisation chart as at 31 December 2020



Annex 4. Establishment plan and additional information on HR management

Category and grade	Authorised for 2019		Occupied as of 31/12/2019			Authorised for 2020		Occupied as of 31/12/2020			Authorised for 2021	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts
				Grade filled	Actual grade				Grade filled	Actual grade		
AD 16	-	0	-	0	0	-	0	-	0	0	-	0
AD 15	-	3	-	3	1	-	3	-	3	0	-	3
AD 14	-	7	-	7	3	-	8	-	8	5	-	9
AD 13	-	11	-	10	12	-	12	-	12	9	-	13
AD 12	-	43	-	43	24	-	44	-	44	28	-	45
AD 11	-	43	-	43	34	-	47	-	47	34	-	51
AD 10	-	41	-	43	36	-	44	-	44	34	-	51
AD 9	-	45	-	43	26	-	46	-	46	34	-	55
AD 8	-	59	-	59	85	-	66	-	66	90	-	71
AD 7	-	65	-	65	55	-	76	-	76	54	-	94
AD 6	-	23	-	23	57	-	46	-	46	65	-	65
AD 5	-	0	-	25	8	-	3	-	3	7	-	15
Total AD	***0***	***340***	***0***	***364***	***341***		***395***	***0***	***395***	***360***		***472***
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	7	-	7	2	-	7	-	7	3	-	7
AST 9	-	6	-	6	5	-	8	-	8	5	-	9
AST 8	-	16	-	16	4	-	19	-	19	8	-	10
AST 7	-	22	-	22	13	-	15	-	15	12	-	19
AST 6	-	42	-	25	26	-	15	-	15	33	-	20
AST 5	-	46	-	33	35	-	39	-	39	36	-	38
AST 4	-	57	-	55	54	-	52	-	52	50	-	46
AST 3	-	46	-	46	66	-	44	-	44	62	-	32
AST 2	-	7	-	7	26	-	0	-	0	19	-	2
AST 1	-	0	-	0	11	-	0	-	0	8	-	0
Total AST	***0***	***251***	***0***	***219***	***242***		***201***	***0***	***201***	***236***		***185***
AST/SC1	-		-			-		-			-	
AST/SC2	-		-			-		-			-	
AST/SC3	-		-			-		-			-	
AST/SC4	-		-			-		-			-	
AST/SC5	-		-			-		-			-	
AST/SC6	-		-			-		-			-	
Total AST/SC	***0***	***0***	***0***	***0***	***0***			***0***	***0***	***0***		
Grand subtotal	***0***	***591***	***0***	***583***	***583***		***596***	***0***	***596***	***596***		***657***
Grand total	**591**		**0**	**583**	**583**	**596**		**0**	**596**	**596**	**657**	

Grade filled refers to the number of staff occupying posts of a given grade, regardless of the staff member's actual grade. *Actual grade* refers to the number of staff in a certain grade. E.g., in 2019 there were 43 staff members occupying AD 9 posts (grade filled); however, only 26 staff members were actually grade AD 9 (actual grade), occupying either AD 9 or higher grade posts. Staff members can occupy a higher grade post than their actual grade but not vice-versa.

Contract agents	Authorised budget 2019 (in FTE)	As of 31/12/2019:		Authorised budget 2020 (in FTE)	As of 31/12/2020:		Authorised budget 2021 (in FTE)
		Executed FTE	Headcount		Executed FTE	Headcount	
Function Group IV	52	76	79	52	98	76	110
Function Group III	131	56	60	131	73	62	81
Function Group II	10	41	32	10	28	26	10
Function Group I	0	0	0	0	0	0	0
Additional CA[1]	40	14	28	35	0	33	25
TOTAL	**233**	**187**	**199**	**228**	**199**	**197**	**226**

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

Seconded national experts	Authorised budget 2019 (in FTE)	As of 31/12/2019:		Authorised budget 2020 (in FTE)	As of 31/12/2020:		Authorised budget 2021 (in FTE)
		Executed FTE	Headcount		Executed FTE	Headcount	
Total	30	28	31	30	28	32	30

Interims: from 1 January 2020 to 31 December 2020, there have been a total of 42 interims, including 6 that transitioned from 2019, and the average length of an interim assignment during 2020 was 6.84 months.

Information on the entry level for each type of post

The entry grades for recruitment of **temporary agents** are AST 1, AST 3, AD 5, AD 6, AD 7, AD 8 (Senior Scientist/Administrator), AD 6 to 8 (Service Head), AD 9/10 (Head of Department) and AD 12 (Head of Division) in line with the functions of the post advertised.

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
Assistant	CA FGIII.09	External	Operations
Administrator	TA AD07	External	Administrative support
Head of Division	TA AD12	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Scientific Communication Officer	CA FGIV.16	External	Operations
Head of Service	TA AD10	External	Administrative support
Assistant	CA FGIII.10	External	Operations
Administrator	TA AD06	External	Operations
Assistant	CA FGIII.09	External	Operations
Junior Scientific Officer	CA FGIV.16	External	Operations
Junior Scientific Officer	CA FGIV.16	External	Operations
Assistant	TA AST03	External	Administrative support
Assistant	CA FGIII.10	External	Administrative support
Administrator	TA AD06	External	Operations
Assistant	CA FGIII.09	External	Administrative support
Junior Scientific Officer	CA FGIV.16	External	Operations
Administrator	TA AD06	External	Administrative support
Administrator	TA AD06	External	Operations
Technical Officer	CA FGIV.14	External	Operations
Assistant	TA AST04		Administrative support
Junior Scientific Officer	CA FGIV.16	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Administrator	TA AD08	External	Operations
Administrator	TA AD08	External	Operations
Administrator	TA AD06	External	Operations
Assistant	CA FGIII.10	External	Operations
Head of Workstream	TA AD08	External	Administrative support
Assistant	CA FGIII.09	External	Administrative support
Assistant	CA FGIII.09	External	Administrative support
Assistant	CA FGIII.09	External	Administrative support
Assistant	CA FGIII.09	External	Administrative support
Assistant	CA FGIII.09	External	Administrative support
Administrator	TA AD06	External	Administrative support
Administrator (ex-Hser ad interim)	TA AD06	External	Administrative support
Administrator	TA AD06	External	Administrative support
Head of Service	TA AD08	External	Operations
Administrator	TA AD08	External	Operations
Assistant	CA FGIII.09	External	Operations
Data Manager	CA FGIV.14	External	Operations
Assistant	CA FGIII.09	External	Administrative support
Assistant	CA FGIII.10	External	Administrative support
Administrator	TA AD06	External	Operations
Administrator	TA AD08	External	Operations

