EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 May 2020
EMA/33568/2020
European Medicines Agency

Annual activity report 2019

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Management Board's assessment report

The Management Board,

having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,

having regard to the Financial Regulation applicable to the budget of the European Medicines Agency ('the Agency') and in particular Article 48 thereof,

having regard to the 2019 work programme of the Agency, adopted by the Management Board at its meeting in December 2018,

having regard to the annual report 2019 of the Agency adopted by the Management Board at its meeting in March 2020,

having regard to the annual activity report 2019 of the Agency presented to the Management Board at its meeting of 10 June 2020,

1. Recognises that 2019 was yet another challenging year for EMA marked by the preparations for the withdrawal of the United Kingdom from the European Union; commends the considerable effort made by the Agency to implement the final phase of its Brexit BCP;
2. Is pleased that the Agency successfully maintained the quality and continuity of its operations whilst executing the relocation from its premises in London to Amsterdam;
3. Acknowledges the results presented in the annual report 2019, as well as the reduced work programme delivered in 2019. Notes that a number of activities and projects that were originally intended to continue in 2019, had to be put on hold during the year, to reassign resources to support the relocation or other more critical tasks. Looks forward to the Agency resuming activities that had been temporarily suspended or reduced as soon as possible;
4. Recognizes that due to the current global Covid-19 pandemic, 2020 will be yet another extremely challenging year for EMA that may jeopardise the Agency’s intentions for 2020 to be the final year of transition and starting the relaunch of activities.
5. Welcomes the Agency’s future-proofing initiative to review its organisation by strengthening its ability to perform new activities and be best prepared for upcoming challenges such as big data, digitalization and new scientific methods and technologies. Finds it important that the activities of working parties are also reviewed and aligned with the EMA future-proofing initiative and the new strategic priorities and challenges.
6. Suggests that the decisions to restart any activities that had been suspended or reduced for the last few years, should be viewed in the context of this future-proofing exercise. When reinstating activities, these should be assessed against meeting the objectives of the Agency and alignment with the future strategic priorities, to strengthen the Agency’s ability to perform important new activities together with the European medicines regulatory network and tackle important challenges ahead such as big data, digitalization and new scientific methods and technologies.
7. 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.

8. Shares the Executive Director's concern that the addition of significant new tasks and increasing workload over the years is not supported by corresponding increase in staff and resources, and that such shortage of staff puts the Agency's continuity of operations under significant pressure.

RELOCATION TO AMSTERDAM

9. Appreciates the on-time delivery of a fully-fitted and furnished, tailor-made permanent building for the Agency's operations by the Dutch government. Welcomes the signing of the agreement for EMA new permanent premises in Amsterdam.

10. Recognizes the immense complexity and efforts involved in relocating the Agency and is impressed with the successful and seamless execution of the move from London to Amsterdam in March, followed by a second move to EMA permanent premises in January 2020. Appreciates the continued support provided to the staff and experts by the Agency to facilitate smooth relocation and settling in the Netherlands. Wishes the Agency luck and success in its new home in Amsterdam.

11. 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 3rd country, and the ensuing financial, operational and reputational risks and implications. Calls on the EU to resolve this matter at a political level and find a way to release EMA from these contractual and financial liabilities.

12. Regrets the significant additional expenditure the Agency has incurred in relation to relocation and Brexit, amounting to EUR 51.44 million, including the costs related to staff relocation to the Netherlands, and to the Agency's buildings.

13. Is pleased that majority of staff successfully moved to the Netherlands and remained with the Agency. Nevertheless, notes that the total workforce available was reduced by around 10% and encourages the Agency to seek ways of working and continuous efficiency improvements to maintain the quality of its work in the new circumstances of reduced workforce.

ACTIVITIES

14. Is pleased with the work done in collaboration with the European regulatory network in supporting companies marketing human and veterinary medicines to prepare for Brexit and minimise the impact on the supply of medicines. Applauds the successful redistribution the UK's portfolio of centrally authorised products to the remaining 27 EU Member States.

15. Appreciates the work on marketing authorisations via the centralised procedure – both in human and veterinary medicines. In 2019, EMA recommended for marketing authorisation 66 new human medicines, including 30 new active substances and 15 new veterinary medicines, including 5 new active substances.

16. 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 for active immunisation against the Ebola virus. In the veterinary field, the medicines approved included four vaccines, one of them developed by means of recombinant DNA technology, notes with satisfaction the increased interest in developing products for minor uses or minor species.

17. Welcomes the continuous increase in scientific advice in both areas and notes with satisfaction that close to 60% of the applicants who received a positive opinion had also received scientific advice from EMA during the development phase.

18. Welcomes the European Ombudsman's opinion on EMA's scientific advice activities, which recognise the value and need for scientific advice and whose recommendations are in line with the Agency's ongoing initiatives to further increase transparency.

19. Applauds 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.

20. Notes however, that almost all activities relating to the Agency's efforts to strengthen transparency and open data commitments, as well as to provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information were suspended in 2019. Encourages the Agency to restart this work as soon as possible, to maintain its role as a recognised pioneer in terms of transparency and openness of operation, and in terms of interaction with patients.

21. Is pleased with EMA continuous efforts to support SMEs which have resulted in the highest number of marketing authorisation applications (24) submitted by SMEs since 2016, representing 20% of all applications received in 2019.

22. Commends the Agency on its responsiveness and collaboration with national competent authorities and the EDQM in tackling the issue of the presence of nitrosamines impurities in human medicines containing chemically synthetized active substances.

23. Praises the work and achievements in the global fight against antimicrobial resistance, and especially the Agency's effort in supporting the development of new antimicrobial agents, collecting data on consumption of veterinary antimicrobials, and encouraging and advising on responsible use of antimicrobials. Is pleased with the continued productive cooperation in this regard between the Agency and its international partners in the United States and Japan.

24. Is pleased with the full implementation by the EU and the United States of the mutual recognition agreement for inspections of manufacturing sites for certain human medicines in their respective territories. Is looking forward to the extension of the MRA scope to veterinary medicinal products and vaccines.

25. Highlights the importance of the HMA-EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability. Regrets that, despite the significance of the medicines' availability issue, many of the Agency's activities included in the work programme in this field and in particular in regards to veterinary medicines, were suspended to allow EMA cope with the relocation challenges, and urges the Agency to prioritize this work when re-instating suspended or reduced activities.

26. Applauds the launch of the Single Point of Contact (SPOC) system to improve information-sharing on important shortages and availability problems of medicines between Member States, EMA and the European Commission, including sharing information on medicines that could be used as an alternative and are available in other Member States. Is pleased with the completion of the first phase of the pilot in 2019 and looks forward to the second phase and full launch of the system.

27. Acknowledges the progress made in developing the new "EMA Regulatory Science Strategy to 2025" which will be a key element of the new European Regulatory Network Strategy to 2025. Is

pleased with the extensive collaboration with a wide range of public health stakeholders and experts in developing this regulatory science strategy.

28. Looks forward to working together with EMA on the new Network strategy 2021-2025.

29. Welcomes the work undertaken by the joint HMA/EMA Big Data task force towards unlocking the potential of big data for medicines regulation in the EU, and the identification of ten priority actions for European regulators. Looks very much forward to the developments of the most ambitious undertaking in this regard – the establishment of the Data Analysis and Real World Interrogation Network – an EU platform to access and analyse healthcare data from across the EU.

TELEMATICS

30. Understands that several Telematics projects had to be postponed or reduced (e.g., substances and products management services, European medicines web portal, etc.) due to Brexit consequences and the relocation of the Agency to the Netherlands in terms of lack of resources, loss of staff and knowledge. Regrets that some projects were over time or over budget.

31. Is pleased with the successful move of the data centre and the significant steps made towards a fully functional Clinical Trial Information System (CTIS). Welcomes the initial work done on the development of a veterinary Union Product and Pharmacovigilance Database, both of which have to be fully functional by January 2022, when the new veterinary medicines legislation will come into force. Suggests keeping close attention to ensure sufficient and timely financing, resourcing and delivery of these two important legal requirements.

32. Recommends continuing further work in developing a feasible and realistic EU Telematics strategy 2020-2025, supported by the whole Network, which prioritizes the most important business initiatives, and includes a realistic operational implementation plan based on the available resources.

LEGISLATION

33. Recognises the considerable work and contributions of the Agency in support of the implementation of the new Veterinary Medicines Regulation. In 2019 EMA worked on finalisation of five and started working on another seven scientific and technical recommendations to the Commission, to feed into the delegated and implementing acts that the EC is preparing as part of the implementation of the new Veterinary Medicinal Products Regulation. Welcomes the launch of a new corporate webpage to help stakeholders to keep track of the changes relating to new Veterinary Medicines Regulation implementation.

34. Is pleased with the work carried out in regards to implementing the two new EU regulations on medical devices – regulation (EU) 2017/745 on medical devices and regulation (EU) 2017/746 on in-vitro diagnostic medical devices. Is pleased with the Agency's progress to ensure compliance with the standards of data protection set out by the new Data Protection Regulation for EU institutions and bodies (Regulation (EU) 2018/1725).

FINANCES AND HUMAN RESOURCES

35. Is pleased that the European Parliament has granted the discharge regarding the implementation of the budget of the Agency for the financial year 2018.

36. Notes that the Agency's final budget for 2019 amounted to EUR 332,959,000; that 89.15% of its revenue derived from the evaluation of medicines and other business related activities; 10.77% from the European Union budget to fund various public health and harmonisation activities.

37. Notes the financial outturn, a deficit of approx. EUR 8.28 million and representing 2.39% of the final budget, which was caused mainly by lower-than-expected fee-related income being collected at the end of the year.

38. Notes the 2019 provisional accounts and that the auditors anticipate issuing a positive opinion on their reliability. Looks forward to give an opinion on the EMA 2019 final accounts, following the receipt of the European Court of Auditors' observations on the provisional accounts.

39. Is concerned to see that during 2019, the workforce available to the Agency decreased by close to 10%, from 855 FTEs at the end of 2018, to 775 FTEs at the end of 2019. Notes with apprehension that the significant increase in resignation rates as a result of relocation of the Agency continues: 82% of those who left the Agency in 2019 left by resignation (in 2018 – 74%), more than double the average resignation rate for the preceding 5 years.

40. Recognises the efforts to replace leaving staff and is pleased that the Agency managed to maintain 98.6% occupancy rate for temporary agents despite the highest turnover since its establishment. Notes that during 2019 the total number of staff joining EMA amounted to 123, while the total number of staff leaving the Agency during the same year amounted to 199.

41. Acknowledges that despite the best recruiting efforts, the Agency will not be able to reach its previous headcount and encourages the Agency to continue closely monitoring the staffing levels, whilst seeking adjustments in its ways of working and continuous efficiency improvements to maintain the quality of its work in these new circumstances.

AUDITS AND INTERNAL CONTROLS

42. Notes the results of the audit of the European Court of Auditors, confirming the reliability of the 2018 accounts and the legality and regularity of the transaction underlying the accounts of the Agency.

43. Is satisfied that no recommendations stemming from audits carried out by the Internal Audit Service of the Commission were open as of 31 December 2019.

44. Notes the positive result of the activities carried out by the Agency's internal audit capability, whereby only 5 very important recommendations stemming from audits carried out up to the end of the year remained under implementation as of 31 December 2019. Understands that some of the audit plans were postponed due to external influences, and expects these to be carried out as soon as possible.

45. Is pleased with the implementation of the new Internal Control Framework and its increased focus on effectiveness of controls instead of purely compliance-based system. Encourages the Agency to continue enhancing and fine-tuning its approach to this exercise, in order to reap most benefits of the new framework;

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

DECLARATION OF ASSURANCE

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

48. Reiterates the concerns regarding the continued EC rejections of EMA requests for additional staff, despite adding significant new responsibilities and continuously increasing workload. Calls for an EU action at a political level to resolve the current unsustainable situation with the EMA premises in London.

49. Congratulates Christa Wirthumer-Hoche on her re-election as Chair of the EMA Management Board for the second term, and Lorraine Nolan as Vice-Chair of the EMA Management Board. Wishes Christa and Lorraine success in their roles.

50. Thanks the scientific committees' members, experts, and patient representatives, as well as all NCAs and EMA staff for their exceptional commitment, and appreciates the good collaboration in the network.

Amsterdam, 10 June 2020

[Signature on file]

Christa Wirthumer-Hoche
Management Board Chair

Introduction

The consolidated annual activity report provides an overview of the activities and achievements of the European Medicines Agency (EMA) in 2019. The EMA annual activity report 2019 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 his 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 2019 comprises four main parts and annexes, as follows:

Part I: Key achievements in 2019. This section provides an overview of the Agency's major achievements.

Part II: Work programme implementation. This section mirrors the structure of the annual work programme of EMA for the year 2019 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 III: Organisational management and internal control. This section provides information on EMA governance; information on budgetary, financial and human resources management assessment provided by the EMA management; assessment of audit results during 2019; 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 and the assessment of the effectiveness of the internal control systems.

Part IV: Management assurance. The report concludes with a declaration of assurance in which the EMA Executive Director, in his 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.

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, those intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals, 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 on 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 experts 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.

1. Key achievements in 2019

2019 was yet another challenging year for EMA marked by the preparations for the withdrawal of the United Kingdom from the European Union and managing its implications, but it was also a year that has proven the robustness and flexibility of the EU network. Despite the challenges faced, the Agency managed to maintain its core operations and deliver the adopted, reduced scope work programme 2019.

1.1. Addressing Brexit consequences and relocating the Agency to the Netherlands

On 29 March 2017, the United Kingdom invoked Article 50 of the Treaty on European Union, formally starting a two-year countdown to the UK's departure from the EU (Brexit). On 20 November 2017, the General Affairs Council (Art. 50) decided to relocate EMA to Amsterdam, the Netherlands. 2019 was a critical year for EMA in this regard, as the Agency left its premises in London and reinstated operations in its new home.

1.1.1. Move to Amsterdam

Following the announcement of the new seat of the Agency, EMA immediately began working with the Dutch authorities to prepare for the move and take up its operations in Amsterdam. The move was planned in two steps – first moving to the temporary premises before the originally planned Brexit date (29 March 2019), and later taking up residence in its permanent building.

On 30 March 2019 Amsterdam formally became the new seat of the European Medicines Agency.

EMA will move once more in January 2020 from the temporary premises in Amsterdam Sloterdijk to its permanent location in Amsterdam Zuidas. The Dutch authorities confirmed on 15 November the practical completion of the fully-fitted and furnished EMA building, which is tailor-made to the requirements of EMA's operations. To make the new building operational, installation and testing of IT and audio-visual technical equipment, as well as moving furniture from the temporary premises to the new building took place at the end of 2019. Staff will gradually move into the final premises as of 13 January 2020 and the first meetings in the new building will take place in the same week. The move into the EMA building marks the final step of the Agency's relocation journey to the Netherlands.

In parallel, EMA continued working on solutions to the situation with its premises in London, so that the obligation to pay rent until the expiry of EMA's lease would not cause unnecessary burden on the Agency's budget. A potential sub-tenant was identified at the end of 2018.

On 2 April, the Council issued a favourable opinion, setting the maximum financial envelope at €67 million for the project, entailing financial inducements to the sub-tenant and other expenses. For the sub-letting of premises in in 30 Churchill Place, Canary Wharf, London/UK a positive opinion by budgetary authority was received in June 2019.

EMA reached an agreement with Canary Wharf Ltd over its premises at 30 Churchill Place, London and sublet its 26,450 m^2 to a subtenant, who took a sublease from EMA from 1 July 2019 until the expiry of EMA's lease in June 2039.

1.1.2. Business continuity planning

EMA priority in Brexit circumstances remained 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.

Brexit-related guidance for companies

EMA, the European Commission and the Member States continued to work closely together to provide guidance to help companies marketing human and veterinary medicines in the EU prepare for the UK's withdrawal from the EU and minimise the impact on the supply of medicines. This aimed at ensuring that companies would be ready to take the necessary steps to enable undisrupted supply of their medicines in the EU for the benefit of patients, based on the assumption that the UK would become a third country after Brexit.

By the end of 2019 good progress had been made by companies to take the required steps to ensure that their centrally authorised medicines could remain on the EU market. Just one marketing authorisation transfer for a human medicine was still pending. Good progress had also been made for products with qualified persons for pharmacovigilance (QPPVs) still based in the UK (280 already transferred, 58 still to be transferred) and pharmacovigilance master files (PMFs) based in the UK (350 already transferred, 64 remaining).

Redistribution of UK portfolio of medicines

In preparation for Brexit, the EU27 Member States and EMA had started the redistribution of the UK's portfolio of medicines to other EU Member States in 2018. By 1 July 2019, the appointed rapporteurs and co-rapporteurs from the EU27 plus Iceland and Norway took over full responsibility for over 370 centrally authorised products (CAP) that previously had UK rapporteurs or co-rapporteurs.

Brexit preparedness and relocation activities carried out in 2019

During 2019 EMA continued considerable work to address the Brexit impact on the Agency's operations, including but not limited to:

- Moving the Agency from London to temporary office in Amsterdam in March;
- Signing lease agreement for the permanent premises, and handover of the permanent building by the Dutch authorities on 15 November 2019;
- Preparing for the move from the temporary office to permanent premises in Amsterdam;
- Finalising and implementing the Seat Agreement, Lease Agreement, and service level agreement;
- Finalising and implementing all documents for the set-up of Agency operations in the temporary offices and also in the final, permanent premises;
- Conducting procurement procedures for the necessary contracts for the permanent building.

1.1.3. Impact of business continuity plan on the Agency's activities

The Agency has been implementing a staged business continuity plan (BCP) since May 2017, to allow it to prepare for and deal with the challenges and impact of the relocation on the Agency's operations, including executing the physical move to the new EMA premises and coping with the loss of staff. This BCP has been focused on maintaining and continuing the core activities relating to the authorisation, supervision and maintenance of medicines without disruption through gradually reducing and suspending some of its activities, based on their impact on public health and the Agency's ability to function. Phase 4 of the BCP started on 1 January 2019 allowing the Agency to continue to focus its efforts to safeguard core activities related to the evaluation, maintenance and supervision of medicines during the crucial period of physical relocation.

Most activities that were temporarily suspended or reduced at the end of 2018 as part of earlier stages of EMA's BCP remained on hold in 2019, for example, guideline development (unless exceptions were

agreed), engagement in international activities, most working party meetings and the Agency's proactive publication of clinical data.

These will be restored in a stepwise manner, once the Agency has the necessary capacity to restart the activities.

1.1.4. Impact of relocation on staff numbers

By the end of 2019 the Agency's available workforce[2] was 775 full-time equivalent (FTE) – significantly less than at the end of 2018 when it was 855 FTE.

The previous pattern of higher than usual numbers of staff leaving – and specifically resigning – continued throughout 2019. By 31 December 56 staff members (temporary agents (TA) and contract agents (CA)) had left the Agency, with 82% of these staff members leaving the Agency by resignation. These have been the highest turnover and resignation figures the EMA has experienced since its establishment. As a comparison indicator, in the previous 5 years EMA had an average of 45% of staff leaving due to resignations. 14 seconded national experts (SNE) also left the organisation during 2019.

The Agency's major recruitment drive continued in 2019 to make sure that staff who decide not to relocate or were unable to relocate to Amsterdam could be replaced as soon as possible. The improved recruitment processes allowed the Agency to attract 101 new staff members (TA, CA and SNE) and achieve a 98.6% occupancy rate for its establishment plan.

Although recruitment is ongoing to replace staff who decide not to relocate, the Agency will not reach its previous headcount, which included a large number of staff on short-term contracts. EMA lost a total of 199 resources within 2019 (including short-term contracts), which puts the Agency's continuity of operations under significant pressure, including the EMA capacity to deliver core activities.

Additionally, even with more efficient recruitment processes there still remains a gap between the staff member leaving and the new replacement starting. Also the temporary loss of productivity while the new employees acclimatise and learn their tasks must be taken into account.

1.1.5. Resuming business post-relocation

From June 2019, the Agency was able to reinstate a small number of previously temporarily suspended or reduced activities, mainly those aimed at ensuring that the Agency is fit-for-purpose in the longer term. These included, for example, IT systems supporting the medicines evaluation process and the digitalisation of administrative processes.

In addition, some of the EU network working groups directly contributing to EMA's core activities restarted. Specifically, meetings of the Good Manufacturing and Distribution practice, the Inspectors Working Group, the Good Clinical Practice Inspectors Working Group, the Pharmacovigilance Inspectors Working Group, the Quality Working Party and the Process Analytical Technology team resumed their work in September 2019.

Similarly, meetings of the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) restarted as of September 2019.