Head of Department	TA AD10	External	Operations
Head of Service	TA AD08	External	Operations
Head of Service	TA AD08	External	Operations
Administrator	TA AD06	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Assistant	CA FGIII.10	External	Administrative support
Assistant	CA FGIII.10	External	Administrative support
Head of Office	TA AD08	External	Operations
Head of Department	TA AD10	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Junior Scientific Officer	CA FGIV.16	External	Operations
Administrator	TA AD06	External	Operations
Administrator	TA AD06	External	Operations
Executive Director	TA AD14	External	Operations
Junior Scientific Officer	CA FGIV.14	External	Operations
Administrator	TA AD08	External	Administrative support

Results of the screening/benchmarking exercise as of December 2020

Job type (sub) category	2019 (%)	2020 (%)
Administrative support and Coordination	**17%**	**13%**
Administrative Support	16%	12%
Coordination	1%	1%
Operational	**78%**	**79%**
Top Level Operational Coordination	2%	2%
Programme Management & Implementation	20%	24%
Evaluation & Impact Assessment	40%	37%
General Operational	16%	16%
Neutral	**5%**	**8%**
Finance / Control	5%	8%
Linguistics	0%	0%
Total	**100%**	**100%**

Article 29(3) of the Framework Financial Regulation sets the obligation for all European Union institutions and agencies to carry out a benchmarking exercise, with the aim of justifying administrative expenditure in a structured way, using a common methodology.

Jobs are grouped according to the Commission Screening methodology under three main types: Administrative support and coordination, Operational and Neutral.

The jobs screened include all establishment plan posts (TA) occupied full time, part time, or vacant, and all other types of contracts occupied by a jobholder (CA, SNE, INT, TR, long-term contractors/consultants, external service providers) fulfilling all or most of these criteria: minimum

three month contract, have a badge, occupy an office space, have a phone (personal number), have a computer (personal ID, e-mail).

HR implementing rules adopted in 2020

Implementing rule	Adopted	Effective date
Derogation from Commission Decision on Administrative inquiries & disciplinary procedures	Management Board meeting 19 March 2020	19/03/2020
Commission Decision on procedures for dealing with incompetence	Management Board meeting 19 March 2020	19/03/2020
Commission Decision on the use of drivers	Management Board meeting 19 March 2020	19/03/2020
Model decision on the non-application of Amendment to Commission Decision C (2004)1597/6 of 28 April 2004 on the maximum duration for the recourse to non-permanent staff in the Commission services	Management Board meeting 19 March 2020	19/03/2020
Revised decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests (own rules)	Management Board meeting 11 June 2020	11/06/2020
Commission decision - amendment of leave rules	Management Board meeting 1 October 2020	01/10/2020
Further revision of rules relating to Art. 11, aa1 and 13 of the SR concerning handling of declared interests	Management Board meeting 1 October 2020	01/10/2020

Annex 5. Human and financial resources by activity

Activities	Full Time Equivalence (Temporary and Contract Agents & Seconded National Experts)			Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	TOTAL
	Business as usual	Brexit preparedness	Total FTEs	€'000	€'000	€'000	€'000	€'000	
1 Evaluation activities for human medicines	**347**	**0**	**347**	**48,759**	**21,198**	**5,538**	**126,481**	**11,514**	**213,490**
1.1 Pre-authorisation activities	83	0	83	12,154	2,822	2,882	23,593	28	41,479
1.2 Initial evaluation activities	74	0	74	11,190	2,342	924	15,866	953	31,276
1.3 Post-authorisation activities	86	0	86	11,439	5,547	389	74,739	4,211	96,326
1.4 Referrals	14	0	14	1,756	440	158	37	278	2,669
1.5 Pharmacovigilance activities	61	0	61	7,600	2,236	791	12,246	2,785	25,659
1.6 Other specialized areas and activities	29	0	29	4,619	7,810	393	0	3,259	16,082
2 Evaluation activities for veterinary medicines	**43**	**0**	**43**	**6,008**	**6,563**	**841**	**4,199**	**558**	**18,168**
2.1 Pre-authorisation activities	2	0	2	239	62	94	299	0	695
2.2 Initial evaluation activities	12	0	12	1,594	403	220	1,247	122	3,586
2.3 Post-authorisation activities	12	0	12	1,397	560	112	728	194	2,991
2.4 Arbitrations and referrals	2	0	2	234	77	109	0	203	622
2.5 Pharmacovigilance activities	3	0	3	367	2,187	181	1,924	3	4,663
2.6 Other specialized areas and activities	12	0	12	2,176	3,274	125	0	36	5,612
3 Horizontal activities and other areas	**199**	**0**	**199**	**26,182**	**29,895**	**1,008**	**2,891**	**2,874**	**62,850**
3.1 Committee coordination	44	0	44	5,716	1,347	244	0	0	7,308
3.2 Inspection and Compliance	42	0	42	4,629	1,291	269	2,891	2	9,083
3.3 Partners and Stakeholders	27	0	27	4,255	824	487	0	1,310	6,876
3.3a Transparency and access to documents	27	0	27	3,315	744	0	0	0	4,059
3.3b Information	15	0	15	1,869	1,104	0	0	1,234	4,206
3.4 International activities	15	0	15	2,138	416	8	0	0	2,562
3.5 Information Management (incl. EU Telematics)	28	0	28	4,260	24,169	0	0	328	28,757
4 Corporate Governance and Support activities	**204**	**8**	**212**	**31,946**	**8,084**	**220**	**0**	**1,881**	**42,131**
4.1 Governance, Quality Management and Internal Audi	39	8	47	7,924	1,439	220	0	393	9,975
4.2 Finance	39	0	39	5,613	1,291	0	0	603	7,507
4.3 Information technology	43	1	44	7,357	1,281	0	0	0	8,638
4.4 Human resources	52	0	52	7,169	3,081	0	0	652	10,902
4.5 Infrastructure services	10	0	10	1,201	279	0	0	0	1,480
4.6 Communication (corporate)	21	0	21	2,683	712	0	0	233	3,629
Total	**794**	**8**	**802**	**112,895**	**65,740**	**7,606**	**133,571**	**16,827**	**336,638**

Brexit related expenditure	**43,026**
Expenditure (C1+R0) 2020	**379,664**

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**		**2019**		**2020**	
Grant agreements										
1. STARS	17/07/2019 (EMA's accession)	EUR 7,500	36 months as of 01/01/2019	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
						Number of CA				
						Number of SNEs				
2. ConcePTION	26/04/2019	EUR 85,000	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	Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
3. PREMIER	29/06/2020	EUR 47,000	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
						Number of CA				
						Number of SNEs				
4. SISAQOL	30/10/2020	78,756.25	48 months as of 01/01/2021	Innovative Medicines Initiative 2 Joint Undertaking	Establishing international standards in the analysis of patient reported outcomes and health-related quality of life data in cancer clinical trials					
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	EUR 254,919	36 months as of 01/01/2019	European Union	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
Total contribution agreements						Amount	CA	PA	CA	PA
							€ 0.00	€ 0.00	€ 0.00	€ 0.00
						Number of CA	0		0	
						Number of SNEs	0		0	
Service-level agreements										
EMA does not provide services for other EU entities, hence has no corresponding service level agreements						Amount	CA	PA	CA	PA
						Number of CA				
						Number of SNEs				
						Amount	CA	PA	CA	PA
Total service-level agreements						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**	**€ 0.00**	**€ 0.00**
						Number of CA	**0**		**0**	
						Number of SNEs	**0**		**0**	

Annex 7. Environment management

In 2020, the Agency continued its work on developing an Environmental Management System in line with the EMAS regulation.

Since April 2020, preparations for the Environmental Management activities were resumed and a 'Roadmap for Environmental Management 2020 to 2024"' with a target for registration to EMAS within that period will been put in place as of 14 January 2021. As a first action the Environmental Policy will be reviewed and approved on 14 January 2021, and staff involvement will be secured through re-initiation of the EMA Green Group at the end of January 2021, in accordance with an updated mandate.

As of 2020, the Environmental Management System, EMS, is being updated with specifics of the Agency's new permanent premises.

To implement the Environmental Management activities the following resources have been allocated:

- an Environmental Lead to develop and coordinate the necessary activities;

- a facility officer for environmental activities to align operational facilities management;

- participation by staff as Environmental Ambassadors in the EMA Green Group for staff promotion and involvement in planned activities;

- nominating the Deputy Executive Director to report to the Agency Executive Director and the Executive Group for senior management leadership input.

The information regarding environmental management provided to staff on the EMA intranet has been updated in close collaboration with resources from the Internal Communication office and external stakeholder involvement will be coordinated in contact with the EMA External Communication Department. Information regarding environmental consideration and how to support an environmentally friendly approach in the EMA building is provided in the induction training to all staff.

EMA is also participating in the inter-institutional tender procedure for Green criteria in procurements helpdesk services, launched in late 2020.

The Agency's environmental footprint is tracked in the following areas:

- Energy and water consumption from occupancy of the building
- Waste management: active waste management with separation of glass, plastic, paper/cardboard, metal and food. Active prevention of waste production (paper) by follow-me print regime and laptops for all staff
- Duty travel by staff and Delegates
- CO_2 emissions of the Agency operations

The European Union has, within the Green Deal, updated its target by setting a 55% reduction by the year 2030 compared to 1990. EMA was founded in 1995 with continuous growth over time in line with its increased mission. Since 2013, the number of staff employed has been relatively stable, which is therefore selected as the adjusted base year to use for reduction purposes. The 55% target is hence adjusted to 2013 by using a linear approach, leaving the Agency with a long-term reduction target of 23.4% in comparison with year 2013.

Due to occupancy of the EMA building since January 2020, following temporary premises being occupied for a majority of 2019 (10 March until 31 December 2019), compulsory teleworking due to the COVID-19 pandemic for a majority of 2020 (16 March to 30 September), and reduced office occupancy for the remainder of 2020, there is still fine-tuning to be expected in the EMA building also in 2021.

Once the activities and occupancy of the office premises resumes to the full capacity and all building installations are fully tuned, further targets will be introduced for active and continuous improvements.

Annex 8. Draft annual accounts

Following a positive opinion by the European Court of Auditors, the Agency's annual accounts for the financial year 2019 were successfully adopted by the Management Board in June 2020 and sent to the Budget authority (European Parliament and Council) by 1 July 2020.

At the time of writing, the Court of Auditors had not yet provided the Agency with their observations on the provisional accounts and therefore, the Agency’s final accounts 2020 had not been issued yet. During the assessment of the Annual Activity Report, EMA management board has been actively involved in the review of 2020 annual accounts. The financial year 2020 has seen an increased complexity in accounting and financial matters as a result of the Agency’s relocation and the more recent challenges brought by the outbreak of COVID-19.

Annex 9. 2020 report on staff engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

Engaging in an occupational activity within two years of leaving the service - restrictions applied to applications in 2020:

Case No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
n/a	Assistant	15 years 3 months	6/01/2020	24/01/2020	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 staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 15 years and three months of service.	13/02/2020
n/a	Lead data officer	10 years	12/02/2020	27/02/2020	During a period of six months to be counted as of the date she left the service, she should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 10 years of service.	12/03/2020
n/a	Legal administrator	7 years 6 months	27/02/2020	18/03/2020	The joint committee considers that the former staff member, in the course of her professional activities may not engage in any activity, whether gainful or not, which concerns any legal case involving the EMA, or any case connected to the EMA, and in which she was previously involved directly or indirectly. This restriction shall apply indefinitely.	27/03/2020
n/a	Scientific Committee Manager	3 years	4/03/2020	18/03/2020	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 staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 3 years of service.	26/03/2020

Case No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Restrictions	Date of Executive Director's decision
n/a	Senior Scientific advisor	24 years 6 months	5/03/2020	18/03/2020	During a period of twelve months to be counted as of the date she left the service, the staff member should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 24 years and six months of service.	24/03/2020
n/a	Procedure manager/Procedure assistant	13 years 2 months	23/04/2020	5/05/2020	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 staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 13 years and two months of service.	13/05/2020
n/a	Scientific Officer	8 years 9 months	5/05/2020	8/05/2020	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 staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her 8 years and nine months of service.	29/05/2020
n/a	Scientific Administrator	10 years 7 months 15 days	24/06/2020	7/07/2020	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 staff of the Agency with regard to any professional activity she may have dealt with in the performance of her responsibilities at the Agency during her service.	14/07/2020

Annex 10. Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2020

The table below lists those contracts signed during the reference period 1 January 2020 - 31 December 2020.

All the procedures were carried out in line with the regulations and rules governing the different types of procurement procedures in the EU institutions, to ensure transparency, objectivity and fairness of the process, to eliminate fraud and corruption possibilities, and to ensure EMA obtains best value-for-money. The contracts were awarded to the best candidates, based on thorough evaluations of specific criteria in each case.