The Agency will strive for 2020 to be the final year of transition and for starting the relaunch of activities that were reduced or suspended during this period of change, albeit with a reduced number of staff compared to the staffing situation prior to the start of the Brexit preparatory work in 2016.

[2] Including temporary agents, contract agents, seconded national experts, trainees and interims, and accounting for absences such as parental leave, family leave, maternity leave and unpaid leave absences.

Future proofing EMA

To help the Agency make best use of the reduced resources and be prepared for future scientific and technological challenges, EMA initiated an in-depth review of its organization in 2019. This 'future-proofing' exercise will help EMA strengthen its ability to perform important new activities together with the European medicines regulatory network and tackle important challenges ahead such as big data, digitalization and new scientific methods and technologies.

Operations in the area of human medicines will be integrated to strengthen the therapeutic focus all 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 task forces will focus on areas that are also key priorities for the network such as digital business transformation, data analytics and methods, regulatory science and innovation, and clinical trials and manufacturing strategy. The new structure will come into effect in March 2020.

1.2. Human and veterinary medicines highlights

1.2.1. Human medicines

In 2019, EMA received a total of 117 applications for initial evaluation in 2019, 39% more than in 2018. This increase breaks the downward trend observed in the previous two years. During the year EMA recommended 66 medicines for marketing authorisation. Of these, 30 had a new active substance which had never previously been authorised in the EU.

Some of the medicines approved in 2019 represent a significant advance in their respective therapeutic areas; these include medicines for children, rare diseases, and advanced therapies, such as the first vaccine for active immunisation of individuals aged 18 years and older at risk of infection with the Ebola virus. Among the medicines recommended for marketing authorisation, seven had their orphan designation confirmed by the end of the year (the number of applications for orphan medicines doubled in 2019 from 17 applications in 2018, to 34 in 2019).

Three medicines received a recommendation for marketing authorisation following an accelerated assessment. This mechanism is reserved for medicines that address unmet medical needs. It allows for a faster assessment of eligible medicines by EMA's scientific committees (within 150 days rather than up to 210 days).

Eight medicines received a recommendation for a conditional marketing authorisation (CMA), one of the mechanisms in the EU to give patients early access to new medicines. Conditional authorisation allows early approval of a medicine that addresses an unmet medical need on the basis of less complete clinical data than normally required. This authorisation is subject to specific post-authorisation obligations to ensure that the pharmaceutical company generates complete data on the medicine.

Since the introduction of CMA in 2006, 21 medicines out of 47 have been granted a full marketing authorisation following a CMA. On average, it took around 3.5 years for companies to fulfil their post-authorisation obligations and get their products fully authorised.

One medicine was authorised under exceptional circumstances. This route allows patients' access to medicines that cannot be approved under a standard authorisation as comprehensive data cannot be obtained, either because there are only very few patients with the disease, or the collection of complete information on the efficacy and safety of the medicine would be unethical, or there are gaps in the scientific knowledge. Medicines authorised under exceptional circumstances are subject to specific post-authorisation obligations and monitoring.

In addition, CHMP issued negative opinions on four medicines in 2019. In these cases, the CHMP could not conclude that the benefits of the medicine outweighed the risks.

89% of all opinions (positive and negative) were reached by consensus among the 28 CHMP members, meaning that the experts agreed on all aspects of the marketing authorisations following in-depth discussions.

Around 59% of applicants who received a positive opinion for their medicine had received scientific advice from EMA during the development phase of their product. This early engagement with the developers allows EMA to clarify what kind of evidence is required to evaluate the medicine for authorisation, and so protects patients from taking part in unnecessary or poorly designed clinical trials.

233 applications for orphan designations were received in 2019, reflecting a steady identification of new targets to treat orphan diseases. Of these, 113 were granted a designation, allowing them to benefit from the incentives under the EU Orphan Framework. 104 applications were withdrawn and 2 received a negative opinion from the COMP.

The product information for 405 centrally authorised medicines was updated on the basis of new safety data in 2019. Furthermore, every year, the recommendations of the PRAC on safety warnings are included in the product information of many thousands of nationally authorised products. The revised information is expected to help patients and healthcare professionals to make informed decisions when using or prescribing a specific medicine.

Ensuring integrity of clinical trial conduct and the manufacture and supply of medicines

Medicines development and manufacturing are global activities. It is important for regulators to ensure that EU standards are adhered to no matter where clinical trials or manufacturing take place.

In 2019, one centralised marketing authorisation application was withdrawn as a result of non-compliance with good clinical practice (GCP).

Nitrosamine impurities: the response of the Network

Following the detection of presence of nitrosamine impurities (N-nitrosamines), including N-nitrosodimethylamine (NDMA), in a number of medicines used to control high blood pressure in June 2018, the CHMP conducted a review of sartans. The CHMP concluded its review of sartan medicines in January 2019, setting new strict manufacturing requirements for these medicines. Subsequently, a nitrosamine impurity was also detected in batches of diabetes medicine pioglitazone manufactured in India, and in batches of ranitidine medicines, and the CHMP started a review of medicines containing this active substance. Ranitidine medicines are used widely to reduce the production of stomach acid in patients with conditions such as heartburn and stomach ulcers.

In September 2019 EMA initiated a wider review to provide guidance to marketing authorisation holders on how to avoid the presence of nitrosamines impurities in human medicines. As part of this review, the CHMP has requested marketing authorisation holders for human medicines containing chemically synthesised active substances to review their medicines for the possible presence of nitrosamines and test all products that might be at risk.

EMA and national competent authorities continue to monitor the presence of nitrosamines impurities in medicines, in co-operation with regulators from outside the EU.

1.2.2. Veterinary medicines

In 2019, EMA recommended 15 veterinary medicines for marketing authorisation (10 in 2018, 17 in 2017, 11 in 2016). Of these, five had a new active substance, i.e. one that had not previously been authorised in the EU, and four were vaccines, one of them developed by means of recombinant DNA technology.

The Agency received a total of 34 new requests (the highest number of requests received in a year) for the (re)classification of veterinary medicines under EMA's minor-use-minor-species (MUMS)/limited market policy, indicating an increased interest from medicine developers in developing products for minor uses or minor species. Outcomes for 37 requests were finalised in 2019, with 28 requests classified or reclassified as MUMS, benefiting from reduced data requirements, and additional five requests granted with financial incentives such as access to free scientific advice and reduced application fees.

Three medicines were recommended for marketing authorisation under this scheme which aims to stimulate development of new veterinary medicines for minor species and for rare diseases in major species that would otherwise not be developed under current market conditions.

Product information for 15 veterinary medicines was updated on the basis of new safety data. The revised information is expected to help animal owners and veterinarians to make informed decisions when using or prescribing a medicine. CVMP adopted six positive opinions for extensions of existing authorisations, broadening the use of the medicines concerned.

In 2019 an MRL was established for two active substances.

1.3. Supporting research and development

1.3.1. PRIME

EMA's PRIority MEdicines (PRIME) scheme was launched in March 2016 to support and optimise medicine development, so that patients whose diseases cannot be treated or who need better treatment options have earlier access to new medicines that enable them to live healthier lives.

In 2019, EMA received 60 PRIME eligibility requests and adopted 57 recommendations, accepting 16 applications into the scheme. The rate of products granted access to the scheme was slightly higher in 2019 (28%) compared to 2018 (23%).

1.3.2. Scientific advice and outcome of the Ombudsman enquiry into pre-submission activities

During a medicine's development, a developer can request guidance and direction from EMA on the best methods and study designs to generate robust information on how well a medicine works and how safe it is. This is known as scientific advice, and it is the core of many of EMA's special programmes to encourage development and availability of new and innovative medicines.

In 2019, EMA received a total of 549 requests for scientific advice for human medicines. This represents an increase of 18% compared to 2018. 21 requests for scientific advice were received in relation to veterinary medicines.

In 2019 the European Ombudsman concluded a strategic enquiry into EMA's scientific advice activities. The ombudsman's recognition of the value and need for scientific advice and their recommendations are in line with EMA's ongoing initiatives to further increase transparency. Early interactions with medicine developers and provision of scientific advice are well-established processes with

demonstrated added value in medicines regulation, and contribute positively to public health by helping to bring new, safe and effective medicines to patients. At the same time, EMA recognises the importance of guaranteeing the independence of the medicine assessment which takes place at a later stage. The ombudsman's suggestions for further improvement are being addressed by the Agency and will be implemented in 2020.

1.3.3. Advanced-therapy medicinal products

Advanced therapy medicinal products (ATMP) are medicines based on genes or cells that have the potential for ground-breaking new treatments. They are particularly important for severe, untreatable or chronic diseases for which conventional approaches have proven to be inadequate. With the accelerating pace of scientific development and the growing expectations of patients and public, ATMPs are now seen as a global activity. Many developers and other stakeholders are requesting the need for global regulatory convergence.

On 3 December 2019, an Innovative Medicines Initiative (IMI) Regulatory Science Summit on ATMPs took place in Brussels and included participants from EMA, FDA, EC, industry representatives, patients and Health Care Professionals (HCP), Health technology assessment (HTA) bodies and NCAs. The summit discussed potential IMI topics that remain in the non-competitive space, and where regulators see the opportunities for regulatory research questions to be addressed within a public private partnership.

In 2019, CAT received 70 requests for ATMP classification (27% more than in 2018) and adopted 67 recommendations, an increase of 56% compared to 2018.

1.3.4. Medicines for children

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

A PIP is a development plan aimed at ensuring that the necessary data are obtained through studies in children to support the authorisation of a medicine for children. Where studies in children are inappropriate or unnecessary, a waiver may be granted. In 2019, the PDCO agreed 94 initial PIPs, the highest number in the past five years.

1.3.5. Supporting SMEs

Small or medium-sized enterprises (SMEs) are recognised as a driver of innovation in the EU. The Agency promotes innovation and the development of medicines by SMEs through regulatory and administrative support to these companies. The Agency's SMEs office provides advice and guidance, organises topical workshops and produces a dedicated newsletter for SMEs registered with EMA. These companies also have access to various fee incentives to support their medicine-development programmes.

In 2019, SMEs submitted 24 marketing authorisation applications – the highest number since 2016 and representing 20% of all applications received in 2019. In addition, of these 24 applications, 13 were for orphan designated medicines. This is the highest number in the past five years.

The CHMP gave a positive opinion for 8 medicines developed by SMEs, half of which had a new active substance. This represents 12% of all positive opinions in 2019.

1.4. Antimicrobial resistance

Antimicrobial resistance (AMR) is an increasingly serious public health threat. It threatens the effective treatment of an ever-increasing range of infections caused by bacteria and other microorganisms.

In 2019, EMA contributed to the global fight against antimicrobial resistance by supporting the development of new antimicrobial agents, collecting data on consumption of veterinary antimicrobials and encouraging and advising on responsible use of antimicrobials. Two new antibacterial agents received a positive opinion from CHMP during this year.

In May 2019, EMA opened the Innovation Task Force (ITF), its platform for early dialogue, to all medicine developers working on medicines for the treatment or prevention of life-threatening microbial infections to help strengthen the industry's drug development pipeline for new antimicrobials. Based on the initial experience with product-specific discussions in this new framework, the initiative facilitates increased interaction between developers and the regulator streamlining and optimising respective drug developments in the AMR field and as such facilitating their way to the patients. Promising drug candidates will have the opportunity for further interactions through the various development support measures offered by EMA.

In July 2019 EMA published for a six months public consultation a revised guideline on the evaluation of human medicines indicated for the treatment of bacterial infections. The revision is the result of the cooperation between the Agency and its international partners in the United States and Japan that aims to align the data requirements as much as possible between the three regions.

EMA published in October 2019 the 9th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report, reporting 2017 sales data for 31 participating countries. The report, which is used by risk assessors and risk managers in Member States as a reference for antimicrobial policies and for guidance on responsible use of antimicrobials, showed encouraging results on the sales of veterinary antibiotics. For the 25 countries that contributed data between 2011 and 2017, the sales of antibiotics for animal use decreased overall by 32%.

In addition to this, EMA launched a public consultation on its updated scientific advice on the categorisation of antimicrobials. The update was prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG), composed of representatives and experts from EMA's veterinary medicines committee (CVMP) and CVMP's Antimicrobials Working Party, EMA's human medicines committee (CHMP) and CHMP's Infectious Diseases Working Party, the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), and the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) working group. It was adopted by both CVMP and CHMP in December 2019 in line with EMA's support of a 'One Health' approach that promotes close and integrated cooperation between human and veterinary medicine.

1.5. Safety monitoring of medicines

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

More than 2 million ADR reports were submitted to EudraVigilance in 2019. The number of reports submitted by European patients and consumers reached nearly the record level seen in 2018, reflecting patients' commitment to reporting side effects and inclusion of non-serious EEA reports in EudraVigilance since November 2017.

The number of veterinary medicines' adverse event reports (AER) received in the EudraVigilance system is steadily growing year on year. This long-term trend towards increased reporting is due to the increased number of centrally authorised veterinary medicinal products and the improved awareness among veterinarians of the value of pharmacovigilance reporting, as well as greater control by regulators of the implementation of pharmacovigilance requirements by the veterinary pharmaceutical industry.

1.6. Inspections and compliance

EMA coordinates the verification of compliance with the principles of Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Pharmacovigilance Practice (GVP) and certain aspects of the supervision of authorised medicinal products in the EU. The main verification tool is inspection, which can either be carried out routinely or requested by the CHMP or CVMP in the context of the assessment of marketing authorisation applications and/or matters referred to these committees in accordance with EU legislation.

Mutual reliance and work-sharing are used to ensure best use of resources globally. For GMP inspections, there are several mutual-recognition agreements in place, with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States.

In 2019, the EU and the United States fully implemented the mutual recognition agreement for inspections of manufacturing sites for certain human medicines in their respective territories. In addition, as part of the mutual recognition agreement between the EU and Switzerland, the Swiss Agency for Therapeutic Products (Swissmedic) started to enter information on GMP compliance as well as on manufacturing authorisations related to Swiss manufacturers into the European Union Drug Regulating Authorities good manufacturing and distribution practice database (EudraGMDP). EudraGMDP is a database operated by EMA which supports the exchange of information on GMP compliance, as well as on manufacturing and importation authorisations.

EMA and its European and international partners also launched a pilot programme to increase their cooperation in the inspection of manufacturers of sterile medicines for human use. This new initiative built on the success of and experience gained from a similar collaboration, the international active pharmaceutical ingredients (APIs) inspection programme.

In 2019, 16 GMP inspections conducted by EEA authorities led to the issuing of a non-compliance statement. This means that medicines manufactured at a site with such a non-compliance statement cannot be sold in the EU. GCP non-compliance contributed to 2 application withdrawals in 2019.

1.7. Shortages and availability of medicines

Improving the availability of medicines authorised in the EU is a key priority for the European medicines regulatory network. To better address potential problems with medicines' supply EMA and the Heads of Medicines Agencies (HMA) established a joint task force in 2016. Since its creation, it has developed and coordinated actions to facilitate the prevention, identification, management of and communication about shortages.

In 2019, the task force launched the Single Point of Contact (SPOC) system to improve information-sharing on important shortages of medicines between Member States, EMA and the European Commission. This platform allows Member States to share information on availability problems with medicines as well as information on medicines that could be used as an alternative and are available in other Member States. This could help prevent and better manage shortages.

Its operation is currently being piloted (in two phases) to fine-tune operational aspects prior to full implementation in 2020. The first phase of the pilot ran from April to August 2019 to test the functioning and usefulness of the information exchange of the SPOC system. A second phase is foreseen for 2020 during which additional responsibilities of the SPOC system will be tested to improve further the handling of shortages.

In July 2019, the task force published guidance for marketing authorisation holders (MAH) on detecting and reporting medicines shortages (Guidance on detection and notification of shortages of medicinal products for MAHs in the Union) and guidance to national competent authorities and EMA on good practices in communicating to the public on medicines' availability issues (Good practice guidance for communication to the public on medicines' availability issues).

Both documents lay the foundations for an improved and harmonised EU approach in reporting of and communication on medicines' shortages and availability issues.

1.8. Regulatory Science Strategy to 2025

Regulatory science is at the foundation of everything that the EMA does to make medicines available for the benefit of public and animal health – it includes all scientific disciplines that are necessary to assess the quality, safety and efficacy of medicines and to inform regulatory decision-making throughout the lifespan of a medicine. It encompasses basic and applied biomedical and social sciences, and contributes to the development of regulatory standards and tools. EMA supports the development of regulatory science and aims to ensure that advances in knowledge translate in a timely way into new, safe and effective treatments for patients and animals.

In 2019, a priority for EMA was to shape its plan for advancing regulatory science over the next five to ten years, in both human and veterinary medicines. In the first half of 2019, EMA completed an extensive public consultation process to refine and prioritise key areas. The Agency reached out to a wide range of public health stakeholders and experts at all levels of medicine development, including patients, healthcare professionals, pharmaceutical industry, academia, and other regulatory bodies. The purpose of the public consultation was to seek the widest possible views on whether the proposed core recommendations and supporting actions address the needs of stakeholders.

Following the public consultation, the Agency hosted two multi-stakeholder workshops on human and veterinary medicines in November and December 2019. The meetings served to get agreement on key areas where changes are required in the coming years. The finalised strategy post consultation will be a key element of the next European Regulatory Network Strategy to 2025, which will be developed together with the Member States and the European Commission as well as feeding directly into the Agency's multiannual work programme and work plans of its committees and working parties.

1.9. Big data in medicines' regulation

EMA and national competent authorities took major steps in 2019 towards unlocking the potential of big data for medicines regulation in the EU. The joint HMA/EMA Big Data task force, which is composed of experienced medicines regulators and data experts appointed by the NCAs, EMA and the European Commission, worked intensively throughout the year, leading to concrete recommendations on steps the European medicines regulatory network could take to evolve its approach on how to use evidence from big data for regulatory decision-making.

The HMA/EMA Big Data task force published a report in February 2019 which reviewed the landscape of big data from a regulatory perspective and identified opportunities for improvements in the operation of medicines regulation.

A second report was adopted by EMA's Management Board in December 2019, identifying practical steps to be taken by the Network to increase its capacity to deal with big data. The task force identified ten priority actions for European regulators, the most ambitious being the establishment of an EU platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network, or DARWIN).

1.10. Transparency: Court of Justice opinion pending on EMA's approach

In June 2019, the General Court delivered its judgment in case T-377/18, Intercept Pharma and Intercept Pharmaceuticals v EMA, upholding the lawfulness of the decision of EMA to disclose a periodic safety update report that had been requested under Regulation (EC) No 1049/2001 (commonly referred to as the "Transparency Regulation"). The company had sought to prevent the disclosure of the periodic safety update report on the ground that such disclosure would supposedly undermine the protection of ongoing court proceedings in the United States and would also undermine the protection of the commercial interests of the company. The General Court dismissed all claims of the company.

This case marks the fifth time that the General Court decided a dispute related to the application by EMA of the Transparency Regulation. The other four disputes relate to cases T-235/15, Pari Pharma v EMA; T-718/15, PTC Therapeutics International v EMA; T-729/15 MSD, Animal Health Innovation and Intervet international v EMA; and T-33/17, Amicus Therapeutics UK and Amicus Therapeutics v EMA. In all five cases, the General Court has ruled in favour of EMA; namely, in favour of the disclosure of the documents requested under the Transparency Regulation.

In September 2019, Advocate General Hogan released his opinions on two appellate cases C-175/18 P and C-178/18 P that were pending before the Court of Justice of the European Union. These two court cases 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.

In the context of these cases, the companies claimed that the documents at issue should be presumed to be confidential and that, in any event, they should not be disclosed because such disclosure would undermine the commercial interests of the companies and the decision-making procedure for the purpose of which they had been submitted to EMA.

EMA had won the first-instance cases before the General Court (T-718/15 and T-729/15). The companies appealed the judgments of the General Court before the Court of Justice in March 2018.

In his review of the cases, Advocate-General Hogan supported the companies' claims and proposed that the two cases be sent back to the General Court for a fresh legal re-assessment.[3]

1.11. New EU legislation applicable to EMA

1.11.1. New veterinary medicines regulation

In 2019, EMA worked on the preparation of scientific and technical recommendations to feed into the delegated and implementing acts that the EC is preparing as part of the implementation of the new

[3] On 22 January 2020, the Court of Justice dismissed the appeals in their entirety and upheld EMA's approach to transparency. The Court of Justice 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.

Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), which will become applicable on 28 January 2022. These are legally binding acts that supplement or amend EU laws (for example, defining detailed measures) and set conditions that ensure that EU legislation applied uniformly. The new veterinary medicines regulation will bring substantial changes to the authorisation of centrally authorised products, amongst them are the wider range of products that could be submitted through the centralised procedure, an improved pharmacovigilance and safety monitoring system (including the creation of new EU database), a stricter classification of antimicrobials and an expansion of the on-going analysis on their use, and a simplification of the post authorisation procedures such as variations.

EMA's recommendations are prepared by ad hoc expert groups composed of members of the European network of experts and EMA staff, in collaboration with other EU bodies such as ECDC and EFSA, where necessary. During 2019, EMA coordinated the finalisation of five recommendations to the European Commission and started working on other seven due to be finalised in 2020 (for a detailed list refer to the work programme reporting on pages 50-51 of this report).

To help stakeholders keep track of the upcoming changes, EMA launched a new webpage with information on EMA's scientific and technical recommendations, as well as updates on other activities such as the preparation for implementation progresses.

1.11.2. New medical devices regulation

In February 2019, EMA published the first of a series of guidance documents to help applicants prepare for obligations stemming from the two new EU regulations on medical devices –regulation (EU) 2017/745 on medical devices and regulation (EU) 2017/746 on in vitro diagnostic medical devices which will come into full effect in May 2021 and May 2022, respectively.

1.11.3. Data protection

The new Data Protection Regulation for EU institutions and bodies (Regulation (EU) 2018/1725), also known as EU DPR, entered into force on 11 December 2018. It ensures that the standards of data protection within EU institutions are in line with those provided for in the General Data Protection Regulation (GDPR), applicable to the public and private sector in the Member States.

In 2019, the Agency updated its privacy statements and the Data Processing Register, a repository of all data processing activities under its responsibility. These documents are available on EMA's website and provide citizens with information on how their personal data is handled and how to exercise their rights. In October, a new cookie consent banner was also published on the website. Through the banner, users can choose which cookies they want to allow and find more information on how these are used by the Agency. EMA also implemented new technical measures to improve the security of the server where the website is hosted.

A new set of internal rules concerning restrictions of certain rights of data subjects (Article 25 of the EU DPR) in the context of administrative inquiries and disciplinary proceedings conducted by EMA was also approved and published on the Official Journal. New implementing rules clarifying the role of the Data Protection Officer under the EU DPR were finalised. Moreover, EMA entrusted an external analyst to examine the security of its systems from a data protection perspective; recommendations for improvements have been received and will be analysed in 2020.

Training materials for staff dealing with personal data, including guidelines on how to manage a data breach and how to carry out data protection impact assessments were developed throughout 2019.

2. Work programme implementation

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.

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.

Explanation of symbols used

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

	Results more than 10% above the 2019 forecast/target
	Results within +/- 10% of the 2019 forecast/target
	Results 10%~25% below the 2019 forecast/target
	Results more than 25% below 2019 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*, according to the decisions taken on these activities at the time of adopting the work programme 2019. Traffic lights are also attached to the status indication (green, orange and red, respectively), 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 2019*, 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 2018) or those that were not included in the work programme at the time of adoption by the MB in December 2018.

2.1. Evaluation activities for human medicines

2.1.1. Pre-authorisation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Scientific advice/protocol assistance pre-submission meetings	117	118	97	99	90
Scientific advice and protocol assistance requests, of which:	582	630	634	654	674
Parallel scientific advice with international regulators	6	3	2	5	2
Joint scientific advice with HTA bodies	23	29	27	22	20
Scientific advice for PRIME products	4	28	36	28	26
Protocol assistance requests	126	159	168	150	137
Novel technologies qualification advice/opinions	14	19	9	17	16
PRIME eligibility requests	84	81	57	50	60
Scientific advice finalised	439	490	444	520	530
Protocol assistance finalised	122	156	170	146	137
Orphan medicines applications	329	260	236	275	233
Submitted applications on the amendment of an existing orphan designation	4	2	1	5	1
Oral explanations for orphan designation	87	80	86	95	68
Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	549	630	669	500	671
Finalised procedures for compliance check on PIPs	73	67	96	70	94
Annual reports on paediatric deferred measures processed	189	197	270	170	242
EMA paediatric decisions processed	369	402	407	350	433
Requests for classification of ATMPs	60	46	55	50	70
Innovation Task Force briefing/meeting requests	41	33	22	25	29
Innovation Task Force Art 57 CHMP opinion requests	2	0	5	1	4

Performance indicators

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	Scientific advice/protocol assistance procedures completed within regulatory timeframes	99.5%	100%	100%	100%	100%
	PRIME eligibility requests assessed within regulatory timeframe	-[1]	100%	100%	100%	100%
	Orphan designation opinions delivered within the legal timeframe	100%	100%	96%	100%	100%
	PDCO opinions sent to applicants within legal timelines	99.5%[2]	99.75%	99.9%	100%	99.5%
	Increase in scientific advice requests	14%	8%	0.6%	7%	6.5%
	SME requests for scientific advice (% of total scientific advice requests)	30%	31%	31%	30%	28%

[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	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	100%	REDUCED Activity limited to high level presence in IMI scientific committee with no proactive identification of topics. Input was provided into the ENVI Agencies' joint bid for priority topics in Horizon Europe, IMI annual work plan and call texts. Feedback to the EC on funding for tuberculosis medicines development was given through IMI scientific committee. EMA contributed to the IMI-EMA-FDA regulatory summit on ATMPs and Digital technologies to provide suggestions for funding topics for IMI2 as well as IHI under Horizon Europe. Participation in the European Joint Programme on Rare Diseases (EJP RD) policy board was agreed as well as a number of advisory boards and a consortium partnership on environmental risk
		Identify recurring topics from ITF discussions with the		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		highest potential benefit in terms of driving science and innovation		
		Based on the horizon scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, involving also NCAs, to address specific areas for innovation		SUSPENDED
	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
	3.1-1	Use business forecasting and analysis tools to better inform the EU Network about past and prospective development and improve regulatory preparedness	100%	MAINTAINED 2 quarterly reports were provided to the Agency's scientific committees, and the ATMP pipeline was presented at CAT in December. Ad-hoc reports were prepared for specific topics: cystic fibrosis for FDA cluster; biosimilars for the matrix; long-term (5 years) forecast for EC activity on fee regulation; gene fusion therapy pipeline for Oncology registry. Input was provided into the Horizon scanning dialogue with HTA/payers, and the EC.
	3.2-2	Establish a platform for project-specific engagement with developers, to optimise activities during the development phase		SUSPENDED
	1.3-5	Support a coordinated approach to ATMP-related activities in the Agency and maximise the outputs by involving all relevant actors and stakeholders	100%	REDUCED Activities directly related to product support are maintained. Dedicated product team is up and running and working well. Communication with the network and stakeholders reinforced. Strengthened committees and working parties' interaction.
Ensure needs of specific populations are met, including	1.1-6	Identify specific actions for EMA and PDCO that allow implementation of the European Commission/EMA	20%	REDUCED Activities addressing public health needs and operational improvement are

Objective	MAWP initiative	Activity	% complete	Achievements/results
elderly, children, patients with rare diseases and others		action plan following the EC 10-year report on the Paediatric Regulation		maintained. All other activities suspended. Ongoing activities included regular discussions with FDA colleagues with respect to paediatric oncology, planning an INC workshop at EMA for Q3/4 2020; participation to monthly teleconferences and remote participation to INC workshop
		Contribute to the activities of the International Neonatal Consortium (INC)		SUSPENDED
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders		SUSPENDED
	1.3-5	Review the experience with the “Orphan Notice” and interaction with stakeholders	20%	MAINTAINED The impact of the Notice has been monitored for orphan designations and maintenance procedures.
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	100%	MAINTAINED The delivery of the EMA/EUnetHTA work plan has been regulatory reviewed and items which required “a push” have been brought for discussion at the bilaterals. The overall delivery is on track.
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	40%	REDUCED Follow up through new initiative to create a framework to guide patient data generation for medicines development and benefit-risk evaluation. First draft of reflection paper prepared.
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		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		implementation of new or amended laws and regulations		
		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 systemically absorbed by the human body, and on companion diagnostics	100%	MAINTAINED Consultation on medical device composed of substances: • MEDDEV 2.1/3 guidance agreed with CMDh for the consultation procedure on medical devices composed of substances that are systemically absorbed Consultation on borderline products: • Scientific opinion by CAT/CHMP (February 2019) on the definitions of pharmacological, immunological, metabolic (PIM) and medical diagnosis (linked to revision of MEDDEV 2.1/3) and supporting discussions on definitions of PIM and medical diagnosis with EC Borderline and Classification Working Group • Support revision of MEDDEV guidance 2.4/1(classification) and 2.1/3 (borderline) Article 117 (Medicinal products with integral device): • Publication of the first set of Q&As for implementation of the MDR/IVDR in collaboration with CMDh (February 2019) • Support publication of Guideline on quality requirements for drug-device combinations for a 3-month public consultation (June 2019) General implementation activities: • Publication of medical device webpage to support general implementation activities • Organised 2 teleconferences with DG GROW and DG SANTE to facilitate implementation of new legislation; • Agreement on proposal for fee model for new consultations by the EMA Executive Board (EXB); • Participated in an external conference (RAPS) to support/raise awareness of the

Objective	MAWP initiative	Activity	% complete	Achievements/results
				changes introduced by the medical device Regulations. • Participated in IVD WG meeting in June 2019 with focus on future implementation of companion diagnostic consultation; • Support HMA-EMA Big Data Taskforce in subgroup on medical devices and in vitro diagnostics • Support to HMA Competent Authorities for Medical Devices (CAMD) strategic and operational group teleconferences
Contribute to removing obstacles to optimal utilisation of biosimilar medicines	1.3-5	Coordinate efforts and drive activities to enhance the benefits of biosimilar medicines for public health		SUSPENDED
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 Trainings were delivered to support operational changes. Walk in clinics to address implementation of operational changes were created. Trainings of assistants and shadowing systems were implemented in support of PSUR activities and operational changes.

In addition to the above, an ITF trend analysis was conducted in Q3 and Q4 in support of Regulatory Science Strategy 2025. In Q4, significant resources were deployed for the integration of the ITF working process into IRIS for veterinary and human medicines, with different implications for both. EMA saw a 30% increase in ITF briefing meetings to support developers of AMR medicines.

2.1.2. Initial evaluation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Number of MAA pre-submission meetings	85	63	71	80	72
Initial evaluation applications, of which:	114	90	84	113	103
New non-orphan medicinal products	41	32	31	35	33
New orphan medicinal products	27	19	17	28	27
Similar biological products	12	17	9	15	13
Generic products, hybrid and abridged applications	31	15	23	34	29

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Scientific opinions for non-EU markets (Art. 58)	0	1	1	1	0
Paediatric-use marketing authorisations	1	2	0	0	0
Number of granted requests for accelerated assessment	12	10	11	5	13
Number of consultations of SAGs/ad-hoc expert groups in the context of MAAs	8	14	13	24	15
Reviews on the maintenance of the orphan designation criteria at MAA stage	20	24	45	40	40

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Applications evaluated within legal timeframes[1]	99%	100%	100%	100%	100%
Average assessment time for new active substances and biosimilars (days)	197.2	175.7	205.3	205	192.8
Average clock-stop for new active substances and biosimilars (days)	136.1	136.9	195.2	180	178.1
MAAs initiated under accelerated assessment that have been completed as accelerated assessment	43%	58%	44%	75%	43%
Initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	63%	69%	68%	80%	68%
Labelling review of the English product information annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	97%	95%	96%	90%	98%
Therapeutic guidelines progressed to the next step or finalised (percentage vs planned)	-[2]	60%	70%	70%	80%
Early background summaries drafted and sent to assessment teams (percentage vs planned)	-[2]	100%	100%	100%	100%
Percentage of outcomes/results of workshops on therapeutic objectives published on EMA corporate website	-[2]	90%	100%	100%	n/a

[1] Includes marketing authorisation and plasma master file applications
[2] New indicator introduced in the 2017 work programme

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-14	Strengthen the support in clinical pharmacology and non-clinical aspects to centrally authorised products along their life-cycle		SUSPENDED
	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: improve the structure and information on benefit/risk in the EPAR by including the effects table, and implement new templates and guidance. Explore feasibility of using a more explicit approach in describing value-judgements in the benefit risk assessment		SUSPENDED
		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		SUSPENDED
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	100%	REDUCED Numerous meetings took place to prepare and finalise the roadmap (adopted in December 2019), leading to the selection of the common electronic standard. Analysis of external consultation comments on key Implementing electronic product information (ePI)

Objective	MAWP initiative	Activity	% complete	Achievements/results
				principles completed. Final document and report on the comments received will be published in January 2020.
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 (REA)	100%	MAINTAINED Requests for collaboration in the context of REA production are processed in accordance with operational guidance and evaluation timelines. REA-4/6/7 were completed; REA-5 was withdrawn; preparatory work started for REA-8/9/10/11. Furthermore, the fine-tuning of the operational framework was completed in second half of 2019. In addition, two specific engagements between HTAs and regulators were facilitated outside REA production.

2.1.3. Post-authorisation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Variation applications, of which:	6,204	6,267	6,716	6,526	7,434
Type IA variations	3,019	3,080	3,433	3,258	3,886
Type IB variations	2,000	2,054	2,164	2,143	2,425
Type II variations	1,185	1,133	1,119	1,125	1,123
Line extensions of marketing authorisations	25	21	20	16	27
PASS scientific advice through SAWP	2	1	3	2	3
Consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	6	15	13	12	10
Renewal applications	107	94	90	90	107
Annual reassessment applications	25	19	22	25	25
Transfer of marketing authorisation applications	35	47	377	60	63
Article 61(3) applications	216	234	258	220	286
Post-authorisation measure data submissions	1,016	795	812	900	776
Plasma master file annual update and variation applications	19	22	19	38	17

Performance indicators

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	Post-authorisation applications evaluated within legal timeframes	99%	99%	99%	99%	99%
	Average assessment time for variations that include an extension of indication	165	162	157	180	165
	Average clock-stop for variations that include an extension of indication	73	67	66	90	76
	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%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	3.2-1	Optimise processes that include interactions among multiple Committees		SUSPENDED
Further promote use of scientific advice throughout the lifecycle of the product, including further development of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)	1.3-6	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indication		SUSPENDED
Strengthen the quality of the scientific review process	3.2-16	Improve the benefit-risk methodology and expand it to post-authorisation updates		SUSPENDED

2.1.4. Referrals

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Pharmacovigilance referrals started	8	7	2	10	8
Non-pharmacovigilance referrals started	10	3	15	8	7

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 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	100%	MAINTAINED A mapping of benefit-risk balance reviews by CHMP in referral procedures, including relevant lessons learned was presented to the relevant Committees (CHMP, CMDh) in Q1 2019. Training has been organised to the PRAC in Q1 2019 and an awareness session will be organised by the end of Q4 2019. Work is ongoing in mapping key referrals that are initiated following GMP/GCP non-compliance. Reports summarising experience and learnings are expected by Q2 2020 and for GxP-related referrals by Q4 2020

2.1.5. Pharmacovigilance and epidemiology activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Number of signals peer-reviewed by EMA	2,372	2,062	2,204	1,800	1,806
Number of signals validated by EMA (assessed by PRAC)	61	82	74	40	50
Total PSUR/PSUSA started	761	920	881	823	800

Procedure		2016 result	2017 result	2018 result	2019 forecast	2019 result
	PSURs (standalone CAPs only) started	518	551	554	558	554
	PSUSAs started	243	372	327	265	246
	Number of imposed PASS protocol procedures started	12	6	17	15	12
	Number of imposed PASS result procedures started	3	6	8	6	3
	Number of emerging safety issues received	21	21	8	10	5
	Number of notifications of withdrawn products received	118	302	413	400	462
	Cumulative number of products on the list of products to be subject to additional monitoring	301	336	351	350	342
	Number of incident management plans triggered	7	4	11	7	3
	Number of non-urgent information or rapid alert notifications submitted through EPITT	49	61	44	55	43
	Number of external requests for EV analyses	34	32	17	15	13
	Number of MLM ICSRs created	8,495	14,193	13,275	12,000	9,676

Performance indicators

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 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%	100%
	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%	97%	95%	94%	99%
	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	1.2-4	Coordinate data collection and	contin	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services		analysis to measure pharmacovigilance impact as feedback to improve processes	uous	The prioritisation of regulatory actions for impact research has been improved with a specific impact section in assessment report templates agreed for selected post-authorisation processes in 2018 and is foreseen for implementation in 2020.
	1.2-4 3.4-1	Provide input into the EC 2019 report on EU network pharmacovigilance tasks	100%	MAINTAINED The HMA and EMA Management Board consultation on the Agency's input to the EC's report on the performance of pharmacovigilance tasks by the EU Member States and the EMA ended with the endorsement of the report on 28 June 2019. The EC will use this as the key source of information for its formal report which is expected to be translated and published in all EU languages in line with Commission publication requirements. The contribution from the EMA and Member States will also be published at the time of publication of the EC report. The four-year report on pharmacovigilance tasks of the EU Member States and EMA was published on 17 December 2019.
	3.3-2	Conduct a lessons-learned exercise after one year experience of public hearings	100%	Completed in 2018.
	1.4-1	Finalise (2019) GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in Q1 2019	80%	SUSPENDED
		Conduct public consultation and finalise GVP product- or population-specific considerations V on geriatric population	n/a	SUSPENDED
		Consider review of GVP Module VII on Periodic safety update report and GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators	20%	SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
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	continuous	REDUCED Activity limited to the EMA/HMA task force on big data. A new study continues with regulatory authorities on measurement of switching patients from codeine to alternative treatment following earlier regulatory action. It is also proposed to extend the testing of new analytical approaches for electronic health records with PRAC involvement. The study on alternative treatments to codeine is on-going (EMA, Spain, France, Norway). The process for pilot rapid data analysis initiated with PRAC and agreed by PRAC in July 2019. The pilot started in November 2019. The pilot results to be discussed with PRAC in Q2 2020.
		Develop and maintain inventory to facilitate access to data on real-world data	continuous	REDUCED Activity limited to maintenance activities. The ENCePP database of resources is continuously updated including description of disease registries and other real world data sources used for regulatory decision-making. At the end of 2019, 183 centres, 26 networks and 141 data sources were included in the database.
		Initiate at least four EMA studies on real world evidence data	100%	REDUCED Activity limited to initiating EMA studies on real world evidence data at the request of PRAC. 18 in-house studies started in 2019. In February 2019, EMA signed contracts for 4 externally-funded studies concerning the impact of EU label changes, and revised pregnancy prevention programmes for oral retinoid containing medicinal products (2 studies) and for valproate and related substances (2

Objective	MAWP initiative	Activity	% complete	Achievements/results
				studies). Contract for one externally-funded study signed in December 2019 (Drug utilisation study on ranitidine and other H2 (histamine-2) receptor antagonists).
		Review the scientific advice process for post-authorisation studies to identify possible process improvement opportunities	90%	SUSPENDED
	1.2-5	Based on evaluation of the options and feasibility provide support to the use of registries for targeted products on the EU market from learnings from the pilot process	continuous	MAINTAINED Article "Barriers and Opportunities for Use of Patient Registries in Medicines Regulation" published in Clin Pharmacol Ther. 2019 Apr 10. doi: 10.1002/cpt.1414. The report and summary poster of follow-up survey of stakeholder actions following the 4 workshops on stakeholder registry-related activities was published on EMA website. Contribution to DG SANTE Registries meeting (20 February 2019). The workshop on the use of registries in the monitoring of cancer therapies based on tumours genetic and molecular features was organised on 29 November 2019; the draft report has been finalised and sent for review to the workshop participants. Article “Patient Registries: An Underused Resource for Medicines Evaluation: Operational proposals for increasing the use of patient registries in regulatory assessments” published in Drug Saf. 2019 Jul 13. doi: 10.1007/s40264-019-00848-9.
		Implement the recommendations from 2017 guidance on key principles for use of registries from a regulatory perspective	50%	SUSPENDED
	1.4-1 3.2-3	Implement phase 1 of the pilot on the new process of signals submitted by MAHs, including analysis of operational capacity,	100%	MAINTAINED Information of the operation of the pilot was collected during the pilot in Q1/Q2 to

Objective	MAWP initiative	Activity	% complete	Achievements/results
		functionality of EV tools, added value of MAH involvement, and areas of process and guidance improvements (2018-2019). Analyse the outcome of phase 1 of the pilot and initiate phase 2 of the pilot (2019-2020)		support a report to the European Commission in Q3. The report was submitted to the EC. The EC has decided to extend the pilot for 24 months until the end of 2021.