Contract no.	Type of contract	Name of Contractor	Subject	Value (or estimated value, where applicable)	Procurement procedure and justification if negotiated procedure	Organisational entity
DI/07791	**Framework service contract**	**SAP Belgium NV/SA**	**Acquisition of professional SAP Services related to SAP software licenses**	**EUR 1,200,000.00**	**Negotiated procedure without contract notice (Art. 11)**	**Information Management Division**
EMA/2020/07/SG	**Framework service contract**	**Ashridge Executive & Organisational Development Ltd**	**Coaching & mngt development workshops (interim solution)**	**EUR 139,000**	**Negotiated procedure (>60-139K)**	**Administration and Corporate Governance Division**
EMA/2020/23/DED	**Framework service contract**	**Stern Consultancy Limited**	**Consultancy services on catering**	**EUR 139.000**	**Negotiated procedure (>60-139K)**	**Deputy Executive Director Division**
EMA/2020/16/FI	**Framework service contract**	**Grant Thornton UK LLP**	**Consultancy services on VAT in UK**	**EUR 139,000**	**Negotiated procedure (>60-139K)**	**Administration and Corporate Governance Division**
EMA/2020/01/FI	**Service contract**	**ING Belgium NV/SA**	**Corporate bank accounts - Deposit of surplus funds**	**EUR 1,537,500**	**Open tender**	**Administration and Corporate Governance Division**

EMA/2019/36/CO - Lot 1	**Service contract**	**EBSCO Information Services B.V.**	**Databases and other electronic information sources: Lot 1: MEDLINE Index complemented with full-text journals (MEDLINE COMPLETE or equivalent)**	**EUR 84.000**	**Open tender**	**Stakeholders and Communication Division**
EMA/2019/36/CO - Lot 2	**Service contract**	**Elsevier B.V.**	**Databases and other electronic information sources: Lot 2: Comprehensive biomedical index (EMBASE or equivalent)**	**EUR 209.776**	**Open tender**	**Stakeholders and Communication Division**
EMA/2019/36/CO - Lot 3	**Service contract**	**APM International**	**Databases and other electronic information sources: Lot 3: Newswire database (APM or equivalent)**	**EUR 116.000**	**Open tender**	**Stakeholders and Communication Division**
DI-07860	**Framework service contract**	**Orange Business Belgium SA**	**External and Internet Connectivity Services (EXICON)**	**EUR 1,360,474.00**	**Open tender**	**Information Management Division**
DI-07861	**Framework service contract**	**BT Global Services Belgium bvba**	**External and Internet Connectivity Services (EXICON)**	**EUR 1,360,474.00**	**Open tender**	**Information Management Division**

DI-07862	**Framework service contract**	**Vodafone Global Enterprise Limited**	**External and Internet Connectivity Services (EXICON)**	**EUR 1,360,474.00**	**Open tender**	**Information Management Division**
DI-07863	**Framework service contract**	**Proximus**	**External and Internet Connectivity Services (EXICON)**	**EUR 1,360,474.00**	**Open tender**	**Information Management Division**
EMA/2020/06/DED	**Supplies contract**	**Metos B.V.**	**Induction containers**	**EUR 15,000**	**Negotiated procedure (1-15K)**	**Deputy Executive Director Division**
EMA/2019/28/IT/2.1	**Framework service contract**	**Everis Belgique**	**IT software development, configuration, implementation and maintenance services for technology specific services - Master Data Management (MDM) solutions based on Informatica technologies (Lot 2)**	**EUR 8.000.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/2.2	**Framework service contract**	**Capgemini Nederland B.V.**	**IT software development, configuration, implementation and maintenance services for technology specific services - Master Data Management (MDM) solutions based on Informatica technologies (Lot 2)**	**EUR 8.000.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/2.3	**Framework service contract**	**- Accenture BV (leader) - Next ventures BV - Octopus International SA/NV**	**IT software development, configuration, implementation and maintenance services for technology specific services - Master Data Management (MDM) solutions based on Informatica technologies (Lot 2)**	**EUR 8.000.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/2.4	**Framework service contract**	**Viqtor Davis NL BV**	**IT software development, configuration, implementation and maintenance services for technology specific services - Master Data Management (MDM) solutions based on Informatica technologies (Lot 2)**	**EUR 8.000.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/1.1	**Framework service contract**	**- ATOS Nederland BV (leader) - Seidor Consulting SL - Unisystems Luxembourg SARL**	**IT software development, configuration, implementation and maintenance services for technology specific services - solutions based on Microsoft software, Microsoft technology services and related technologies (Lot 1)**	**EUR 12.000.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/1.2	**Framework service contract**	**- Everis Belgique (leader) - Ilionix Group BV**	**IT software development, configuration, implementation and maintenance services for technology specific services - solutions based on Microsoft software, Microsoft technology services and related technologies (Lot 1)**	**EUR 12.000.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/1.3	**Framework service contract**	**Capgemini Nederland B.V.**	**IT software development, configuration, implementation and maintenance services for technology specific services - solutions based on Microsoft software, Microsoft technology services and related technologies (Lot 1)**	**EUR 12.000.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/1.4	**Framework service contract**	**- Altia Consultores S.A. (leader) - Hellenic Telecommunications Org. S.A. (OTE S.A.)**	**IT software development, configuration, implementation and maintenance services for technology specific services - solutions based on Microsoft software, Microsoft technology services and related technologies (Lot 1)**	**EUR 12.000.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/1.5	**Framework service contract**	**- CANCOM online GmbH (leader) - CANCOM online B.V. - CANCOM GmbH - Delaware Consulting**	**IT software development, configuration, implementation and maintenance services for technology specific services - solutions based on Microsoft software, Microsoft technology services and related technologies (Lot 1)**	**EUR 12.000.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/3.1	**Framework service contract**	**- Seidor Consulting S.L. (leader) - Atos Nederland B.V.**	**IT software development, implementation and maintenance of Enterprise Resource Planning (ERP) solutions based on SAP technologies (Lot 3)**	**EUR 5.600.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/3.2	**Framework service contract**	**- Accenture B.V. (leader) - Octopus International SA/NV - Next Ventures B.V.**	**IT software development, implementation and maintenance of Enterprise Resource Planning (ERP) solutions based on SAP technologies (Lot 3)**	**EUR 5.600.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/3.3	**Framework service contract**	**- Everis Belgique SPRL (leader) - myBrand B.V.**	**IT software development, implementation and maintenance of Enterprise Resource Planning (ERP) solutions based on SAP technologies (Lot 3)**	**EUR 5.600.000**	**Open tender**	**Information Management Division**

EMA/2019/28/IT/3.4	**Framework service contract**	**PwC EU Services EESV**	**IT software development, implementation and maintenance of Enterprise Resource Planning (ERP) solutions based on SAP technologies (Lot 3)**	**EUR 5.600.000**	**Open tender**	**Information Management Division**
EMA/2019/28/IT/3.5	**Framework service contract**	**Capgemini Nederland B.V.**	**IT software development, implementation and maintenance of Enterprise Resource Planning (ERP) solutions based on SAP technologies (Lot 3)**	**EUR 5.600.000**	**Open tender**	**Information Management Division**
2019/EJ/03/PO - Lot 1	**Framework service contract**	**KPN**	**Landline Telephony**	**EUR 625,000**	**Open tender**	**Administration and Corporate Governance Division**
HR/R1/PO/2019/024 - Lot 4	**Framework service contract**	**Abilways**	**Learning and Development services in the field of Communication**	**EUR 239,000**	**Open tender**	**Administration and Corporate Governance Division**
HR/R1/PO/2019/024 - Lot 5	**Framework service contract**	**BDO Ltd**	**Learning and Development services in the field of Economy, finance, audit and internal control**	**EUR 194,000**	**Open tender**	**Administration and Corporate Governance Division**

HR/R1/PO/2019/024 - Lot 2	**Framework service contract**	**Ernst & Young**	**Learning and Development services in the field of Human Resources**	**EUR 136,000**	**Open tender**	**Administration and Corporate Governance Division**
HR/R1/PO/2019/024 - Lot 1	**Framework service contract**	**EIPA**	**Learning and Development services in the field of International affairs, EU governance, policy-making and strategy building**	**EUR 39,000**	**Open tender**	**Administration and Corporate Governance Division**
HR/R1/PO/2019/024 - Lot 3	**Framework service contract**	**Essec**	**Learning and Development services in the field of Negotiation**	**EUR 35,000**	**Open tender**	**Administration and Corporate Governance Division**
EMA/2019/40/LD_1	**Framework service contract**	**AKD BV/BA**	**Legal advice on contracts and procurement in NL - 1st priority**	**EUR 142,000**	**Negotiated procedure (>60-139K)**	**Advisory function-Legal Department**
EMA/2019/40/LD_2	**Framework service contract**	**Dentons Europe LLP**	**Legal advice on contracts and procurement in NL - 2nd priority**	**EUR 142,000**	**Negotiated procedure (>60-139K)**	**Advisory function-Legal Department**
EMA/2019/32/LD	**Framework service contract**	**Dentons Europe LLP**	**Legal advice on real estate and building management (NL law) - 1st priority**	**EUR 143,500**	**Negotiated procedure (>60-139K)**	**Advisory function-Legal Department**

EMA/2019/32/LD	**Framework service contract**	**NautaDuthil N.V.**	**Legal advice on real estate and building management (NL law) - 2nd priority**	**EUR 143,500**	**Negotiated procedure (>60-139K)**	**Advisory function-Legal Department**
EMA/2020/11/LD	**Framework service contract**	**DLA Piper UK LLP company**	**Legal support for 30 Churchill Place (UK law)**	**EUR 1,100,000**	**Negotiated procedure without contract notice (Art. 11)**	**Advisory function-Legal Department**
2019/OP/0029LOT1	**Framework service contract**	**Gopa Com**	**Lot 1 Thematic Communication Services, Advertising & Media planning - 1st priority**	**EUR 162,499.99**	**Open tender**	**Stakeholders and Communication Division**
2019/OP/0029LOT1	**Framework service contract**	**Ecorys Europe**	**Lot 1 Thematic Communication Services, Advertising & Media planning - 2n priority**	**EUR 162,499.99**	**Open tender**	**Stakeholders and Communication Division**
2019/OP/0029LOT1	**Framework service contract**	**Pomilio Blumm SRL**	**Lot 1 Thematic Communication Services, Advertising & Media planning - 3rd priority**	**EUR 162,499.99**	**Open tender**	**Stakeholders and Communication Division**
2019/OP/0029LOT2	**Framework service contract**	**European Service Network SA**	**Lot 2 Thematic Online Communication Campaigns - 1st priority**	**EUR 87,499.98**	**Open tender**	**Stakeholders and Communication Division**

2019/OP/0029LOT2	**Framework service contract**	**Gopa Com**	**Lot 2 Thematic Online Communication Campaigns - 2nd priority**	**EUR 87,499.98**	**Open tender**	**Stakeholders and Communication Division**
2019/OP/0029LOT2	**Framework service contract**	**Tipik Communication AGency**	**Lot 2 Thematic Online Communication Campaigns - 3rd priority**	**EUR 87,499.98**	**Open tender**	**Stakeholders and Communication Division**
OC/EFSA/FIN/2019/01	**Framework service contract**	**Business Integration Partners SPA (4th priority)**	**Management consultancy services**	**EUR 15,000,000**	**Open tender**	**Administration and Corporate Governance Division**
OC/EFSA/FIN/2019/01	**Framework service contract**	**Deloitte Consulting & Advisory (1st in cascade)**	**Management consultancy services**	**EUR 15,000,000**	**Open tender**	**Administration and Corporate Governance Division**
OC/EFSA/FIN/2019/01	**Framework service contract**	**KPMG Advisory CVBA/SCRL (2nd priority)**	**Management consultancy services**	**EUR 15,000,000**	**Open tender**	**Administration and Corporate Governance Division**
OC/EFSA/FIN/2019/01	**Framework service contract**	**PWC EU Services (3rd priority)**	**Management consultancy services**	**EUR 15,000,000**	**Open tender**	**Administration and Corporate Governance Division**
HR/R1/PO/2019/034	**Framework service contract**	**Consortium Abilways/ICG**	**Organisational Development and Collaborative Working services**	**N/A**	**Open tender**	**Administration and Corporate Governance Division**
NP/EFSA/HUCAP/2019/03	**Framework service contract**	**LinkedIn**	**Professional Social Network Services**	**EUR 420,000**	**Negotiated procedure without contract notice (Art. 11)**	**Administration and Corporate Governance Division**

NP/EFSA/HUCAP/2019/03	**Framework service contract**	**Research Gate**	**Professional Social Network Services**	**EUR 22,000**	**Negotiated procedure without contract notice (Art. 11)**	**Administration and Corporate Governance Division**
OC/EFSA/HUCAP/2019/02-1	**Framework service contract**	**PwC EU Services EESV (1st priority)**	**Provision of assistance with staff selection procedures**	**EUR 575,000**	**Open tender**	**Administration and Corporate Governance Division**
OC/EFSA/HUCAP/2019/02-2	**Framework service contract**	**SHL ITALY Srl Unipersonale (2nd priority)**	**Provision of assistance with staff selection procedures**	**EUR 575,000**	**Open tender**	**Administration and Corporate Governance Division**
OC/EFSA/HUCAP/2019/02-3	**Framework service contract**	**May & Company GmbH (3rd priority)**	**Provision of assistance with staff selection procedures**	**EUR 575,000**	**Open tender**	**Administration and Corporate Governance Division**
EMA/2020/04/DED	**Service contract**	**CGREA**	**Provision of electricity to the EMA's new building**	**EUR 2,563,000**	**Negotiated procedure without contract notice (Art. 11)**	**Deputy Executive Director Division**
EMA/2019/18/IT	**Framework service contract**	**Everis Belgique**	**Provision of external service providers for IT Infrastructure Administration, Security Implementation and End User Equipment and Software Management - 1st priority**	**EUR 6,100,000.00**	**Open tender**	**Information Management Division**