2.1.6. Other specialised areas and activities

Workload indicators

Procedure		2016 result	2017 result	2018 result	2019 forecast	2019 result
	Herbal monographs, new[1]	8	4	4	0	0
	Herbal monographs, reviewed	n/a	n/a	7	12	13
	Herbal monographs, revised	9	8	15	4	2
	List entries	2	0	0	0	0

[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		2016 result	2017 result	2018 result	2019 forecast	2019 result
	n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Strengthen the quality of the scientific review processes	3.2-14	Establish a pragmatic approach setting European standards for herbal combination products		SUSPENDED
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
Effectively manage risks to the environment arising from the	4.2-6	Collaborate with the EC on the roadmap “Strategic approach to pharmaceuticals in the environment” and update EMA		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
use of human medicines		guideline on environmental risk assessment (ERA). Participate in EC cross-service group on medicines in the environment		
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
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	20%	MAINTAINED In relation to Ebola outbreak in Democratic Republic of Congo, the Agency was working with WHO in designing the strategy and trials for investigational vaccines and therapeutics. Regular contact with manufacturers was maintained for updates on development. Communication and collaboration with the EU member states continued through a group of expert from NCAs (Ebola Task Force) on scientific and regulatory issues related to potential use in Member States of investigational products, and through regular updates to CHMP. Collaboration with EC aimed at the creation of an EU stockpile mechanism for the investigational products also took place during the first half of the year. Chikungunya, Zika and Lassa vaccines' clinical development are under discussion.
		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 research and development of vaccines including dialogue with the national immunization technical advisory groups of WHO (NITAGs); discussion with	20%	MAINTAINED Interaction with NITAGs has started. Benefit/Risk platform still requires further scoping activities. The Agency hosted observers in its working groups from ECDC.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		EC and ECDC on platform for benefit/risk monitoring of vaccines		
Contribute to European and international initiatives and collaborations in the area of AMR	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) initiative	100%	MAINTAINED A virtual meeting was organised by EMA in April 2019 to follow up on the assigned action 1.4, one of which objectives is to develop the "Reflection paper on the harmonisation of the reporting of consumption of antimicrobials" foreseen to be completed by 2020. EMA also participated in three other teleconferences organised by other TATFAR implementers throughout 2019.
	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	100%	MAINTAINED A representative to the newly established (permanent) OIE working group on antimicrobial resistance was appointed in May 2019, and the group had its first meeting in October 2019. EMA attended the first meeting of the newly established group OIE working group on AMR in October 2019, and participated in a follow-up conference call in December 2019. EMA presented on its activities at the European Antimicrobial Resistance 'One Health' Network meeting in October 2019. EMA also participated in the 7th meeting of the Codex Alimentarius Ad-hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) in South Korea in December 2019.

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.

2.2. Evaluation activities for veterinary medicines

2.2.1. Pre-authorisation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 target	2019 result
Innovation Task Force briefing requests	4	7	5	4	6
Scientific advice requests received	18	17	25	20	21
Requests for classification as MUMS/limited market, of which	25	25	32	25	34
Reclassification requests	6	8	5	5	9

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Scientific advice procedures completed within set timeframes	100%	100%	96%	100%	95%

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/limited market activities report has been endorsed by Management Board in March 2019 and subsequently published on the EMA website.
		Develop training material on the latest revision of MUMS guidelines on data requirements and other guidance		SUSPENDED
Promote innovation and use of new approaches in development of veterinary medicines	2.1-5	Promote access to the Agency's Innovation Task Force through presentations to industry, and as part of existing pre-authorisation procedures	100%	MAINTAINED ITF briefing meetings have been promoted in all suitable early contacts with companies, either during meetings, or when answering written or telephone queries. Four ITF briefing meetings for veterinary products were held in 2019.
	2.1-6	Develop and publish Q&As developed by ADVENT in	100%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		priority areas for technologies that are new to veterinary medicine		The group had one virtual and one physical meeting in 2019 and continued its activity in developing guidance for areas that are new to veterinary medicines also in relation to the new provisions set out in the new veterinary legislation.
		Develop an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials, to control infectious diseases in animals	100%	MAINTAINED This activity was suspended due to BCP in Q1-Q2 2019. At its July 2019 meeting CVMP agreed to progress with the finalisation of the "Discussion document on alternatives to antibiotics" and to review comments received from the restricted consultation phase. The "CVMP Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU" has been adopted in October 2019 by CVMP and published for consultation until April 2020. The content of the document has also been used as the basis for presentations on the topic given at events held in 2019 (e.g. TOPRA, Alternative to antibiotics symposium 2019).
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		SUSPENDED
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		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		emergency situations		
	2.1-4	Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities		SUSPENDED
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis		SUSPENDED
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases		SUSPENDED
		Revise Note for guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use		SUSPENDED
		Develop a concept paper for revision of SmPC guideline for anthelmintics		SUSPENDED

2.2.2. Initial evaluation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Initial evaluation applications	21	17	15	22	23
New MRL applications	6	3	3	3	3
MRL extension and modification applications	1	3	2	2	4
MRL extrapolations	0	0	0	1	0
Art. 10, Biocides	0	0	0	0	0
Review of draft Codex MRLs	5	0	5	0	0

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 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	Finalise training material on revised guideline, procedures and templates for CVMP assessment reports, and provide training on these, with emphasis on benefit-risk		SUSPENDED
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)		SUSPENDED
	2.1-7	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products	100%	Completed in 2018.
Promote uptake of harmonised standards at international level	4.2-5	Reflect on the need for increased international harmonisation in relation to the evaluation of consumer safety of veterinary medicines		SUSPENDED

2.2.3. Post-authorisation activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Variations applications, of which:	410	454	560	498	568
Type IA variations	243	238	331	310	356
Type IB variations	126	130	137	125	139
Type II variations	41	86	92	63	73
Line extensions of marketing authorisations	3	5	1	3	2
Transfers of marketing authorisations	n/a	3	17	10	24

Performance indicators

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	Post-authorisation applications evaluated within legal timeframes	100%	100%	99.9%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure efficient delivery of post-authorisation procedures	2.2-8	Revise and update post-authorisation procedural guidance		SUSPENDED Despite the activity being suspended, the post-authorisation procedural guidance for veterinary medicinal products was revised and the updates published on the corporate website in May 2019.

2.2.4. Referrals

Workload indicators

Procedure		2016 result	2017 result	2018 result	2019 forecast	2019 result
	Arbitrations and Community referral procedures initiated[1]	8	1	5	5	9

[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		2016 result	2017 result	2018 result	2019 target	2019 result
	Arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-1	Provide the EC with CVMP recommendation on prioritisation developed in 2017, for the EC to consider the need for further referrals		SUSPENDED

2.2.5. Pharmacovigilance activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Periodic safety-update reports (PSURs)	175	161	158	160	159
Total adverse-event reports, of which:	38,162	50,885[1]	66,844[1]	60,000	70,392
Adverse-event reports (AERs) for CAPs	18,419	26,671	35,835	30,000	33,656
Adverse-event reports (AERs) for NAPs	15,257	24,214	31,009	30,000	36,736

[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	2016 result	2017 result	2018 result	2019 target	2019 result
PSURs evaluated within the established timelines	98%	98%	99%	90%	96%
Adverse event reports for CAPs monitored within the established timelines	96%	98%	98%	95%	95%

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	2.2-4	Support Member States in the upload and quality control of data into the European database of veterinary medicinal products, and link these data to adverse event reports for CAPs and non-CAPs, to allow signal detection	100%	MAINTAINED The mapping tool to import data from European database of veterinary medicinal products into EVVet was further updated in Q1 and Q4 2019 to improve importing product data from Member States. Support to Member States continued through 2019.
	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
	2.2-6	Ongoing monitoring of		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		incidents, evaluation of lessons learned and update of the incident management plan (IMP) and process in light of experience		
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	100%	MAINTAINED The Pharmacovigilance bulletin has been published in April 2019.
		Develop and implement criteria for proactive risk communication concerning CAPs		SUSPENDED This activity is superseded by the new veterinary legislation (NVR) implementation activities: the draft strategy document has been taken forward as part of the NVR expert group on pharmacovigilance communication (GVP practices IA).

2.2.6. Other specialised areas and activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
n/a					

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support increased availability of veterinary medicines	2.1-3	Conclude the report on the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) and consider follow up	50%	MAINTAINED The reflection paper on dose optimisation of established veterinary antibiotics in the context of SmPC harmonisation was published in July 2018 for public consultation ending in January 2019. Comments were received from 5

Objective	MAWP initiative	Activity	% complete	Achievements/results
				stakeholders and the PPHOVA authors started revising the reflection paper which is foreseen to be finalised now in Q3/Q4 2020.
	2.1-11	Develop a reflection paper on resistance in ectoparasites		SUSPENDED
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (guideline 7, 12-16 and 19-21)	100%	MAINTAINED Work on the draft guidelines continued throughout 2019. The revision of the nine VICH guidelines is progressing by topic (rather than by guideline) and the need for extensive discussion on one particular topic has slowed overall progress on the entire package of guidelines. Work in the VICH Expert Working Group will continue in 2020 with a view to publishing the draft guidelines for consultation towards the end of the year. Contribution of EWP-V to this activity via its experts is expected until finalisation.
	2.2-2	Set up and develop a work plan for an ad hoc expert group, to explore practical measures that could form the basis for harmonisation of the SmPCs of veterinary medicinal products in the context of the revision of the veterinary medicines legislation		SUSPENDED
	2.2-9	Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation	100%	MAINTAINED Following receipt of the first package of mandates in January, the CVMP convened 9 expert groups to work on the recommendations for: • Revision of Annex II (DA, 2 expert groups, deadline Q3 2019) • List of variations not requiring assessment (IA, 1 expert group, deadline Q3 2019) • Criteria for designation of antimicrobials for human use only (DA, 1 expert group, deadline Q4 2019) • Collection of data for antimicrobials (DA, 1 expert group, deadline Q3 2019)

Objective	MAWP initiative	Activity	% complete	Achievements/results
				• Good pharmacovigilance practices (IA, 3 expert groups, deadline Q2 2020) • Pharmacovigilance system master file (IA, 1 expert group, deadline Q2 2020) In February a further mandate was received and an expert group established in collaboration with the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation. • Technical specifications for the Union Product Database (IA, 1 expert group, deadline Q3 2019) The advices concerning the mandates on the revision of the Annex II, the list of variations not requiring assessment, and the collection of data for antimicrobials were adopted by the CVMP at the July meeting. The advice on the technical specifications for the Union Product database was finalised in August. The four advices were submitted to the Commission by 31 August 2019. The advice on the criteria for the designation of antimicrobials for human use only was adopted by the CVMP at the October meeting and submitted to the Commission on 31 October 2019. The work on the advices on good pharmacovigilance practice and pharmacovigilance system master file has progressed as planned and the requested interim report was submitted to the Commission on September 2019. The second package of mandates was received from the EC in July 2019. The CVMP constituted 3 expert groups to work on the recommendations for: • Rules on VMP for oral administration (DA, deadline Q2 2020) • List of antimicrobials reserved for humans (IA, deadline Q4 2020) • Format of data collection for antimicrobials (DA, deadline Q2 2020) The Inspectors Working Group has constituted 1 expert group to work on the recommendations for:

Objective	MAWP initiative	Activity	% complete	Achievements/results
				• Good Distribution Practice for VMPs (IA, deadline Q2 2020) • Good Distribution Practice for active substances (IA, deadline Q2 2020) The work on all mandates has been initiated and is progressing as planned.
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	50%	MAINTAINED Contribution has been provided to two steering committee meetings during the first half of the year.
	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 management of shortages and ensure the adequate supply of essential veterinary medicines	100%	MAINTAINED A new guidance for MAH on reporting shortages (H&V), a guidance for NCA and EMA on communication on shortages (H&V) and a metrics document (H&V) on availability/shortages were developed with the involvement of CMD groups. A pilot will be launched regarding the guidance for MAH in Q1 2020. Phase I of the pilot for SPOC system on availability/shortages (H&V) finished in August 2019, phase II will start in Q1 2020 with direct involvement of the Veterinary Medicines Division. A regulatory manual (H&V) on availability/shortages is under preparation. The need for a H&V guidance on withdrawal applications is under evaluation.
Provide high-quality and consistent scientific outputs	3.2-15	Revise guideline on summary of product characteristics for antimicrobials		SUSPENDED
	2.2-7	Consider and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity	100%	MAINTAINED Six veterinary trainings in areas of interest (quality, safety and efficacy of pharmaceuticals, quality of immunologicals and ERA) have been held in cooperation with NCAs during 2019. Pharmacovigilance signal detection discussion sessions are also held every two months to keep the network adequately trained.
Promote uptake of harmonised	4.2-6	Contribute to training events that raise awareness and		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
standards at international level		enhance uptake of VICH standards by non-VICH countries		
	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		SUSPENDED
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-4	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins		SUSPENDED
	2.4-3	Set up a system for the 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	0%	MAINTAINED Despite the plans to continue with this activity, during 2019 it was suspended as the assigned resources had to be redirected to provide support to the EC in drafting implementing and delegated acts specified in the new veterinary legislation
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	100%	MAINTAINED A virtual meeting was organised by EMA in April 2019 to follow up on the assigned action 1.4, one of which objectives is to develop the "Reflection paper on the harmonisation of the reporting of consumption of antimicrobials" foreseen to be completed by 2020. EMA also participated in three other teleconferences organised by other TATFAR implementers throughout 2019.
	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 EMA attended the first meeting of the newly established group OIE working group on AMR in October 2019 and participated in a follow-up conference call in December 2019. EMA presented on its activities at the European Antimicrobial Resistance 'One Health' Network meeting in October 2019. EMA also participated in the 7th meeting

Objective	MAWP initiative	Activity	% complete	Achievements/results
				of the Codex Alimentarius Ad-hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) in South Korea in December 2019.
	2.4-2	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine and publish the outcome in the ESVAC annual report	100%	MAINTAINED The outline of the 9th ESVAC report was agreed with the ESVAC Sales Expert Advisory Group in the first half of 2019. The final report was circulated to the EC, Member States and CVMP in October, and published on 15 October 2019. The annual ESVAC Network meeting was held in October.
	2.4-5	Provide advice to the EC, in collaboration with ECDC and EFSA, on updating the previous advice on the impact on public health and animal health of the use of antibiotics in animals (categorisation of antimicrobials and early hazard characterisation)	100%	MAINTAINED The updated advice on the 'categorisation of antimicrobials' was circulated for public consultation in February 2019 with deadline for comments by end of April 2019. Due to the large amount of comments received (41 stakeholders responded extensively), the Antimicrobial Advice ad hoc Expert Group (AMEG) at their meeting in May decided to ask EC a further extension of the deadline until end of 2019 for completing the task. The revised advice has been adopted by CVMP and CHMP at their respective meetings in December 2019 and the final document will be published in January 2020. The other part of the scientific advice, 'Preliminary risk profiling for new antimicrobial veterinary medicinal products' was adopted by CVMP and CHMP in June 2019 and published on the EMA's website.
		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 prepared	50%	MAINTAINED The JIACRA group met three times in 2019 to work on its third report. Three more meetings are foreseen in 2020 to finalise the report by the end of 2020.
Effectively	2.4-7	Finalise the draft guideline on		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
manage risks to the environment arising from the use of veterinary medicines		higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome		
		Develop a reflection paper on the potential risks associated with the use of veterinary medicinal products in aquaculture		SUSPENDED
	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 preparation of their strategy on managing pharmaceuticals in environment		SUSPENDED The EC strategy has been published in March 2019.

In addition to the above, gap analysis and the impact assessment of the new veterinary regulation were being reviewed during the first half of 2019, taking into consideration the final text of the adopted regulation. Finalisation is expected by end 2019.

2.3. Horizontal activities and other areas

2.3.1. Committees and working parties

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Number of reimbursed meetings	441	529	408	348	321
Committee meetings[1]	76	76	76	76	76
Training	21	30	29	33	29
Workshops	66	32	35	6[2]	4[2]
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	283	396	273	221	212
Number of virtual meetings (audio-, video- and web-conferences)	4,969	4,802	4,793	6,799	3,443
Number of reimbursed delegates	7,972	8,743	7,214	6,500	6,015
Number of non-reimbursed delegates	n/a	1,464	1,064	1,000	523

[1] Indicator updated to include Management Board meetings
[2] Due to the relocation of the Agency and associated logistical challenges, as well as lack of facilities in the new temporary premises, the 2019 forecast and 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		2016 result	2017 result	2018 result	2019 target	2019 result
	Percentage of delegate satisfaction with meeting support service	n/a	n/a[1]	n/a[1]	n/a[1]	n/a[1]
	Up-to-date electronic declarations of interests submitted by committee members and experts, prior to participating in a committee, SAG or other meeting	99%	100%	99%	100%	99%
	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	100%	99%	100%	100%	96%

[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.

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 the processing of Type IA variations		SUSPENDED
Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Develop a regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines		SUSPENDED

2.3.2. Inspections and compliance

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
GMP inspections	672[1]	314	332	370	386
GLP inspections	0	0	1	1	0
GCP inspections	121	136	140	130	137
Pharmacovigilance inspections	8	15	20	8	9
PMF inspections	-[1]	83	84	66	111
Notifications of suspected quality defects	181	161	147	200	175
Notifications of GMP non-compliances[2]	17	23	25	20	19
Number of medicinal products included in the sampling and testing programme	48	58	53	67	67
Standard certificate requests	3,787	4,023	3,703	3,000	2,565
Urgent certificate requests	487	531	1,069	2,030	2,399
Parallel distribution initial notifications received	2,850	2,639	2,304	2,200	2,468
Parallel distribution notifications of change received	1,847	1,975	2,184	2,000	2,103
Parallel distribution notifications of bulk change received	8	6	11	15	12
Parallel distribution annual updates received	3,815	3,798	5,245	6,000	4,270

[1] PMF inspections included in GMP inspections results.
[2] Previously: 'Other GMP inspections related notifications'.

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%
Standard certificates issued within the established timelines	91.6%	64.2%	0%[1]	90%	28%
Average days to issue standard certificate	7	10.3	27.3[1]	10	59.6[2]
Urgent certificates issued within the established timelines	100%	100%	99%	100%	97%
Parallel distribution notifications checked for compliance within the established timeline	99%	96%	97%	90%	37%
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	34%	39%	38%	35%	42%

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	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 Activity limited to exchange on product specific issues. Within the EMA-FDA GCP initiative, regular and specific product-related teleconferences took place over 2019. The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) also participated in the teleconferences as an observer to the EMA/FDA GCP initiative. Four joint EMA-FDA GCP inspections and four observational inspections were coordinated. In addition, regular teleconferences took place within the EMA-EU Member States-FDA GCP BE Inspections initiative. In 2019 teleconferences with WHO under the confidentiality agreement between EC-EMA-WHO continued in the area of GCP BE Inspections. EMA-EU MS and Swissmedic agreed on the process of exchange of information for inspections in Switzerland.
	4.3-2 4.3-4	Explore the possibility to set up a pilot phase with the FDA on sharing information on pharmacovigilance inspections	continuous	REDUCED Activity limited to exchange on product specific issues. Information on pharmacovigilance inspections is shared on an ad-hoc basis. No product related discussions were held

Objective	MAWP initiative	Activity	% complete	Achievements/results
				during 2019.
	4.1-5	Monitor and review effect of implementing EudraGMDP rules for planning module on cooperation with Member States in coordinating third-country inspections	100%	Completed in 2018.
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 Activity limited to exchange on product specific issues. Continued regulatory support to the work of the European Observatory on the Supply of Medical Radioisotopes to facilitate the transition from High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) is being provided. EMA has participated at the meeting on 25th September.
	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	65%	MAINTAINED Continued support has been provided to the HMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use in 2019. Concerning the Thematic working group 2 - Supply chain disruptions, a definition of a shortage, reporting guidance and metrics have been developed and agreed by the Network. Support was also provided to the setting up of a process for internal cooperation and sharing of information on shortages within the EU network (SPOC system) which is being piloted since April 2019.
Improve application of equivalent standards of good manufacturing and clinical practice throughout the world	4.2-1	Support training activities in India and China, including establish a panel of European inspectors available to participate in capacity-building workshops in these countries		SUSPENDED Despite this activity being suspended, EMA participated in the 4th India Pharmaceutical Forum 2019 and the Drug Information Association (DIA) China 2019 Annual meeting and IPA Workshop and US FDA Workshop for APIs in India.
Improve knowledge and	4.1-2	Develop further GxP guidance for industry on data integrity		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
understanding of data integrity and implications for regulatory decision-making				
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors from international regulators		SUSPENDED
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	100%	MAINTAINED The Joint Audit Programme continues to support the EU-US MRA initiative. FDA confirmed the capability of further 8 Member States bringing the total to 28 Member states recognised. The batch testing waiver for import of medicinal products manufactured in the US was implemented as from 11 July 2019. The Joint Audit Programme will continue to support the extension of the MRA scope to veterinary medicinal products. The implementation and maintenance of the MRA for human medicinal products will be further supported via regular re-audits of Member States.