EMA/2020/43/IT	**Framework service contract**	**OTE-ARHS-ALTIA Consortium Hellenic Telecommunications Organization S.A.- OTE AE (leader) ARHS Developments SA ALTIA Consultores S.A**	**Provision of external service providers for IT Infrastructure Administration, Security Implementation and End User Equipment and Software Management - 2nd priority**	**EUR 6,100,000.00**	**Open tender**	**Information Management Division**
EMA/2020/44/IT	**Framework service contract**	**AON Consortium Accenture BV (leader) Octopus International SA/NV Next Ventures BV**	**Provision of external service providers for IT Infrastructure Administration, Security Implementation and End User Equipment and Software Management - 3rd priority**	**EUR 6,100,000.00**	**Open tender**	**Information Management Division**
EMA/2019/13/IT	**Framework service contract**	**BeYOND Consortium Everis Belgique (leader) Sopra Steria Benelux**	**Provision of external services for IT software development, implementation and maintenance for the existing systems and new systems as required by the new veterinary legislation - 1st priority**	**EUR 44,000,000.00**	**Open tender**	**Information Management Division**

EMA/2020/33/IT	**Framework service contract**	**ASCLEPIUS Consortium Trasys International EEIG (leader) Capgemini Nederland B.V. Sword Technologies**	**Provision of external services for IT software development, implementation and maintenance for the existing systems and new systems as required by the new veterinary legislation - 2nd priority**	**EUR 44,000,000.00**	**Open tender**	**Information Management Division**
EMA/2020/34/IT	**Framework service contract**	**AMON Consortium Accenture BV (leader) Montreal Associates (Systems) SL, Octopus International SA/NV Next Ventures BV**	**Provision of external services for IT software development, implementation and maintenance for the existing systems and new systems as required by the new veterinary legislation - 3rd priority**	**EUR 44,000,000.00**	**Open tender**	**Information Management Division**
EIOPA-OP-031-2019 - Lot 1	**Framework service contract**	**Target Training GmbH**	**Provision of training services (Personal Development)**	**EUR 647,727.27**	**Open tender**	**Administration and Corporate Governance Division**
EMA/2020/19/SG	**Framework service contract**	**Tharseo Ltd**	**Staff support and well-being**	**EUR 15,000**	**Negotiated procedure (1-15K)**	**Administration and Corporate Governance Division**
EMA/2019/21/CO	**Supplies contract**	**LM Tietopalvelut Oy**	**Subscriptions to general and international press**	**EUR 32,000**	**Negotiated procedure (>15-60k)**	**Administration and Corporate Governance Division**

EMA/2019/39/CO_01	**Framework service contract**	**Opmeer Drukkerij BV**	**Supply of printing services**	**EUR 132,000.00**	**Negotiated procedure (>60-139K)**	**Stakeholders and Communication Division**
EMA/2019/39/CO_02	**Framework service contract**	**Drukkerij Kedde BV**	**Supply of printing services**	**EUR 132,000.00**	**Negotiated procedure (>60-139K)**	**Stakeholders and Communication Division**
BUDG-19-PO-01	**Framework service contract**	**Baker Tilly Belgium**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**BDO Ltd**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**Deloitte**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**EY Belgium**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**KPMG**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**Lubbock Fine Ltd**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
BUDG-19-PO-01	**Framework service contract**	**Mazars France**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**

BUDG-19-PO-01	**Framework service contract**	**PWC**	**Technical assistance services for audits and controls**	**EUR 360,000**	**Open tender**	**Advisory function-Audit**
DI-07820	**Framework service contract**	**T-Systems International GmbH**	**TESTA-ng II Ext - Secured and highly available connectivity among member states**	**EUR 40,000**	**Negotiated procedure**	**Information Management Division**

Annex 11. Administrative appropriations – Building policy

Financial Regulation, Article 87(3.a) 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	10,507,286	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (NL government Agency)	Y	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	Not applicable	None
Total			**40,520**	**23,231**	**63,751**	**10,507,286**					

The Dutch government provided the Agency with a temporary building (SPARK building) at no rental cost to the Agency for the interim period from January 2019, whilst the final premises were being constructed and fitted out. In January 2020, the Agency moved into its permanent premises in Domenico Scarlattilaan 6, 1083 HS, Amsterdam. The process of vacating the SPARK building began on 6 January and finished on 27 March 2020, with the termination of the corresponding lease agreement.

Financial Regulation, Article 87 (3.b) 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 87 (3.c) Building projects submitted to the European Parliament and the Council

In January 2020 the Agency moved into its permanent premises at Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands, and does not have any other planned building projects.

Annex 12. Annual report 2020

Please see the Agency's Annual report 2020, publicly available on the EMA corporate website.

Annex 13. Project implementation 2020

Project progress and delivery as of 31 December 2020 against what was planned in the work programme 2020 is reported using the following traffic-light system:

Time / budget	
	Project within +/-10% 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 during 2020, in comparison to what was planned and approved at the end of 2019 (i.e. as noted in the work programme 2020). Notes explaining the changes are added.

In cases where the project start- or end-dates foreseen in the work programme 2020 were revised during 2020, the current dates are added in the relevant cells, with the original date from the work programme 2020 shown as crossed out.

In line with the BCP implemented at the Agency, delivery of some of the projects in the adopted work programme was reduced or postponed. To reflect the current impact of the COVID-19 crisis, the status of the projects is indicated in the report under 'Results 2020' as *continues*, *reduced* or *suspended*, according to the decisions taken on these projects by 1 January 2021; this status indication is not linked to the results delivered in 2020, but only reflects the BCP status of a given project.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2020
				Time	Budget	Scope	
Clinical trials programme							
• 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	Q3 2014	2021-2022				CONTINUES - External audit happened as planned, in November/December 2020. - Development is now focusing on improving the quality and stability of the system, rectifying findings from user testing and findings from first audit fieldwork, to prepare the Go-Live version for end of January 2022.
• EudraCT linked to CTIS (EudraCT legacy)	Regulation (EC) 536/2014, Art. 80-82,98	2018	2021-2023				CONTINUES This project has been integrated under the CTIS new way of working and we will be delivered under the CTIS project.
e-Submission programme							
eCTD4 pre-project	n/a	2021	2022				SUSPENDED UNTIL 2021
Single Submission Portal	n/a	2021	2022				SUSPENDED UNTIL 2021
Veterinary change programme							
EudraVigilance veterinary v3.0	Regulation (EC) 726/2004, art.57(d)	2017	2022				CONTINUES - Integration with the technical element of the Human Pharmacovigilance has been delivered - The first iteration of the Datawarehouse and the Web interface have been delivered and tested

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2020
				Time	Budget	Scope	
							- On plan for the January 2022 go-live
New Veterinary Legislation	New veterinary legislation	Q1 2019	2022				CONTINUES - The programme has been defined with 3 new projects: The Union Product Database (UPD), the Antimicrobial Sale and Use (ASU), the Manufacturers and Wholesale Distribution Database (MWD); - The Union Product Database project has delivered its first version in production in 09/2020 - On plan for the January 2022 go live
Online programme							
European medicines web porta	Regulation (EC) 726/2004 Regulation (EC) 1235/2010, art.26	2021	2022				SUSPENDED UNTIL 2021
EMA Intranet	n/a	2021	2022				SUSPENDED UNTIL 2021
EMA Extranet	n/a	2021	2022				SUSPENDED UNTIL 2021
Data integration programme							
Substances and products management services	Regulation 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 Draft veterinary regulation, art.51	2017	2024				CONTINUED: Resources have been redirected under the New Veterinary Legislation programme, in order to support the delivery of the Union Product Database. MB decision from December 2019 allowed the project team to restart the activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2020
				Time	Budget	Scope	
	Clinical trials regulation 536/2014, art.8193) Pharmacovigilance fees regulation 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU						Re-planning of the activities and re-baselining of the project plan to be able to resume fully the activities by Q2 2021 - Resources have been onboarded and work resumed - Start of the integration of the Art.57 Database into PMS
Administration digitalisation	n/a	2019	2021				CONTINUES Provide better tools to overcome manual processing and repetitive tasks: onboarding tool launched in Q2 2020; onboarding portal published in Q2 2020 E-recruitment and Learning Management System were closed in Q2 2020 New Goals and Performance system and Succession Planning started in Q2 2020
IRIS Scientific advice SIAMED with Knowledge Management	n/a	2019	2021				CONTINUES Roadmap to capture the scientific knowledge has been drafted Process and system analysis and design were carried out in Q2 2020

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2020
				Time	Budget	Scope	
							ITF was integrated in IRIS Q2 2020 Scientific Advice was integrated in IRIS Q3 2020
Data centre refresh	n/a	2020	2021				- Project started Q2 2020 and will also update the Agency cloud strategy - Will be delivered in Q2 2021
Application Maintenance and Development (AM&D) sourcing project	n/a	2019	2021				CONTINUES The first tender for IT Framework Contract out of 4 was completed Q2 2020 and all other tenders in Q4 2020 Project will be closed in Q1 2021
Knowledge Transfer to the new DIMSIS contractor	n/a	2020	2020				CANCELLED as the vendors stay the same under the new DIMSIS Framework contract

Annex 14. Pharmacovigilance Fee Regulation: Key Performance Indicators and performance information for the calendar year 2020

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 2020, and section 3 presents the more detailed performance information required by the regulation.

Part 1: key Performance indicators

KP1: procedures started within the year for which a fee has been charged

Pharmacovigilance activities financed by PhV fees	2020 actual
Number of PSURs and PSUSAs procedures started	823
Number of imposed PASS protocol procedures started	3
Number of imposed PASS report procedures started	3
Number of pharmacovigilance referral procedures started	2
Number of pharmacovigilance annual fee chargeable units invoiced	155,867

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	2020 estimated %	2020 actual procedures	2020 actual %
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **CAPs only**:		579	
· Micro sized enterprises	2.25%	7	1.21%
· Small and medium sized enterprises	7.50%	34	5.87%
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **NAPs or CAPs/NAPs**:		5,363	
· Micro sized enterprises	2.50%	35	0.65%
· Small and medium sized enterprises	7.50%	199	3.71%
MAHs invoiced for **Imposed PASS protocol** procedures started for **CAPs only**:		3	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	1	33.33%
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**:		1	
· 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**:		2	
· Micro sized enterprises	2.5	0	0.00%
· Small and medium sized enterprises	7.50%	0	0.00%
MAHs invoiced for Pharmacovigilance **referral** procedures started for **CAPs only:**		0	

· 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:**		28	
· Micro sized enterprises	2.50%	0	0.00%
· Small and medium sized enterprises	7.50%	0	0.00%

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	2020 estimated %	2020 actual	2020 percentage
Pharmacovigilance **annual fee** chargeable units invoiced		155,867	
· Micro sized enterprises	2.50%	1,264	0.81%
· Small and medium sized enterprises	7.50%	9,151	5.87%
· Generics (non-SME)	36%	67,034	43.01%
· Authorised homeopathic, authorised herbal, and well-established use products	0%	26,316	16.88%

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	[13] Invoiced in 2020	Cash collected in 2020	[14] Percentage	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	17,691	17,639	85% (97% in 2019)	11,917
Income recovered for imposed PASS protocol procedures started	64	53	83% (100% in 2019)	27
Income recovered for imposed PASS report procedures started	106	105	99% (49% in 2019)	56
Income recovered for pharmacovigilance referral procedures started	369	358	97% (100% in 2019)	246
Income recovered for pharmacovigilance annual fee chargeable units invoiced	9,174	9,094	99% (99% in 2019)	n/a

[13] 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 2020 and processed in 2021, whereas the amounts shown in the tables below show only the value of the invoices related to the applications started between January and December 2020. In addition, some of the applications received at the end of the year were processed in the Financial system in January 2021.
[14] Invoices are issued with 30 days credit which means that the payment of the invoices issued in November and December 2020 were paid for in 2021. The final 2020 cash recovery rate as of April 2021 is 100% for PSURs and PSUSAs, PASS and Annual fee and 98% for referrals.

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 2020

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 2018, 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	**8**
Post-authorisation safety studies	**1**
Referrals initiated as a result of the evaluation of pharmacovigilance data	**2**
TOTAL	**11**

2) Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.		2020	
		Units	Cost €'000
Identifying and managing duplicates	Number of duplicate couples assessed	160,047 (176,736 in 2019)	1,264
	Number of 'master' reports generated based on duplicated data	85,168 (92,480 in 2019)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded:	54,366 (101,388 in 2019)	
	Number of adverse reaction reports recoded	76,990 (79,552 in 2019)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review	120 (123 in 2019)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected	145,320 (136,848 in 2019)	
[25] Monitoring of substance groups and selected medical literature	Number of literature references were screened and reviewed	549,312 (546,439 in 2019)	1,140
	Number of individual case safety reports (ICSRs) were entered into Eudravigilance database and made available to National Competent Authorities and Marketing Authorisation Holders.	9,535 (9,635 in 2019)	

[25] 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	928	12,246
Cost for assessment of post-authorisation safety studies	106	121
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	220	324
Annual cost for information technology systems and literature monitoring		6,423
Overall pharmacovigilance costs	**20,368**	

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[26]	Number of joint submissions[27]	Number of MAHs who submitted joint report[28]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
823	n/a	1,805	n/a	40,107	284	5,403	152	2	34	1	16,075,413

[26] Total number of CU generated for the products falling into the scope of the procedure - total number of CU (to be) invoiced
[27] Number of received joint submissions
[28] Total number of MAHs in received joint submissions

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[29]	Total number of MAHs[25]	Number of joint submissions[30]	Number of (parent) MAHs in case of joint submission	Total number of MAHs in case of joint submission	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
3	n/a	3	3	0	0	0	1	0	0	0	46,478
3	n/a	3	3	1	1	1	0	0	0	0	79,800