2.3.3. Partners and stakeholders

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Requests for SME qualification	582	582	487	543	536
SME status renewal requests	1,185	1,185	1,334	1,466	1,235
Number of cases of patient/consumer engagement[1] in EMA activities	750	950	493	550	769
Number of cases of healthcare professionals engagement[1] in EMA activities	-[2]	450	212	200	212
New scientific, regulatory and telematics curricula developed	8	8	2	1	2
Number of training events advertised to the EU Network	140	140	60	50	40
Number of reimbursed training events to the EU Network	25	25	8	12	12

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Number of messages circulated via 'Early Notification System'	380	380	440	400	411
Number of EMA communications pro-actively sent to stakeholders	172	172	175	150	128
Number of EPAR summaries and EPAR summaries updates published	283	283	343	300	286
Number of summaries of orphan designation published	240	240	169	110	117
Access to documents requests	823	823	822	850	783
Documents released following requests for access to documents	2,876	2,876	2,422	2,700	1,429
Requests for information	4,843	4,843	7,554	5,500	7,200
Number of documents published on the EMA corporate website	7,369	7,369	4,840	7,100	9,012
Number of pages published and updated on the EMA corporate website	4,790	4,790	6,307	3,600	3,383
Number of press releases and news items published	187	187	183	80	143
Requests for interviews and comments by media representatives	2,149	2,149	1,517	1,800	1,476
Number of reports, brochures and leaflets produced	25	25	85	30	206

[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] New indicator introduced in 2017

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Satisfaction level of patient and consumer organisations	97%	n/a	n/a[1]	n/a[1]	n/a[1]
Satisfaction level of healthcare professionals organisations	n/a	n/a	n/a[1]	n/a[1]	n/a[1]
Satisfaction level of SMEs	94%	93%	95%	n/a[1]	n/a[1]
Percentage of responses to ATD requests provided within set timelines	97%	96%	96%	90%	89%
Percentage of responses to RFI requests provided within set timelines	100%	98%	97%	95%	96%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	77%	81%	85%	75%	84%
Number of NCAs that have opened their training for inclusion in EU NTC learning	14	8	7	7	10

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	management system					
	Number of users registered to the EU NTC Learning Management System	2,117	3,583	4,424	4,600	5,121
	Number of NCA experts registered to the EU NTC learning management system	1,225	2,668	3,480	3,600	3,143
	Satisfaction level of partners/stakeholders with EMA communications	n/a	82%	n/a	n/a	n/a
	Average rating of pages on corporate website during the year	3.6	3.3	3.1	3.2	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	85%	MAINTAINED • Interaction to stimulate and support academia participation in the consultation on the Regulatory Science Strategy and the consecutive workshop. • EMA is now full partner in the Horizon 2020 STARS project ("Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice"). • Proposal for fee waivers for academia applying for scientific advice/protocol assistance developed but subject to further discussion in the context of the overall review of the orphan designation fee policy. • Regular dialogue with European Reference Networks (ERN) and identification of experts on both sides took place as needed.
	3.4-6	Publish annual report on EMA interactions with industry associations		SUSPENDED
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals and their organisations		SUSPENDED
	3.4-5	Implement recommendations to promote GPs' interactions		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		with EMA and support regular engagement with GPs, including through written consultations, teleconferences, participation in dedicated meetings and other		Despite this activity being suspended, a joint position statement between EMA and UEMO/EFPC/WONCA was published on 6 June 2019 and presented at WONCA-Europe annual conference on 28 June 2019. Ongoing calls took place with UEMO/EFPC/WONCA for EMA GPs expert group.
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		REDUCED Activities directly related to product support are maintained. Non-product support activities suspended.
Further strengthen Agency's transparency and open data commitments	1.4-3	Complete the reflection paper on providing access to individual patient data		SUSPENDED
	1.4-5	Assess implementation of the policy on publication of clinical data and publish annual report		SUSPENDED
		Hold regular discussions in the technical group on anonymisation of clinical data		SUSPENDED
	1.4-5 1.4-6 1.4-7	Publish the transparency road map for public consultation (2018). Agree draft principles of transparency (2019)		SUSPENDED
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	0%	MAINTAINED No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
	3.1-6	Implement the second phase (2018) and launch the third phase (2019) of the multinational assessment team approach post-authorisation	0%	MAINTAINED No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
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	50%	MAINTAINED
		Develop in collaboration with the Network, the EU Medicines Agencies Network Strategy to 2025	5%	MAINTAINED Work on the new Joint Network strategy to 2025 was agreed in the June HMA

Objective	MAWP initiative	Activity	% complete	Achievements/results
				meeting. The exercise was formally launched on 18 December 2019.
	3.1-3	Work with the Network to include training courses in NTC learning management system and to promote the use of NTC courses, to maximise the use of the EU NTC learning management system	continuous	MAINTAINED A total of 40 new courses were available through the EU NTC Learning Management system in 2019. This number included 12 face-to-face courses, with the majority of these hosted by individual NCAs within the European regulatory network). Over 380 experts participated in these face-to-face courses
		Work with the Network to prioritise training needs	continuous	MAINTAINED Efforts in this area in 2019 included the development and delivery of training on Oncology to CHMP members and assessors, and prioritisation of training needs in veterinary area under the direction of the veterinary coordination group.
	3.1-2	Review and update existing curricula to ensure provision of up-to-date training	continuous	MAINTAINED Training curriculum on real-world evidence (RWE)/pharmacoepidemiology was identified and draft table of contents discussed at PRAC, CHMP and Biostatistics Working Party (BSWP). Training curriculum on assessment of herbal medicinal products developed and agreed by HMPC.
	1.3-8	Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency	50%	REDUCED Activity limited to observer status. No meetings were held in January to April 2019. Meetings resumed in May and full secretarial support was provided for plenaries and drafting groups from then on.
		Foster the visibility and activities of the EU Innovation office network to ensure effective and harmonised support to early innovators at local and European level	0%	REDUCED Activity limited to observer status.
Increase awareness on the	1.3-8	Identify in cooperation with the EU Innovation office network	25%	REDUCED

Objective	MAWP initiative	Activity	% complete	Achievements/results
evolution of the regulatory framework		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.		Activity limited to observer status.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency's work, outputs and medicinal products	3.3-6	Review and improve the format and content of EMA information on medicines for patients and healthcare professionals (i.e. EMA summaries in lay language)		SUSPENDED
	3.3-6 3.3-7	Implement user-testing for EMA communication products which target the general public		SUSPENDED
	3.3-10	Run a pilot to test and improve the crisis communication plan		SUSPENDED
	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		SUSPENDED
	3.3-3	Improve the corporate website by adding new tools and features, such as tools to improve search, search-engine optimisation, accessibility, analytics and others		MAINTAINED
	3.3-1	Develop and implement an annual communication plan, in line with the framework strategy for external communication	100%	MAINTAINED Communications plan was adopted by EXB in June 2019.
	3.3-4	Continue development and implementation of a social media strategy, including consolidate social media channels and grow followership		SUSPENDED
	3.4-6	Develop streamlined process to support the planning, monitoring and reporting of membership organisation	100%	- A yearly planning cycle was implemented for all major professional membership conferences- Participation in 23 conferences, covering 99 sessions

Objective	MAWP initiative	Activity	% complete	Achievements/results
		activities and events Propose yearly strategy content for external meetings such as BIO, DIA, RAPS and TOPRA Represent the Agency in steering committees, programme committees and advisory boards of such organisations		
	3.3-5	Develop new digital and multimedia communication tools		SUSPENDED
Improve provision of and access to strategic information resources		Implement Information Literacy Programme		SUSPENDED
		Proactive development and provision of InfoCentre collection and services, including e.g., journals, eBooks and databases that address the changing needs of the Agency	50%	REDUCED Activity reduced to all relevant resources are purchased, reviewed, maintained and made accessible in 2019 All relevant subscriptions were renewed/reviewed in 2019. Books have been purchased proactively. Access to online resources are monitored continuously.
		Support open access publication of relevant scientific articles (Open access requests reviewed and approved as necessary, payment procedure initiated)	50%	MAINTAINED Following up on 29 open access requests approved.
		Develop pilot to measure reach of open access publications (Assessment on the methods to measure the impact of open access publications completed)		SUSPENDED

2.3.4. International activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Interactions with FDA	n/a	654	584	700	454
Interactions with PMDA/MHLW	n/a	138	122	200	96

Procedure		2016 result	2017 result	2018 result	2019 forecast	2019 result
	Interactions with Health Canada	n/a	91	175	700	125
	Interactions with any other stakeholders	n/a	498	734	500	506
	Number of information and/or document exchanges	n/a	929	920	750	461
	Number of teleconferences organised	n/a	166	172	150	142

Performance indicators

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	n/a					

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
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. - Article on EU-M4all (Article 58) has been accepted for publication in Expert Review of Clinical Pharmacology - Pre-submission meeting request for Dengue Tetravalent Vaccine (art. 58) - Discussion with UNICEF on a potential collaboration with EMA on biological medicines for LMIC countries - Presentation for the TOPRA webinar on EU-M4all on 4 November - Support to development of African Medicines Agency; collaboration with AMRH at SCoMRA Scientific conference; sharing knowledge and experience on functioning of an international regulatory agency (EMA) - Collaborative Registration Procedure with WHO - products: Prezista, Gardasil - teleconference with potential art. 58 NGO applicants: Europe IAVI – the International AIDS Vaccine Initiative - Information sharing with MHLW/PMDA on participation in SRA Collaborative

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Registration Procedure.
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		SUSPENDED
Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	4.2-2	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	100%	REDUCED - MRA with US FDA - human completed July 2019; work ongoing for veterinary (coordination of Joint Audit Programme audits in preparation for assessment) and vaccines; pre-approval inspection for human medicines; and joint inspections on vaccines - Observed and joint inspections on sartans (Nitrosamines issues) - Ongoing work for pilot programme to rationalise international GMP inspection of sterile finished medicinal products manufacturers located in third countries (pilot expected to start in March 2020). - Full involvement of PMDA in GCP inspection collaboration after pilot in 2018
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	100%	REDUCED - International collaboration on Nitrosamines - Continued joint regulators/industry Track & Trace group of ICMRA (EMA lead), first draft of ICMRA document produced - member of ICMRA project on shortages, (innovation, communication as well)
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 Despite the activity being suspended due to the BCP, the following took place in 2019: - Two fellowships from FDA to EMA: Oncology and International affairs (Europe Office) - One fellowship from EMA to FDA: ATMP

Objective	MAWP initiative	Activity	% complete	Achievements/results
				and quality - Creation of a webpage where trainings offered by EMA and the EU network that are open to non-EU regulators are made available and updated. The process raises awareness of organisers to consider non-EU regulators when planning and developing training - ATMPs leadership meeting with FDA - Ongoing discussions with India and with international partners (FDA, WHO, PMDA, PIC/S) for a curriculum in the region
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU		SUSPENDED
		In collaboration with WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO training platform		SUSPENDED
Prepare regulators for innovative products and technologies		ICMRA strategic priority on innovation	80%	- Chair of the innovation network at ICMRA - Identification of 2 new deep dive exercises to be performed in 2020
Ensure appropriate representation in relevant fora to ensure convergence of standards	4.2-7	Implement mechanisms to ensure representative and consistent representation of the network in international fora, and to provide feedback to the network including ICH, VICH, WHO, OIE, IRCH and PIC/S, ICMRA, IPRF, IGDRP	50%	- Participation at the DG DEVCO meeting in Brussels on Quality of medicines: exchanges and possible areas of further cooperation and collaboration. - There have also been efforts for better coordination of EMA and Network at the level of the WHO Partnership Platform. - Concerning ICH and the International Pharmaceutical Regulators Programme (IPRP), participation in briefings of the CMDh and in briefings at CHMP. Participation in the Singapore meeting. - ICMRA executive committee teleconferences - ICMRA day at DIA (June 2019) - Reappointment of representatives from EMA and NCA in IPRP groups - Participation in 2 sessions of the monthly

Objective	MAWP initiative	Activity	% complete	Achievements/results
				meeting of WHO PQ (with UNFPA and UNICEF, Copenhagen) on collaborative registration procedure and on nitrosamines - Chair of the Paediatric Medicines Network of WHO - Streamlining and reappointing EU representatives at IPRP groups ICMRA - Handover of the ICMRA secretariat and takeover of all related work
Expand work-sharing and mutual reliance initiatives	4.3-1	Support the Commission with the implementation of a Mutual Recognition Agreement with the US	100%	- Participation in the US National Academies of Sciences, Engineering and Medicine (NASEM) meeting on mutual recognition agreements and reliance in the regulation - Active participation in EU-US MRA for human medicinal products (completed July 2019) - Meetings with MS to support MRA capability assessment, in particular to resolve emerging assessment issues e.g. meeting in Hannover to progress CoI, teleconferences with MS/FDA, teleconferences with MS to help advance responses. Escalation for resolution of critical findings and support to Slovakia - Support to collaboration of US FDA-EU EMA on pre-approval inspections - Active participation in EU-US MRA for veterinary medicinal products - Support to EC with discussions on VMPs, vaccines and ATMP
Expand work-sharing and mutual reliance initiatives	4.3-1	Increase collaboration with non-EU partners and organisations	100%	- Signature of confidentiality arrangement with European Directorate for the Quality of Medicines & HealthCare (EDQM) - Ongoing confidentiality arrangement with Health Canada, text agreed between EMA and Health Canada, currently undergoing inter-service consultation at Commission level. - Face-to-face meeting with Japan and Taiwan in the margins of DIA US - Support for EU-US collaboration on complex generics (including possible parallel scientific advice) - Support for efficiency and growth of cluster platforms, e.g. inclusion of

Objective	MAWP initiative	Activity	% complete	Achievements/results
				additional partners (Health Canada in patient engagement, SwissMedic in biosimilars), supporting development (shortages), encouraging participation e.g. API, supporting development of terms of reference - Review of clusters finalised with submission of article for publication in July 2019 - Ongoing discussions on heparin - Ongoing discussion on ranitidine - Ongoing discussion on sartans - Support to creation of opioid task force - Support to the use of parallel scientific advice in public fora and within FDA - suggestion for improvement of internal process for EMA - Start of support to South Africa for the SAHPRA's Backlog Clearance Program - Contribution to the WLA document from WHO and agreement with Japan - Visit of Ministry of Health of Indonesia in June - Support to SAHPRA and their Backlog Clearance Program by sharing unredacted assessment reports for 9 CAPs - ongoing work with CMDh for NAPs - Participation in the meeting on Ebola vaccine collaborative assessment in Rwanda (July) - Participation in the meeting organised jointly by the Ministry of Health, MFDS and the Korean Network for Clinical Trials (September) - Participation in 5 sessions of the DIA Japan meeting (November) - Participation in the GCP-training session, with the Peking University Clinical Research Institute (PUCRI) and with regulators from the Chinese National Medical Product Administration (NMPA)(November) - Visit of the NMPA Deputy Commissioner and a delegation of NMPA (October) - Head of Industry Development & Communication Section of the Centre of Regulatory Coordination & Strategic

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Planning, Ministry of Health, Malaysia visited the Agency in October as a visiting expert for training on variations - Preparation of a confidentiality arrangement template for 3 additional countries - Preparation of the update of the confidentiality arrangement with Health Canada - Visits from FDA (2 in 2019, oncology and international affairs) - Participation in the WLA meeting in Geneva - Bilateral meetings in the margins of the ICMRA Summit in Rome in October with MHLW/PMDA, Brazilian Health Regulatory Agency (ANVISA), India, FDA - US (October 2019) - Contribution to the process of development of the Opioids Steering Group - Resolution of issue with 1572 form (clinical trial) through agreed waiver process from the US

2.3.5. Information management

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
Number of Telematics information services provided by EMA	22	23	25	25	25
Number of ongoing Telematics IT projects where EMA is the delivery organisation	13	11	3[1]	4	3
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	6	6	5	7	8

[1] The EudraCT Legacy project has been postponed to 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	2016 result	2017 result	2018 result	2019 target	2019 result
Satisfaction of EMA internal and external users (% satisfied or very satisfied)		94%	91.92%	80%	87.9%

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Availability of corporate/Telematics IT systems and corporate website		100%	98.11%	98%	88.8%

Achievements

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

2.4. Support and governance activities

Workload indicators

Procedure	2016 result	2017 result	2018 result	2019 forecast	2019 result
n/a					

Performance indicators

Performance indicators related to core business	2016 result	2017 result	2018 result	2019 target	2019 result
Posts on the Agency establishment plan filled	98%	98%	98.3%	97%	98.65%
Total TA staff recruited against vacant posts[1]	n/a	15	29	42	36
Staff turnover rate[1]	n/a	4.1%	4.57%	10%	7.25%
Time to fill position from vacancy notice to establishment of reserve list					
Standard procedure[2]	-[3]	-[3]	-[3]	< 3 months	79% < 3 months
Medium procedure[2]	-[3]	-[3]	-[3]	< 4 months	n/a
Large procedure[2]	-[3]	-[3]	-[3]	< 6 months	n/a
Revenue appropriations implemented	100%	96%	93.88%	97%	96.29%
Expenditure appropriations implemented	96%	93%	90.76%	97%	98.56%
Payments against appropriations carried over from year N-1	96%	89.9%	90.57%	97%	94.94%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1	0.9%	1%	1.23%	1%	2.19 %
Title 2	7.9%	11.8%	16.31%	15%	10.79%
Title 3	25.9%	28.1%	30.21%	25%	29.16%
Payments made within 30 days' time	99%	97.3%	97.04%	98%	97.59%

Performance indicators related to core business		2016 result	2017 result	2018 result	2019 target	2019 result
	Availability of Telematics/corporate IT systems and corporate website (% of time)	100%	99.3%	98.11%	98%	88.8%
	Change in energy consumption (per workstation)	-19.6%[4]	-5%[4]	-3%[4]	n/a[5]	n/a[5]
	Change in water consumption (per workstation)	-52.8%[4]	+13%[4]	-7%[4]	n/a[5]	n/a[5]
	Change in paper consumption (per workstation)	-22.7%[4]	-13%[4]	-8%[4]	n/a[5]	n/a[5]
	Change in non-recyclable waste produced in restaurant and kitchenette (per workstation)	-46.0%[4]	+13%[4]	-5%[4]	n/a[5]	n/a[5]
	Change in recyclable waste produced (per workstation)	-26.3%[4]	+10%[4]	-22%[4]	n/a[5]	n/a[5]
	Change in recycling rate (per workstation)	-5.2%[4]	-4%[4]	3%[4]	n/a[5]	n/a[5]
	Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	+1.4%[4]	n/a	-6%[4]	n/a[5]	n/a[5]
	Overall net CO_2 emissions (per workstation)	-10.2%[4]	n/a	-14%[4]	n/a[5]	n/a[5]

[1] New indicators introduced in 2017 work programme.
[2] *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
[3] New indicator introduced in 2019 work programme.
[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		MAINTAINED In the framework of the Administration Digitalisation Programme, a work stream for integrated planning has been created to further establish the integrated planning framework: as one of the first activities, a pilot within the administration division for integrated planning was carried out during the reporting period, its results will be further incorporated to the development efforts.
	3.2-5	Implement a competency management framework		MAINTAINED
Maintain high level of	3.1-8	Conduct the annual review of the Agency's handling of		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
independence, integrity and transparency in all aspects of Agency's work		independence		
		Implement the action plan of the anti-fraud strategy		Due to the business continuity conditions in place at the Agency, this action has been carried over and is likely to be resumed in 2020 once the Agency has settled at its new premises.
Implement new GDPR legislation	4.1	Enhance the protection of personal data in all aspects of the Agency work	100%	MAINTAINED Several key documents have been prepared or already adopted and their publication is in the final stage, including Management Board decision on internal rules on restrictions of data subjects' rights under Article 25 of EU Data protection regulation, EMA Implementing Rules under EU DPR, revised privacy statements; draft data protection impact assessment on the Clinical Trials Data Base. Internal audit consultancy confirmed that there are no gaps in the planned implementation measures for the new personal data protection legislation. All measures planned have been launched and are ongoing. In addition to this, the following activities have been finalised: IT security review; update of Central Register of records of data processing activities; preparation of new privacy statements; data protection training modules for all staff and on specific topics. EDPS investigation case 2018-0688 has been closed and recommendations implemented in. Input has been provided to the EDPS in ongoing cases 2018-0319 D-0692 (use of Microsoft products and services) and 2017-0632 (website inspection).

3. Organisational management and internal control

This section answers the question of how the achievements described in the previous section were delivered by the Agency and in which context the Agency had to operate.

3.1. EMA governance

3.1.1. Management Board

The Management Board (MB) is the European Medicines Agency's integral 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 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.

- EMA preparedness on Brexit

Throughout the year, the Board was updated on the Agency's ongoing Brexit related business continuity plan to safeguard core activities related to the evaluation and supervision of medicines.

Reports on the preparations for 2020, a year of further transition for EMA which will include the Agency's move to its newly built premises in Amsterdam were also provided to the Board at each meeting. Status updates on EMA staff retention following the Agency's relocation to Amsterdam were also provided.

- EMA premises in London

In addition to updates on the Agency's preparations and execution of the move to Amsterdam, the Board was updated also on the developments in regards to subletting the Agency's former premises in London. Concerns regarding financial aspects as well as the Agency acting as a commercial landlord in a future 3rd country were raised by both the Board members and the Executive Director.

- Re-election of Christa Wirthumer-Hoche as Chair of the EMA Management Board

At its March meeting, the Board re-elected Christa Wirthumer-Hoche as its chair for a new three-year mandate. This is Dr Wirthumer-Hoche's second and final mandate as chair, as the rules of procedure of the Board foresee a maximum of two terms. Dr Wirthumer-Hoche is Head of the Austrian Medicines and Medical Devices Agency, a post she has held since October 2013.

- Election of Lorraine Nolan as Vice-Chair of the EMA Management Board

At its October 2019 meeting, the European Medicines Agency's Management Board elected Lorraine Nolan as vice-chair of the Board for a three-year period. Dr Nolan is Chief Executive of the Health Products Regulatory Agency (HPRA) in Ireland, a post she has held since January 2016. She has served as a member of EMA's Management Board since March 2016.

- New representatives of the European Parliament and Civil Societies on the Board

In June, a new representative of the European Parliament, Matthias Groote, was nominated to the Management Board. Mr Groote, who is the former chair of the Committee on the Environment, Public Health and Food Safety (ENVI) will serve a three-year term, renewable once. The mandate of Mr Tonio Borg, the second European Parliament representative to the Board, was renewed for another term.

Later in the year, the Board welcomed two new civil society representatives. Marco Greco, president of the European Patient Forum (EPF) and Ioannis Natsis, policy manager for universal access and affordable medicines at the European Public Health Alliance (EPHA) will represent patient organisations. Nancy de Briyne and Wolf-Dieter Ludwig, representatives of veterinarians' and doctors' organisations respectively, were re-appointed as civil society members to the Board.

- Activities required by the Founding and Financial Regulations

The Board's operational tasks include reporting on the use of European Union (EU) contributions for the Agency's activities. In 2019, these activities involved:

- the assessment of the Executive Director's annual activity report for 2018;
- adopting the EMA's annual report for 2018,
- delivering an opinion on the Agency's final accounts, and
- adopting the Agency's work programme and budget for 2020 and preliminary work programme and budget for 2021.

- Updates on the development of the Clinical Trials Information System for the EU Clinical Trial Regulation

The EU Clinical Trial Regulation (CTR) Coordination Group, reports to the EMA MB and is responsible for providing oversight of the progress, and giving strategic advice and recommendations to the EMA MB. The group was established in order to monitor implementation activities in relation to the CTR, coordinate the activities of the various working groups and parties contributing to the preparation of implementation of the CTR, identify and propose solutions to critical issues, and to coordinate communications in relation the CTR implementation.

Throughout the year, the Board was updated on the status of the ongoing development of the Clinical Trial Information System (CTIS) by means of monthly reports and presentations at the Board meetings.

- 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.

- Annual revision of the EMA Information Management Strategy and Information Management Strategic Plan

The Management Board endorsed the revised EMA Information Management Strategy 2019-2021 and the Information Management Strategic Plan 2019-2021. According to the EMA's IT governance, yearly review and endorsement by the Board takes place as part of the annual planning cycle to take into account changes in the environment and priorities. The current proposal was based on a reflection on how the Agency has delivered on its strategy in the last year.

- 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 reports on audit activities, audit findings and monitoring of main audit recommendations from the European Court of Auditors (ECA), the Internal Audit Service of the European Commission (IAS), as well as the Internal Audit capability of the Agency (IAC).

The Annual report of internal audit and advisory activities at the European Medicines Agency 2018 was provided to the Board in June.

In October, the Director of the IAS and Director of the ECA presented to the Board their activities in connection to the audits performed at EMA. At this meeting, the Management Board adopted an update of the Annual Audit Plan 2019. In December, the Management Board adopted Audit Strategy 2020-2022 and the Annual Audit Plan for 2020.

- Periodic reports from Chairs of Scientific Committees and Working Parties and other bodies

To ensure that members are kept informed of the work of the scientific committees and working parties, Chairs of these groups were invited to report to the Board, stimulating excellent discussions on aspects of their activities.

In March, the chair of PDCO, Dirk Mentzer, updated the Board on the work of the committee and the steps taken since publication of the Commission's ten-year report on the impact of the EU's Paediatric Regulation.

Susanne Keitel, Director of EDQM, and Laura Oliveira Santamaria, Chair of CMDh, were invited to the December Management Board meeting for a discussion concerning the Management of Nitrosamine presence in medicines. At this meeting, the Board endorsed the *Handling of new information on nitrosamine presence in medicines*, laying down an EU regulatory network short-term and temporary approach. The Board welcomed the cooperation on the issue that is already ongoing at European level and encourages continued discussion with regulators from outside the EU.

3.1.2. Executive Director

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. He is responsible for all operational matters.

3.1.3. Executive Board

The Executive Board (EXB) is the governing body of the Agency that considers both the strategic issues (including setting the Agency's long-term vision; deciding on strategy and implementing it; setting short-term priorities and goals; planning and allocating resources; preparing for new legislation; making high-level policy; and deciding on portfolios of programmes and projects), and high-level cross-Agency operational issues — including work programme monitoring; budget monitoring; programme and project monitoring; KPIs and risk monitoring; audit reporting; and staff-related matters.

EXB is chaired by the Executive Director (deputy Executive Director in his absence). All heads of division, head of the portfolio board and international affairs, head of the legal department, and the senior medical officer sit on the EXB.

3.1.4. Other management bodies

Other organisational bodies involved in the day-to-day administration of the Agency are:

Medicines Leadership Team

The Medicines Leadership Team (MLT) is the key governance and decision-making body of the scientific operations divisions. It considers product-related issues (pre-PRAC or pre-CHMP/CVMP), as well as organisational, procedural, and regulatory matters. MLT is comprised of heads of human medicines, veterinary medicines, and communication divisions, and heads of departments within these divisions.

Portfolio Board

The Portfolio Board (PB) is the body in the Agency's internal programme governance structure that is responsible for the oversight and review of the Agency projects throughout all the phases. The PB has particular responsibility for improving quality, efficiency, and effectiveness of the Agency's procedures and processes, and ensures strategic alignment of projects. PB reports to the Executive Board, which retains responsibility for the decisions about inclusion of initiatives (programmes or projects) in the portfolio, allocation of the portfolio budget at any time, and appoints the members of the Portfolio Board, based on the knowledge necessary to carry out the work of the PB.

PB works closely with the EMA Portfolio Office, to ensure that programmes and projects in the Agency's portfolio are monitored and managed according to agreed standards, and within the governance arrangements.

Scientific Coordination Board

The Scientific Coordination Board (SciCoBo) is a high-profile management body, created to ensure the strategic coordination between the scientific committees of the Agency. It is chaired by EMA's Head of Scientific Committees Regulatory Science Strategy Support, and its members comprise the chairs of the seven Agency's committees.

3.2. Budgetary and financial management

At the time of writing, the Court of Auditors had not yet provided the Agency their observations on the provisional accounts and therefore, the Agency's final accounts 2019 had not yet been issued. Thus, the data below is based on the provisional accounts.

3.2.1. Financial highlights of 2019

The financial consequences of Brexit, i.e., the Agency's departure from the UK and move to the Netherlands continued to be felt in 2019, with expenditure estimated at EUR 51.4 million.

The financial outturn, a deficit of approx. EUR 8.28 million, representing 2.39% of the final budget, was caused mainly by lower-than-expected fee-related income being collected at the end of the year.

A revised version of the Agency's Financial Regulation came into effect on 1 July 2019 and meant that the handling of assigned revenue changed. The Agency expects external assigned revenue stemming from incentives from the Dutch government and internal assigned revenue stemming from the sub-letting of its former headquarters in Canary Wharf, London, until 2039.

The Agency complied with the ceilings/KPIs for the amounts carried forward (C1 to C8): title I (10%), title II (20%) and title III (30%), with the following percentages achieved for the automatic carry-forward: title I: 2.19%, title II: 10.79%, title III: 29.16%.

14 transfers were carried out in 2019. Transfers mainly increased appropriations related to building expenditure, as well as slightly increased meeting costs and activities.

3.2.2. Budget overview

Authorised appropriations in the European Medicines Agency's initial budget for 2019 totalled EUR 332,959,000, representing a 1.42% decrease compared to the 2018 initial budget (EUR 337,761,000).

Two amending budgets were processed in 2019. The first amendment increased the number of national experts on secondment, enabling the Agency to use support of such experts during the critical

Brexit period. The second increased appropriations in order to provide the possibility of claiming from the European Commission the return of the 2018 budgetary surplus one year earlier, resulting in a final budget of EUR 346,762,000.

3.2.3. Revenue (income from evaluation activities and EU contribution)

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

Revenue entered in the accounts as at 31 December 2019 amounted to a total of EUR 339,889,499.26. Of this amount, EUR 329,738,138.46 related to the adopted budget, i.e. fund source C1, while EUR 10,151,360.80 related to assigned revenue, fund sources R0 and CL.

Of total C1 income, 89.15% derived from the evaluation of medicines and other business related activities, 10.77% from the EU budget to fund various public health and harmonisation activities, including positive outturn of previous year, and 0.09% from various sources (2018: 89.69%/10.28%/0.03%).

3.2.4. Expenditure (commitments and payments)

Commitments on fund source C1 totalled EUR 341,768,988.36 or 98.56% of final appropriations (2018: 90.78%). Payments totalled EUR 287,978,964.65 or 84.26% of commitments (2018: 82.12%).

3.2.5. Appropriations carried forward from 2019 to 2020

Automatic carry-forward

Automatic carry-forward to financial year 2020, C1 to C8, totalled EUR 53,790,023.71 or 15.51% of appropriations (total carried forward from 2018 to 2019: EUR 53,321,802.27 or 17.39%).

3.2.6. Implementation of appropriations carried forward from 2018 to 2019

Automatic carry-forward from financial year 2018 to 2019, i.e., fund source C8, totalled EUR 53,321,802.27. Payments against these appropriations equalled EUR 50,623,573.53 or 94.94% of appropriations (2018: 90.57%) and EUR 2,698,228.74 were cancelled.

Non-automatic carry-forward, i.e., fund source C2, from financial year 2018 to 2019 amounted to EUR 1,500.000. Payments against C2 appropriations amounted to EUR 1,453,959.92 or 96.93% of appropriations (2018: 92.41%), and EUR 46,040.08 were cancelled.

3.2.7. Appropriations from external assigned revenue

The Agency's final 2019 budget included appropriations stemming from assigned revenue. In accordance with the revised Financial Regulation which came into effect on 1 July 2019, this revenue and corresponding expenditure are now managed under separate fund sources, i.e. R0 for external assigned revenue, and CL for internal assigned revenue.

External assigned revenue stems from inducements related to the Agency's new headquarters in Amsterdam. While the appropriations do not expire, the revenue and expenditure must balance over time.

Internal assigned revenue 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.

3.2.8. 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 2019 one transfer was made which exceeded the 10% ceiling for transfer between titles. All transfers involved expenditure appropriations and one of them also revenue appropriations. The transferred expenditure appropriations were primarily needed to cover building-related expenditure on the Agency's former headquarters in London.

Additional appropriations were also required to cover the cost of restarting some scientific meeting activities, as agreed under the implemented business continuity plan.

3.2.9. Cancellation of appropriations

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

In budget 2019, fund source C1, expenditure appropriations, totalling EUR 4,993,011.64 remained unused, corresponding to 1.48% of final appropriations (2018: EUR 31,158,119.96, 9.22%).

The underuse of commitment appropriations is due to:

Title I

- Lower expenditure on salaries, mainly due to staff resignations and postponement of recruitment due to the relocation of the Agency. This affected mostly contract agent staff and seconded national experts. Moreover, expenditure on allowances and payments related to staff members' relocation to the Netherlands was lower than forecast. These savings were partially offset by higher than budgeted expenditure on employer's social security payments and duty station weightings;
- Lower than budgeted contributions to European schools, due to initial numbers of children registered being lower than expected.

Title II

- Higher than estimated costs related to the Agency's former headquarters in London, in particular rent and service charges, legal fees and building-related expenditure;
- Partially offset by savings realised on IT maintenance cost and lower expenditure on corporate IT projects including business consultancy, due also to the impact of the relocation of the Agency to another Member State.

Title III

- Lower expenditure on business IT development, due to delays incurred in various projects.

The unused amount must be seen in conjunction with collected revenue being EUR 17,023,861.68 (5.91%) below budget revenue appropriations, contributing to a negative outturn (before adjustments for exchange rate, cancellations of carry-over, etc.) of EUR 12,030,849.90 or 3.47% of final appropriations (2018: surplus of 8,978,245.03, 2.66%).

3.2.10. Payment of interest on late payments

In compliance with the Agency's standard contract, established in accordance with Article 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, the payment accrues default interest at the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union, increased by 8%[4]. 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 2019, 1,240 payments out of a total of 51,537, i.e. 2.41% of all payments, were made later than 30 days after receipt of a valid invoice (2018: 1,714 payments or 2.96% of all payments). This resulted in default interest of EUR 7,706.95 being paid to suppliers and contractors (2018: EUR 3,291.10).

3.2.11. Brexit-related expenditure

Financial planning for 2019 included Brexit expenditure amounting to EUR 38.6 million. Key expenditure items include cost related to staff members' transfer to the Netherlands, and to the Agency's buildings.

Final expenditure is estimated at EUR 51.4 million and includes additional building-related payments.

Planning for 2019 also included an estimated 62.0 FTEs dedicated to Brexit-related activities. The hours recorded for the year amounted to 48.0 FTEs.

3.3. Human resources management

The allocation and recruitment of staff is based on the Agency's objectives, priorities, and specifically for 2019 – its business continuity needs. Throughout 2019, several senior management meetings were dedicated to resourcing, reporting and planning, in order to align the staff allocations with the planned activities, priorities and business continuity needs with a particular focus on the Agency's relocation to temporary premises in Amsterdam to bridge the time until the permanent headquarters would be ready for occupation.

Considering EMA's future needs and the BCP in place in 2019, work regarding human resources focused mainly on relocation of the Agency, talent acquisition including addressing relocation-triggered staff departures and future-proofing of the Agency:

- Relocation of the Agency

Preparations and executing the Agency's relocation from London to Amsterdam, including supporting management and staff for a smooth transition from EMA former headquarters in London to temporary building in Amsterdam, remained a key priority in 2019. Preparations and support for the move to the permanent building in January 2020 started in the last quarter of 2019.

Throughout the year dedicated communication provided up-to-date and transparent information to staff via e.g., the relocation microsite, regular updates in the General Assembly, regular staff

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

relocation presentations as well as through constructive dialogue between management and the Staff Committee.

Reassurance and support for staff included organisation and facilitation of housing in the Netherlands fairs, taxation guidance, school presentations, Dutch bank account opening possibilities for staff and partner career days. Close cooperation with the Dutch government counterparts through the dedicated ORP work stream ensured smooth staff support while flagging concerns on appropriate level, and supported implementation of the new seat agreement in the Netherlands. This included set-up of a Netherlands Helpdesk for staff in the temporary Agency building and winding down of the service in December 2019.

The administrative relocation workload increased due to the processing of queries, registrations, entitlements and payments, such as:

- 800+ expatriation allowance re-assessments
- 350+ installation allowance payments
- 400+ daily subsistence allowance payments
- 400+ removal reimbursements
- 800+ registrations of new bank account data
- 1500+ individual registrations of staff and family members with the Dutch Ministry of Foreign Affairs in accordance with the host state agreement
- 1000+ relocations visits of staff

Procurement of a new medical service provider was also successfully concluded. A Netherlands based service provider was awarded the contract covering pre-employment medicals, annual medicals, sick leave certification assessment, occupational health reviews and invalidity procedures.

- Talent acquisition

In terms of talent acquisition, the focus was to further refine selection and recruitment processes to hire the right candidates for the right jobs at the right time.

- The Agency fine-tuned its candidate attraction strategies, employer branding, its Employer Value Proposition and how it reaches out to widen its pool of potential candidates. A new recruitment marketing tool was launched and a partnership was developed with a publishing company.
- Talent Acquisition implemented additional assessment tools such as remote test solution and online testing (video, personality, ability, job-related) to help the Agency conduct in-depth assessments of skills and competencies and hire qualified candidates that meet the Agency's objectives and needs.
- On-boarding processes were re-designed to ensure selected candidates receive relocation assistance for quicker integration into the Agency.

To ensure business requirements of the Agency are properly staffed, a new tender for the provision of interim support staff was successfully concluded. Preparatory work for the re-launch of a traineeship programme compliant with Dutch labour legislation and interactions with the host state competent authorities were also commenced with a view to launching the programme in 2020 or 2021.

- Future-proofing of the Agency

HR management focused on planning, ensuring compliance and providing support to EMA management in the preparation and implementation of the Agency's future-proofing exercise in 2020. This upcoming restructuring of the Agency's core scientific internal operations involved organisational design,

workforce transition, and workforce change management with the objective of strengthening our identity as an innovative, high-performing, adaptable, digital and data-driven organisation.

Additionally,

- refining HR processes continued in 2019, to improve service delivery to staff and management;
- behavioural competency and management and leadership frameworks are now used not only to assess candidates during the selection process, but are also included as means to assessment performance for the purposes of preparing annual appraisals. This is helping to identify some non-technical learning needs and informed part of the content of the Agency's first management development programme in 2019;
- the Agency refined its reclassification procedure to reflect the nature of its evolving matrix environment and provided management with a further tool to help them make merit-based judgements.

During 2019, the Agency recruited 102 statutory members of staff (36 TA and 66 CA). 16 national experts were seconded to the Agency and 5 new interim assignments provided services to the Agency. The total number of staff joining EMA therefore amounted to 123. During the same year, 72 statutory staff members (35 TA, 37 CA), 14 SNEs and 47 trainees left the Agency. 66 interim assignments were also terminated. The total number of leavers was 199.

The rate of resignations amongst statutory staff continued to increase during 2019. Historically a low figure, this rate increased significantly over the past few years mainly due to the Agency's relocation. The rate of resignations reached an all-time-high in 2019, with 82% of staff leaving the Agency by resignation (in 2018 – 74%).

The occupancy rate amongst temporary agent staff was 98.6%.

3.4. Assessment by management

3.4.1. Management supervision

Managers at all levels monitor and measure the Agency's performance on several dimensions.

Work programme implementation is monitored through mid-year and annual reports, which are reviewed at senior management level and at the Management Board. Project implementation against budget, timelines and delivery are monitored and reported on bi-monthly basis to the Portfolio Board and to senior management twice a year. Budget monitoring is conducted throughout the year, to ensure timely response and adjustments (transfers, amending budgets or other) in case of significant deviations.

The status of implementation of the actions stemming from internal and external audit recommendations is continuously monitored by the division integrated quality management (IQM) coordinators and reported regularly to management.

Cross-agency issues identified through the supervisory activities are monitored and followed up by the Strategic Planning and Governance department; reports are presented regularly to the Executive Director and senior management, and where required, improvements are agreed.

In 2019, each Authorising Officer by delegation signed a Declaration of Assurance confirming that the resources made available to them had been used for their intended purpose and the internal control systems had been efficient and effective.

3.4.2. Business planning, budgeting and reporting

The Agency has implemented planning, monitoring, and reporting tools that provide the Executive Director with adequate information on the activities of EMA and, ultimately, serve as the key elements to underpin the director's annual declaration of assurance.

A longer-term (5-year) strategy for the Network was adopted in December 2015, and sets out the strategic objectives of EMA. These are translated into more specific objectives and implementation activities within the EMA's multiannual work programme. The annual work plans are derived from the multiannual work programme, and reflect key workload and performance indicators, as well as specific additional objectives and activities set in attaining the Agency's strategic objectives in the current year. Key risks identified and their mitigating actions are also included in the work programme. Forecasts of human and financial resources for given activity areas are included in the work programme.