6) Performance information relating to referrals initiated as a result of the evaluation of pharmacovigilance data							
Number of procedures started	Number of MAHs	Number of CUs	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
2	28	107	0	0	0	0	369,200

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	152	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	0	0
Annual fee for information technology systems and literature monitoring	440	7

[29] Number of (parent) MAHs and total number of MAHs
[30] In case of joint submission:
• number of (parent) MAHs = number of (parent) MAHs in case of joint submission
• total number of MAHs = total number of MAHs in case of joint submission

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	34	1
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	0	0
Annual fee for information technology systems and literature monitoring	167	3

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2020
Generic application (Article 10(1) of Directive No 2001/83/EC)	2,040
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,881
Authorised homeopathic medicinal product	81
Authorised herbal medicinal product	261

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 (€)
3,798	155,867	440	7	167	3	72,418	25,735	2,995	1,695	9,174,360	58.86

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	*** PASS**	***Referral**
Austria	42	0	0
Belgium	18	0	0
Bulgaria	1	0	0
Czech Republic	12	0	0
Germany (BfArM)	40	1	1
Germany (PEI)	59	0	0
Denmark	56	2	0
Estonia	12	0	0
Spain	46	0	0
Finland	32	0	0
France	56	1	0
Greece	4	0	0
Croatia	26	0	1
Hungary	17	0	0
Ireland	41	0	0
Iceland	1	0	0
Italy	30	0	0
Lithuania	20	0	0
Latvia	15	0	0
Malta	3	0	0
Netherlands	80	1	1
Norway	18	0	0
Poland	42	0	0
Portugal	54	0	0
Romania	4	0	0
Sweden	85	1	1
Slovenia	3	0	0
Slovakia	6	0	0
Total	**823**	**6**	**4**

11) Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.							
	PSUR and PSUSA			PASS		Referrals	
NCAs	No. of procs.	Total hours	Average per proc.	No. of procs.	Total hours	No. of procs.	Total hours
Austria	21	1,002	48				
Belgium	13	1,268	98				
Croatia	17	1,495	88			1	178
Czech Republic	2	83	42				
Denmark	31	3,852	124				
Estonia	8	641	80				
Finland	15	1,136	76				
France	57	6,188	109	1	72	1	204
Germany	83	8,877	107	2	167		
Hungary	3	392	131				
Ireland	35	2,946	84				
Italy	28	2,346	84	1	102		
Latvia	14	1,708	122				
Norway	5	222	44				
Portugal	54	2,063	38				
Romania	2	132	66				
Slovakia	3	253	84				
Slovenia	1	108	108				
Spain	22	1,476	67				
Sweden	80	4,747	59				
Grand Total	**494**	**40,935**	**83**	**4**	**341**	**2**	**382**

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. Ongoing procedures will be reported in the next reporting period.

Not all NCAs were in a position to provide data for 2020.

Terms and abbreviations

Term/abbreviation	Definition
ACE	EMA Analytics Centre of Excellence
ACPC	Advisory Committee on Procurement and Contracts
AD	administrator function group

Term/abbreviation	Definition
Agency	European Medicines Agency
AI	artificial intelligence
API	active pharmaceutical ingredient
Art.	article
AST	assistant function group
BCP	business continuity plan
the Board	EMA Management Board
Brexit	commonly used term for the United Kingdom's planned withdrawal from the European Union
CA	contract agent
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCI	Commercially confidential information
CHMP	Committee for Medicinal Products for Human Use
CMA	conditional marketing authorisation
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
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
Court (of Auditors)	European Court of Auditors
COVID-19	coronavirus disease 2019, caused by SARS-CoV2 virus, also known as 2019-nCoV virus
CTIS	clinical trials information system
CVMP	Committee for Medicinal Products for Veterinary Use
DARWIN EU	Data Analytics and Real World Interrogation Network, a platform to access and analyse real world healthcare data
DCP	decentralised procedure
DG DIGIT	European Commission Directorate-General for Informatics
DG RTD	European Commission Directorate-General for Research and Innovation
DG SANTE	European Commission Directorate-General for Health and Food Safety
DPO	data protection officer
e.g.	*exempli gratia*, for example
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
e-DoI	electronic declaration of interests
EDPS	European Data Protection Supervisor
EEA	European Economic Area
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
ENVI	Committee on the Environment, Public Health and Food Safety of the European Parliament
EP	European Parliament

Term/abbreviation	Definition
ERA	environmental risk assessment
etc.	*et cetera*, and so forth
ETF	EMA pandemic task force
EU	European Union
EU27	the 27 European Union countries after the UK leaves the EU
EU DPR	Data Protection Regulation for EU institutions and bodies, Regulation (EU) 2018/1725
EU-IMP	European Union incident management plan
EU TMB	EU Telematics Management Board
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance, system for managing and analysing information on suspected adverse reactions to medicines
EVVet	EudraVigilance veterinary
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
FTE	full-time equivalent
GCP	good clinical practice
GDPR	General Data Protection Regulation
GMP	good manufacturing practice
GxP	good practice (e.g. laboratory, clinical, manufacturing)
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HR	human resources
i.e.	*id est*, that is
IAC	internal audit capability of EMA
IAS	Internal Audit Service of the EC
ICF	internal control framework
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICU	intensive care unit
INT	interim contract
IRIS	Regulatory and Scientific Information Management platform
i-SPOC	Single point of contact system for pharmaceutical industry for reporting directly to EMA information on current or anticipated shortages of medicines
IT	information technology
KPI	key performance indicator
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
Management Board	EMA Management Board
MB	EMA Management Board
Member State	Member state of the European Union
MEP	Member of the European Parliament
MFF	multiannual financial framework
MRP	mutual recognition procedure
MS	member state(s) of the European Union
MUMS	minor use minor species/limited market policy
NAP	nationally authorised product

Term/abbreviation	Definition
NCA	national competent authority
Network	European medicines regulatory network
OLAF	European Anti-Fraud Office
P3i	EMA's methodology for portfolio, programme, project management and IT delivery lifecycle
pandemic	COVID-19 pandemic
Parliament	European Parliament
PDCO	Paediatric Committee
PMF	pharmacovigilance master file
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicines – a scheme to foster development of medicines with high public-health potential
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
(EU) Regulatory Network	European medicines regulatory network
SARS-CoV2	severe acute respiratory syndrome coronavirus 2, also known as 2019-nCoV (2019 Novel Coronavirus) and COVID-19
SNE	seconded national expert
SPOC	Single point of contact system (for information-sharing on important shortages of medicines between Member States, EMA and the European Commission)
SPOR	Substances, Products, Organisations, Referentials – an EMA programme
Steering Group	EMA Covid-19 Steering Group
TA	temporary agent
UK	United Kingdom
Union	European Union
UPD	Union Pharmacovigilance Database
US	United States
vs	*versus*, against, as compared to
WHO	World Health Organization