Annual work programmes go through two iterations at the Management Board, with the final work programme adopted in December of the preceding year.

Starting with the 2017 planning cycle, and in accordance with the Financial Regulation requirements and Commission guidelines, multiannual and annual work programmes are combined into a single programming document, along with multiannual and annual budget and staff planning documents. Article 33 of the regulation requires the programming document to be sent to the budgetary authorities by 31 January each year.

Implementation of the strategy and work programme objectives and activities is tracked through mid-year reports and annual activity reports. The mid-year report is also used to identify and address any significant deviations from the work programme plans. These are reviewed at senior management level, and by the Management Board. Project implementation against budget, timelines, and delivery is reviewed on a regular basis at Portfolio Board and at senior management level. Budget monitoring is conducted throughout the year, to ensure timely response in case of significant deviations.

Planning timelines are developed at EMA, providing a comprehensive overview of the planning, monitoring, and reporting activities of the Agency, with deadlines for each of those, and the links between the different activities.

The 2019 planning cycle was conducted in line with the requirements of the regulation and considering the implications of BCP regarding the Agency’s relocation to the Netherlands.

3.4.3. Project management controls

In 2019 the project budget approval process remained unchanged. The Executive Board has the overall responsibility for the portfolio of programmes and projects, deciding on the priorities and making available budget and resources; changes to the portfolio have to be approved by the EXB. The Agency's Portfolio Board has been delegated with the following competences: overall responsibility to oversee the Agency’s programme and project portfolio, including proposals for portfolio re-prioritisation to the EXB; approving programmes and projects in the agreed portfolio; approving or declining requests for changes; monitoring progress and resolving issues that may compromise delivery or benefits realisation. PB reports to the EXB, while the latter retains responsibility on taking decisions concerning initiatives (programmes or projects) to be included in the portfolio; allocation of the portfolio budget at any time; portfolio re-prioritisation and, in exceptional circumstances, propose solutions for unresolved issues. In the gated approval process the idea or concept for a project (i.e. Gate 1 request) has to be approved or declined by the PB, taking into account the portfolio, priorities and budget agreed by the EXB, before resources can be assigned to deliver the project business case. The preliminary business case with identified benefits and costs is subject to approval by the PB.

Advice on technology and IT architecture matters is provided by the Enterprise Architecture Board (EAB), when relevant. Particular attention is given to the business need of the proposal, the related risks, business architecture fit, and the benefits that the proposal aims to achieve. Following this, a project is approved or declined by the PB at Gate 2. On approval, the project starts and is thereafter overseen by the PB. As soon as the analysis and design are completed, a final business case is presented for approval at Gate 3. Project progress past Gate 3 continues to be overseen by the PB. Gate 4 is an optional check-point for large projects and/or projects that introduce significant business changes, and aims to ensure completion of deliverables and business readiness prior to project closure. At the end of the project, a closure report is presented to the PB for assessment and approval.

For projects of small size or that face contractual constraints, a combination of gates can take place.

Bi-monthly reports are presented to the PB to review the status of the portfolio, programmes and projects, and monitor the delivery of the portfolio as a whole during their entire lifetime. The same reports are presented to the EXB twice a year, in January and in July. Telematics IT Directors and IT Directors Executive Board receive a summary of the bi-monthly report for the Telematics projects only.

The PB ensures that all programmes and projects comply with the standards in the Agency's P3i methodology.

Ex-ante and retroactive (formerly ex-post) evaluations are conducted by the Agency in line with 'EMA internal notice on project-related retroactive and ex-ante evaluations - Guiding principles in relation to programmes and projects'.

Ex-ante evaluations are conducted when projects are at Gate 2, on the basis of the preliminary business cases (including cost estimates), before the projects and budget expenditure are formally initiated. When the total project costs estimated at Gate 2 exceed EUR 1 million, an evaluation is conducted against the criteria established by Article 11(1) of the Financial Implementing Rules. The follow-up actions (i.e. Gate 3 and project closure milestones) are also identified.

Retroactive evaluations are conducted at project closure when projects are being formally closed. When actual costs at project closure exceed EUR 3 million, the evaluation is carried out against the criteria established by Article 11(3) of the Financial Implementing Rules.

For projects where gate approvals are combined, the ex-ante and retrospective (formerly ex post) evaluations still take place, following the standard criteria based on budgetary thresholds.

By applying the safeguards foreseen in the EMA programme and project governance and gate procedure, EMA adopts a proportionate approach to evaluations, as required by Financial Implementing Rules Article 11(4).

The results of ex-ante and retroactive evaluations are tabled every 6 months in a Management Board meeting: in the March meeting, covering the period from 1 July to 31 December; and in the October meeting, covering the period from 1 January to 30 June.

3.5. Fraud prevention

In 2019 the permanent actions of the Anti-Fraud Strategy Action Plan were regularly performed, such as the annual fraud-specific risk assessments and continuous monitoring and assessment of the adequacy and effectiveness of the anti-fraud measures in place.

One specific action mandated by the Anti-Fraud Strategy Action Plan for 2019 was the performance of proactive random verifications at Divisions' level, to be performed by the Heads of Division in

cooperation with the Anti-Fraud Office and with Information Security. Due to the business continuity, this action has been carried over and is expected to be resumed in 2020.

Finally, during 2019 the Agency's Anti-Fraud Office continued its cooperation with the European Anti-Fraud Office (OLAF), in relation to both spontaneous reporting, development of targeted anti-fraud training and exchange of best practices in relation to fraud matters.

Within the Inter-Agency Legal Network (IALN) EMA continued to chair the Anti-Fraud Working Group that was created with the aim to harmonise the approaches to anti-fraud matters among EU agencies. A report on anti-fraud developments was presented by EMA at the IALN meeting in November 2019.

3.5.1. Handling external source cases

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

A policy to handle allegations of improprieties submitted by external parties is in place since March 2017, complementing the policy on whistleblowing applying to the Agency's staff. The goal of the policy is to create an environment where individuals from outside the Agency feel confident to raise their concerns on improprieties.

This policy outlines EMA's approach to external sources of information disclosing allegations of improprieties relevant to EMA's competence. "Improprieties" are defined as irregularities concerning EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products, i.e., any conduct or omission amounting to a violation of any legal provision governing the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use.

The policy sets out the key principles underlying the handling of the information received from external sources and helps EMA assess these reports and coordinate any further investigation in a structured way, while protecting the identity of the reporter. The key principles relate to the confidentiality of the information received (including management and processing of personal data), acknowledgement of receipt, treatment of the information, interaction with EMA Anti-Fraud Strategy, analysis of the competence, transfer of information to other authorities and the notification to the external source. A dedicated inbox has been created for external sources to report improprieties to the Agency (reporting@ema.europa.eu).

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

In 2019, EMA received 20 reports from external sources. Majority of the cases regarded allegations of improprieties on GMP non-compliance or misconduct during manufacture of medicinal products (8 cases) and GCP non-compliance or misconduct during clinical trials (5 cases). In 7 cases, the external source remained anonymous. EMA followed-up on each of these cases in accordance with the policy and SOP. 3 cases were closed due to insufficient information provided by the external sources in order

to start investigating the case. In 6 cases, EMA coordinated the investigation with the involvement of the relevant NCA. For 11 cases, the EMA was not competent on the matter and handed the case over to the concerned NCA, i.e., regarding medical devices, food supplements, clinical trials at national level and stolen medicines. None of the cases entailed the need for EMA or the NCA to take specific regulatory action. In total, 13 cases received in 2019 were closed and 11 cases received in previous years were closed.

3.6. Assessment of audit results during the reporting year

3.6.1. Internal Audit Service

In 2019, the Internal Audit Service (IAS) met with the EMA management to undertake their risk assessment exercise leading to their three-year Strategic Internal Audit Plan for 2020-2022.

The assessment identified that the main risk factors relating to the Agency's activities are 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 are 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.

3.6.2. Internal audit capability

In 2019, the Agency's audit function (internal audit capability – IAC) carried out audit activities and associated tasks in line with the EMA's annual audit plan adopted by the Management Board in December 2018.

The IAC performed one legally required pharmacovigilance audit *('Capacity-building activities in human and veterinary pharmacovigilance performed by EMA for its staff and the EU Network')* and two consultancy engagements *('Readiness of the Agency to implement the new data protection regulation requirements' and 'Assessment of delays in development of IT systems/ tools and resource constraints identified in previous audits').*

Some audits planned for 2019 were postponed due to the relocation of the Agency to the Netherlands and delays in development of the related software. The postponed audits related to 'Security Management' and the 'EU Clinical Trials Portal and Database' audit as required by Article 82 of Regulation (EC) 536/2014.

Based on the results of the audits, the IAC is of the opinion that the internal control systems put in place by the Agency provide reasonable assurance regarding the achievement of the business objectives set up, with the exceptions of the relevant findings of the above mentioned audits for which management has prepared the improvement action plan and monitors the implementation continuously.

3.6.3. European Court of Auditors

The European Court of Auditors adopted its 'Annual report on EU agencies for the financial year 2018' on 15 October 2019.

The report provides a positive opinion with regards to the reliability of the accounts and legality and regularity of the transactions underlying the accounts. It includes no critical findings, only one observation[5] that do not call the Court's opinion into question.

3.7. Follow-up on recommendations and action plans for audits

3.7.1. Internal Audit Service

No recommendations were open as of 31 December 2019.

3.7.2. Internal audit capability

As of 31 December 2019, 5 very important recommendations stemming from audits carried out up to 31 December 2019 were under implementation. No critical recommendations remained open.

3.8. Follow-up on observations from the discharge authority

EMA reported on the follow-up of the observations made by the discharge authority for 2017 in its annual report under Article 110(2) of the Framework Financial Regulation. The report is publicly available on the website of the Budgetary Control Committee of the European Parliament[6].

On 14 May 2020, the European Parliament voted positively on the discharge for EMA's 2018 accounts. This is the final approval of the budget implementation for 2018, and the decision is based on a review of the annual accounts and the Court of Auditors' annual report.

3.9. Assessment of the effectiveness of internal control systems

3.9.1. Effectiveness of internal control framework

As in the previous years, the Agency reviewed the implementation of the internal controls in 2019.

In 2017 the Commission had adopted a new Internal Control Framework (ICF). In December 2018 the Agency adopted this new framework for its own use, replacing the previous Internal Control Standard. As of this year and in line with the Commission's requirements, the Agency is reviewing internal control system against the new ICF.

The new framework is comprised of 17 internal control principles that cover five core components of the internal control framework:

- control environment (principles 1-5)
- risk assessment (principles 6-9)
- control activities (principles 10-12)
- information and communication (principles 13-15)
- monitoring activities (principles 16-17)

These 17 principles in large part reflect the topics of the previous internal control standards, however, some of the previous elements are no longer included and some other, new elements and aspects are added to the framework.

[5] https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2018/AGENCIES_2018_EN.pdf

[6] https://www.europarl.europa.eu/cmsdata/186397/EMA%20report%20on%20follow%20up%20to%20EP%20discharge%202017-original.pdf

With the new framework, the approach to this exercise has also changed slightly. The new framework moves away from a purely compliance-based to 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. As a result, the approach to this exercise is less rigid, less descriptive than before and more focused on assessing the effectiveness of controls.

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 internal control framework.

As 2019 was the first year of implementing the new ICF, the approach to the exercise will require further development and fine-tuning, e.g., the questionnaire will be revised and fine-tuned to ensure more effective and comprehensive coverage of the principles, and a different approach, such as staff survey, might be used to assess more effectively certain elements like staff satisfaction or awareness of specific aspects.

The assessment concluded that in general the internal control components and the principles function well, even though some enhancements and fine-tuning may be beneficial for some elements covered. Suggested actions and proposals for consideration were drafted to address the opportunities for improvement identified. A number of ongoing improvement initiatives were also identified during the review, which will also further strengthen the controls.

3.9.2. 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. The SAP financial system is an effective tool for mitigating financial risks associated with the payment processing. Please see the table below for details:

	2018	2019
Number of transactions verified	64,834	84,806
Number of transactions rejected	432	361
• of which related to manual adjustments, technical rejections or interface issues following the decentralised verification	104 (24%)	123 (34%)
• of which other issues (incorrect currency, calculation errors, wrong allocation, etc.) or procedural issue (missing document, change of requirement, wrong cost centre, etc.)	328 (76%)	238 (66%)
Overall rejection rate	0.7%	0.4%

Five commitments were rejected following initiating agents' request and a technical issue. The balance of transactions was rejected for various financial reasons (incorrect currency, calculation errors, wrong allocation, etc.) or procedural issue (missing document, change of requirement, wrong cost centre, etc.). However, none of them showed a breach of contract provisions. All rejections were later corrected, amended and validated with due respect to budgetary principles and procedures in force.

26 exceptions were recorded into the register of exceptions during 2019.

3.9.3. Ex-post control system

Ex-post controls are part of the management and internal control procedures; they are required under the Financial Regulation Article 46. 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.

The same approach used in ex-post exercise for 2018 was applied to ex-post control plan for 2019, namely, temporary reduction of ex-post control activities for 2019 applying a risk-based approach to the selection of financial and non-financial processes. As a result, in 2019 the Agency completed 4 ex-post controls, of which two were financial and two were non-financial.

The areas subjected to financial ex-post controls were Type II variation (human medicines) financial process and Type II variation (veterinary medicines) financial process. The areas subjected to non-financial ex-post controls were Compliance with the Internal Guidance on the use of IT contractors on Time and Means basis and Daily Subsistence Allowance (DSA) and Installation Allowance Payments 2019 (verification of correctness and compliance with requirements).

Overall, the ex-post controls highlighted no significant weaknesses of the processes analysed, although a few areas with potential for improvement were identified. These are being addressed by specific improvement action plans.

3.9.4. Annual review of sensitive functions

In line with the EMA ‘Guidance on sensitive functions’, a risk assessment to identify the Agency’s sensitive functions was carried out in 2019. A regular review and monitoring of the process of identification and management of the sensitive functions is mandated by the above guidance. The annual reassessment of sensitive functions carried out at the Agency aims at preventing fraud and corruption at EMA and at protecting its financial interests. This aim is achieved by ensuring that EMA has control measures in place and by establishing an organisational approach and methodology to identify and manage the risks associated with sensitive functions at the Agency.

In 2019, the review was performed by the Quality and Risk Management Office. The functions considered sensitive were recorded in the Sensitive functions register 2019. 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.

The outcome of the exercise and the annual report on sensitive functions 2019 final report were reviewed by the Anti-Fraud Office and endorsed by the Agency’s Executive Director in December 2019.

In 2020 this exercise will need to take into consideration the impact and changes in sensitive functions stemming from the Agency gradually resuming activities that were reduced or suspended during the Brexit and relocation BCP period, as well as from the changes brought about by the future-proofing exercise.

3.9.5. Advisory Committee on Procurement and Contracts and procurement management

The Advisory Committee on Procurement and Contracts (ACPC) is an advisory body to the Executive Director on the compliance of procurement and contracts with the Agency's financial rules. The ACPC has been set up to examine procurement contracts prior to signature, on behalf of the Agency.

In 2019, the ACPC dealt with 10 procurement files, most of which were linked to EMA relocation to Amsterdam, and issued 8 favourable opinions and 2 favourable opinions under conditions for the signature of the contract.

3.9.6. Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2019, reconciliations for 100% of the data between the product- and procedure-tracking systems and SAP were carried out on a regular basis. Findings were detected in the parallel distribution area and rectified with a financial impact in terms of delays in fee recovery for transactions of 2018 and 2019 financial year.

3.9.7. Data protection

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

EU DPR entered into force on 11 December 2018. For its initial implementation, several measures have been carried out within the Agency during 2019, including the following:

- In accordance with Article 25 EU DPR, a '*Management Board Decision on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of administrative inquiries, disciplinary proceedings and other investigations*' has been adopted by the MB on 12 June 2019 and published in the Official Journal of the European Union on 9 August 2019.[7]
- '*EMA Implementing Rules under Regulation (EU) 2018/1725 concerning the Data Protection Officer, the role of (internal) data controllers and compliance with data subjects' rights*' have been adopted by the Executive Director on 2 September 2019.
- Update of Data Processing Register in accordance with Article 31 EU DPR and publication of the Register[8] as well as the update or preparation of privacy statements.[9]
- Data protection impact assessments (DPIAs) in specific areas (EU Clinical Trial Portal and Database, and EudraVigilance Database) have been initiated and the preparation of the DPIA reports is ongoing in accordance with Article 39 EU DPR.
- An IT security review was completed to carry out an analysis by data protection consultants on the security design of EMA applications storing/processing personal data to ensure that the level of IT security complies with EU DPR.
- In addition, the Agency has been involved in discussions regarding the data protection aspects of processing health and medical data for public health regulation and research purposes. Agency's Data Protection Officer (DPO) and Assistant DPO have provided material support to the business and scientific colleagues in many different areas, such as the implementation of the Clinical Trial

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.209.01.0019.01.ENG&toc=OJ:L:2019:209:TOC
[8] https://www.ema.europa.eu/en/central-register-data-processing-records
[9] https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement

Data Base under the Clinical Trial Regulation[10], the issue of joint controllership regarding the Clinical Trials Information System, the secondary uses of clinical trial data for scientific purposes outside the clinical trial protocol and the interplay of data protection and pharmacovigilance legislation.

The increased workload on the Agency in the area of data protection is not expected to decrease in 2020, also in light of the new guidelines and recommendations provided by the EDPS and the European Data Protection Board requiring EU institutions and bodies to continuously review and update internal processes and procedures which involve the processing of personal data (e.g. in accordance with guidelines on personal data and electronic communications in the EU institutions[11], guidelines 4/2019 on Article 25 Data Protection by Design and by Default[12] and guidelines 2/2020 on transfers of personal data between EEA and non-EEA public authorities and bodies[13]).

The increased amount of workload in the area of data protection and the lack of additional resources assigned to the Agency constitutes a serious issue which has been brought to the attention of the Management Board at its meeting on 19 December 2019.

3.10. Management of competing interests

3.10.1. Management Board

The policy on the handling of competing interests of the Management Board remains unchanged, since the revision in October 2016. The revision addressed an observed inconsistency between the policy for scientific committees' members and experts and this policy, as regards restrictions for grants/other funding to an organisation/institution, as well as for close family members. The restrictions for grants/other funding were aligned with those in policy for scientific committees' members and experts, whilst maintaining the restrictions for close family members as stated in the policy for Management Board.

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.

[10] Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
[11] https://edps.europa.eu/data-protection/our-work/publications/guidelines/guidelines-personal-data-and-electronic_en
[12] https://edpb.europa.eu/sites/edpb/files/consultation/edpb_guidelines_201904_dataprotection_by_design_and_by_default.pdf
[13] https://edpb.europa.eu/sites/edpb/files/consultation/edpb_guidelines_202002_art46guidelines_internationaltransferspublicbodies_v1.pdf

No breach of trust procedures were initiated for Management Board members in 2019.

3.10.2. Scientific committee members and experts

The policy on the handling of competing interests of scientific committees' members and experts was last updated in October 2016 and is in force since 1 December 2016.

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 sign 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 expert's e-DoI and assigns each DoI an interest level, based on whether the expert has any declared interests, and whether these are direct or indirect.

After the system assigns an interest level, the Agency uses the information provided in the e-DoI to determine if an expert's involvement should be restricted or excluded in the 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 to handling competing interests that 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 which take into account the nature of the declared interest, before determining the length of time any restrictions may apply:

- An executive role, or a lead role in the development of a medicine during previous employment with a pharmaceutical company, results in non-involvement in EMA activities that include the concerned company or product during the term of the mandate.
- For the majority of declared interests, a three-year cooling-off period is foreseen. Restrictions to involvement decrease over time, and make a distinction between current interests and interests within the last three years.
- For some interests, such as financial interests, there is no cooling-off period required when the interest is no longer present.

Requirements for experts who are members of scientific committees are stricter than for those 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 those for the other committee members.

All members proposed for the Agency's scientific committees have their e-DoI screened before their formal nomination. In case that 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.

Completed e-DoIs, their interest levels, and the e-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 or unsigned, until they submit an updated and signed e-DoI.

EMA has in place a breach-of-trust procedure, which sets out how the Agency deals with incorrect or incomplete e-DoIs by experts and committee members. In 2019, 2 breach-of-trust procedures were initiated as one committee member provided training to a pharmaceutical company, which is considered as a consultancy, and another committee member accepted a lecture fee from a pharmaceutical company for a presentation at a scientific conference, which is considered as a financial interest. After assessment of additional information provided by the committee members, they were invited to a hearing at the Agency in order to gather their views on the facts and to provide replies to remaining questions. The outcome of these breach-of-trust procedures was that the engagement in the activity or the acceptance of the financial interest was negligence on the part of the members to comply with the EMA policy, but it was unintentional, and it was not through gross negligence. The procedure of each case was closed with a request to the committee members to study the policy and to attend training on the policy. The two committee members for personal reasons voluntarily resigned from the committee during the procedure, one because of the high workload as committee member and the other because of a preference to continue with the activity.

The Agency updated the procedure in October 2018 to include disclosure of confidential information. In 2019, a committee member and an expert each disclosed the outcome of a non-finalised regulatory procedure in a press release while the committee meeting was still ongoing. The disclosure by each person was unintentional and did not occur through gross negligence, therefore, no further disciplinary sanctions were required. The procedure of each case was closed with a request to study the rules on confidentiality and to refrain from disclosing confidential information in future.

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 2019, 4 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 2019, 595 e-DoIs were checked before new experts were uploaded in the EMA Experts database as an *ex-ante* control. No *ex-post* control on handling of competing interests was organised in 2019 due to the business continuity status of the Agency. No major problems with the e-DoI completion by the experts were identified.

3.10.3. 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.

The decision on rules relating to Art.11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the EMA and candidates before recruitment was last updated in October 2016 and is effective since 1 January 2017.

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.

An impact assessment performed on the possible revisions of EMA's policies on conflict of interest in 2018 revealed that it was appropriate to focus on the declaration by EMA staff of past intellectual property rights related to medicinal products or uses of such products, including patent ownership and patent applications, along the lines of one of the European Ombudsman's recommendations from the 2016 and 2017 review of independence. Therefore, an amendment to the "*Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment*" was adopted by the Management Board on 13 December 2018 and became effective as of 1 January 2019. The e-DoI was amended in September 2019 to allow staff to declare patent applications or intellectual property rights held in the past 5 years. Likewise, the declaration of candidates prior to the start of their contract also includes this additional question.

As 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.

On 4 October 2018 the Agency adopted the Commission decision on outside activities and assignments and on occupational activities after leaving the service. Under the new rules, 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 2019 to 31 December 2019, staff made a total of 30 applications, resulting in 21 authorisations without restrictions, 7 staff authorisations with restrictions, 2 SNE cases

had 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 period of time, e.g. 6 - 12 months.

More information on restrictions applied to applications in 2019 is given in Annex 7.

3.10.4. 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 is 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.

3.11. Telematics strategy implementation

During 2019, the Network continued implementation of the Telematics strategy. Lack of resources, loss of staff and the consequent loss of knowledge as a result of the relocation of EMA to the Netherlands remained a risk for Telematics delivery.

In light of a decision related to stepwise implementation of a Europe-wide Substance Registration System (EU-SRS), the Heads of Medicines Agencies during the February meeting in Romania endorsed a detailed project plan and costing for the implementation of EU-SRS. A Substance Validation Group was established to work on the proof of concept.

The status of projects remained stable with some significant developments in the Clinical Trials Information Systems. In June, CTIS entered a phase of Agile iterative delivery: the first release was validated in September by the nominated product owners of EU Member States, sponsors and the EC. In addition, a six-monthly monitoring report assessing the performance of the IT supplier against agreed key performance indicators was endorsed by the EMA Management Board in October. The latest release of the system was validated in December by the nominated product owners.

In 2019, EMA received some of the mandates for the Regulation (EU) 2019/6 on veterinary medicines from the EC, which request the Agency's contribution towards implementing acts, including the one for Union database on veterinary medicinal products. The governance structure for the Veterinary medicines regulation programme was endorsed by EMA's Management Board in October. The Union product database project entered initiation stage; the EVVet3 project to implement the Union pharmacovigilance database is ongoing.

Common European Submission Portal (CESP) phase 1 continued to deliver. Horizon 2020/Unicom WP3 funding was secured to support further developments in 2020 including work to support IDMP compliant application forms. Collaboration with the SPOR Programme governance, the electronic application form (eAF) Management Group, the Telematics Architecture Board (TEAB) and the EU Network Data Board (EUNDB) continued.

Other highlights of 2019 include the adoption of an updated version of the eSubmission Roadmap by the HMA in June, updated versions of the PSUR repository, industry and NCA user interfaces, a new release for the electronic application forms (eAF), and a new process for registering new/development substances in EudraCT.

The EU Telematics implementation roadmap 2015-2017 was extended to cover the period up to the end of 2019. The extended roadmap was designed to guide the ongoing Telematics developments until the new EU Telematics strategy 2020-2025 is devised. Strategy development was put on hold during 2019 due to EMA's relocation to the Netherlands and the lack of resources available to progress the strategy.

3.12. Information security strategy

The Information Security strategy 2019-2020 is in place and its aim is to enhance the Agency's activities in domains such as security governance and awareness, information security, technology security and risk management. In 2019, the main focus was to support the relocation activities in terms of IT security and the enforcement of the Agency classification policy, and the following activities were completed:

- Security requirements and design for the EMA building were validated;

- Security simulation campaigns were performed to reinforce staff awareness about IT security;
- Cloud security service was enhanced;
- Continuous monitoring of IT risk management process and regular review of IT risks was conducted.
- Relevant audit security recommendations were completed.
- Information classification policy was enforced across all Agency with the implementation of the classification tool, relevant tool tips, guidelines and training to all users.

4. Management assurance

4.1. Review of the elements supporting assurance

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

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.

4.2. 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 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.

4.3. 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 2019 assurance, the Agency, draws attention to two important matters:

1. The imposed reduction of 10% of the Agency's establishment plan since 2014, and the fact that during the same period fee-related workload (as reflected by increased fee income from like-to-like tasks) has grown by 31%. Furthermore, significant new tasks such as the implementation of the Veterinary Medicinal Products regulation, GDPR, Medical device regulation and Clinical trial regulation, were also assigned to the Agency during this period without any increase in the establishment plan staff, except for partial allocation of staff for the implementation of the new Veterinary regulation.

   Furthermore, the Agency faces more than a 15% reduction of contract agent positions in 2020 and 2021 due to the requirement to phase out short term contract agent positions, further reducing the available workforce. Uncertainty about the Agency's capacity to cope with this loss continues to remain a significant business continuity risk. In the meantime, the Agency's request to increase fee-financed posts for 2021 has been rejected.

   This, combined with the permanent loss of short term contract staff during the relocation to the Netherlands and expected increase in workload once the Agency re-introduces the activities currently reduced or suspended to allow coping with the relocation implications, could result in risks to delivering on future public health and legal obligations. Among others, these include developing and updating key IT systems underpinning authorisation of products, training and coaching of personnel to maintain EU expertise in scientific and technological developments, responding to a backlog of access to documents requests, resuming clinical trial data publication, addressing a backlog in certificates of pharmaceutical products.

2. The lease agreement for the Agency's previous premises in London sets a rental period until 2039 with no exit clause. The European Union committed to contribute to resolving this matter at a political level. Although the UK government stated that it will look into facilitating the relocation of EU agencies located in London, in particular as regards reducing the withdrawal costs, no support was provided to EMA by the UK government during the relocation. However, the contractual liabilities for the Agency's London premises were not dealt with as part of the political negotiations on the Withdrawal Agreement. The Agency was subsequently relocated out of the UK by the anticipated Brexit date of the 29th of March 2019 while other EU bodies remained in the UK beyond such date.

   On 20 February 2019 the High Court of Justice of England and Wales ruled that Brexit is not a cause for frustrating EMA lease agreement in London. The Agency sought contractual possibilities to dispose of the premises and mitigate the financial burden on the EU budget of bearing the full

amount in rent remaining to be paid until 2039. The Agency sublet its premises to a subtenant from July 2019 for the full period until the expiry of EMA's lease in June 2039 under the financial terms fully in line with the parameters agreed by the EU budgetary authority. However, EMA still remains legally bound by the lease and remains financially responsible for its former premises in the UK. As of 31 December 2019, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by EMA until the end of the lease term is £355.28 million.

As a result of this long-term liability and responsibility for premises, EMA must divert some of its financial and human resources away from the Agency's public health remit to managing a commercial property in a third country for which the Agency has no business use – activity not foreseen in the Agency's founding regulation. The Management Board of the Agency has stressed on numerous occasions that this situation cannot be sustained in long term, and requires resolution at a political level.

Declaration of assurance

I, the undersigned, Guido Rasi, 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-assessments, ex-post controls, the work of the internal audit capability, the observations of the Internal Audit Service, and the lessons learned 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 institution.

Amsterdam, 15 May 2020

[Signature on file]

Guido Rasi

Executive Director

Annexes

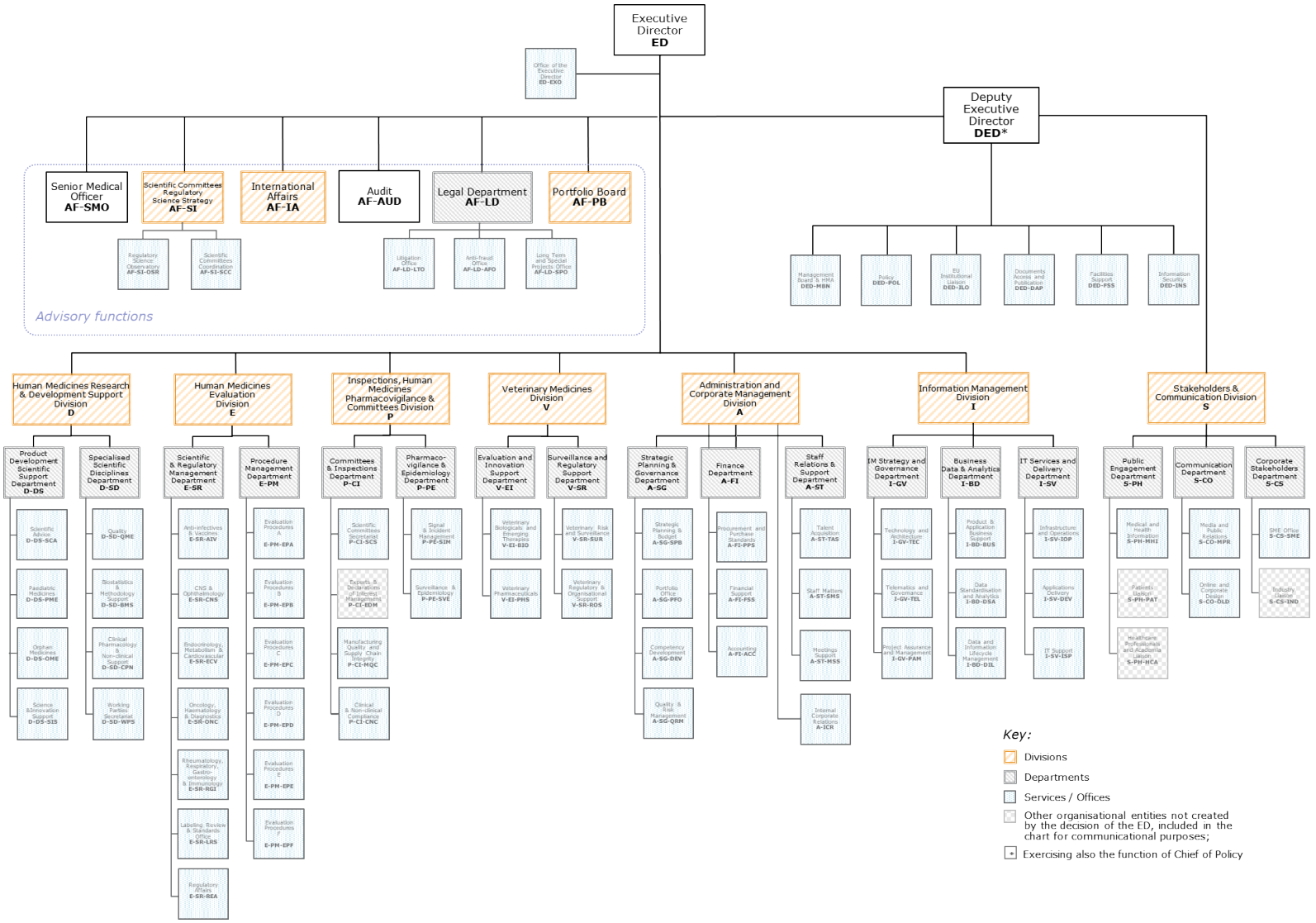
Annex 1. Core business statistics

Business statistics can be found in Part I and II.

Annex 2. Statistics on financial management

Annual accounts and a financial report will be made available following their adoption by the Management Board.

Annex 3. Organisation chart as at 31 December 2019



Annex 4. Establishment plan

Category and grade	Authorised for 2018		Occupied as of 31/12/2018			Authorised for 2019		Occupied as of 31/12/2019			Authorised for 2020	
	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	1	-	3
AD 14	-	7	-	6	3	-	7	-	7	3	-	8
AD 13	-	11	-	11	10	-	11	-	10	12	-	12
AD 12	-	43	-	42	26	-	43	-	43	24	-	44
AD 11	-	43	-	43	33	-	43	-	43	34	-	47
AD 10	-	41	-	41	26	-	41	-	43	36	-	44
AD 9	-	45	-	45	35	-	45	-	43	26	-	46
AD 8	-	59	-	59	72	-	59	-	59	85	-	66
AD 7	-	65	-	65	52	-	65	-	65	55	-	76
AD 6	-	23	-	23	60	-	23	-	23	57	-	46
AD 5	-	0	-	0	18	-	0	-	25	8	-	3
Total AD	*0*	*340*	*0*	*338*	*336*	*0*	*340*	*0*	*364*	*341*	*0*	*395*
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	7	-	7	3	-	7	-	7	2	-	7
AST 9	-	6	-	5	4	-	6	-	6	5	-	8
AST 8	-	16	-	16	4	-	16	-	16	4	-	19
AST 7	-	22	-	22	16	-	22	-	22	13	-	15
AST 6	-	42	-	39	22	-	42	-	25	26	-	15
AST 5	-	46	-	43	38	-	46	-	33	35	-	39
AST 4	-	57	-	57	45	-	57	-	55	54	-	52
AST 3	-	46	-	46	62	-	46	-	46	66	-	44
AST 2	-	7	-	6	28	-	7	-	7	26	-	0
AST 1	-	0	-	0	23	-	0	-	0	11	-	0
Total AST	*0*	*251*	*0*	*243*	*245*	*0*	*251*	*0*	*219*	*242*	*0*	*201*
AST/SC1	-		-			-		-			-	
AST/SC2	-		-			-		-			-	
AST/SC3	-		-			-		-			-	
AST/SC4	-		-			-		-			-	
AST/SC5	-		-			-		-			-	
AST/SC6	-		-			-		-			-	
Total AST/SC	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	
Grand total	*0*	*591*	*0*	*581*	*581*	*0*	*591*	*0*	*583*	*583*	*0*	*596*

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.

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, AD7, 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.

Interims: from 1 January 2019 to 31 December 2019, there have been 73 interims, and the average length of an interim assignment during 2019 was 1.87 months.

Annex 5. Results of the screening exercise as of December 2019

Job type (sub) category	2018 (%)	2019 (%)
Administrative support and Coordination	18%	17%
Administrative Support	17%	16%
Coordination	1%	1%
Operational	78%	78%
Top Level Operational Coordination	1%	2%
Programme Management & Implementation	23%	20%
Evaluation & Impact Assessment	39%	40%
General Operational	15%	16%
Neutral	4%	5%
Finance / Control	4%	5%
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).

Annex 6. 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	342	0	342	47,745	15,241	8,747	111,178	5,758	188,668
1.1 Pre-authorisation activities	78	0	78	10,652	1,969	4,615	19,585	5	36,827
1.2 Initial evaluation activities	75	0	75	11,430	1,844	1,426	13,235	708	28,642
1.3 Post-authorisation activities	86	0	86	11,540	3,639	579	67,918	1,327	85,003
1.4 Referrals	12	0	12	1,520	304	227	-	141	2,192
1.5 Pharmacovigilance activities	64	0	64	8,190	2,780	1,323	10,439	3,361	26,093
1.6 Other specialized areas and activities	26	0	26	4,413	4,705	577	-	216	9,911
2 Evaluation activities for veterinary medicines	42	0	42	5,681	3,609	1,260	4,410	426	15,387
2.1 Pre-authorisation activities	2	0	2	236	59	128	380	-	804
2.2 Initial evaluation activities	13	0	13	1,767	356	348	1,468	212	4,150
2.3 Post-authorisation activities	13	0	13	1,486	425	177	811	146	3,044
2.4 Arbitrations and referrals	2	0	2	185	41	172	-	68	465
2.5 Pharmacovigilance activities	4	0	4	582	2,448	251	1,752	-	5,033
2.6 Other specialized areas and activities	8	0	8	1,425	282	184	-	-	1,891
3 Horizontal activities and other areas	181	0	181	25,427	16,537	1,367	6,001	1,581	50,913
3.1 Committee coordination	42	0	42	5,289	1,259	331	-	-	6,879
3.2 Inspection and Compliance	39	0	39	3,979	1,133	372	6,001	-	11,486
3.3 Partners and Stakeholders	28	0	28	4,602	777	648	-	627	6,654
3.3a Transparency and access to documents	21	0	21	2,804	590	-	-	-	3,394
3.3b Information	18	0	18	2,344	541	-	-	954	3,840
3.4 International activities	12	0	12	2,145	384	16	-	-	2,545
3.5 Information Management (incl. EU Telematics)	22	0	22	4,263	11,853	-	-	-	16,116
4 Corporate Governance and Support activities	150	48	198	30,167	6,549	296	-	958	37,970
4.1 Governance, Quality Management and Internal Audit	25	42	66	10,933	1,851	296	-	150	13,229
4.2 Finance	31	0	31	4,150	869	-	-	108	5,127
4.3 Information technology	38	5	43	8,050	1,441	-	-	-	9,491
4.4 Human resources	43	1	43	5,205	1,656	-	-	456	7,317
4.5 Infrastructure services	1	0	1	83	82	-	-	-	165
4.6 Communication (corporate)	13	0	13	1,747	650	-	-	244	2,641
Total	715	48	763	109,020	41,936	11,670	121,590	8,723	292,939

Brexit related expenditure	51,444
Expenditure (C1+C2+R0)	344,382

Annex 7. Report for 2019 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 2019:

Case No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Decision of the Head of Administration and Corporate Management	Date of Executive Director's decision
1	CA	3 years and 9 months	5/02/2019	18/02/2019	During a period of 12 months as of the date s/he leaves service, the staff member should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 3 years and 9 months at the Agency.	14/03/2019
2	CA and TA	9 months as CA 10 years and 8 months as TA	15/03/2019	16/04/2019	During a period of 6 months as of the date the staff member leaves the service, he/she should refrain from individually liaising with any member of staff of the Agency with regards to any professional activity she may have dealt with in the performance of her/his responsibilities at the Agency during her 11 years and 5 months of service.	21/05/2019
3	SNE	1 year	3/04/2019	16/04/2019	During a period of 6 months to be counted as of the date s/he left the service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his 1 year of service.	21/05/2019
4	TA	12 years and 6 months	23/04/2019	16/05/2019	During a period of 12 months to be counted as of the date s/he left service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 12 years and 6 months of service.	5/06/2019

Case No	Job title / function at EMA	Length of service	Date of application	Date of Joint Committee opinion	Decision of the Head of Administration and Corporate Management	Date of Executive Director's decision
5	TA	15 years and 2 months	11/06/2019	20/06/2019	During a period of 12 months to be counted as of the date s/he leaves the service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 15 years and 2 months of service	23/07/2019
6	CA	10 months 16 days	18/07/2019	19/07/2019	During a period of 6 months as of the date s/he leaves the service, he/she should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 10 months and 16 days of service	23/08/2019
7	CA	2 years 9 months	16/09/2019	23/09/2019	During a period of six months as of the date s/he leaves the service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 2 years and 9 months of service.	15/10/2019
8	TA	10 years 10 months	18/11/2019	28/11/2019	During a period of six months to be counted as of the date s/he leaves the service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her 10 years and 10 months of service.	12/12/2019
9	SNE	1 year 3 months	2/12/2019	16/12/2019	During a period of six months as of the date s/he leaves service, s/he should refrain from individually liaising with any member of staff of the Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her one year and three months of Secondment.	23/01/2020

Annex 8: Risks

As in previous years, the most significant risks that could have potentially impacted the achievement of the Agency's objectives in 2019 were related to Brexit. The Agency had been continuously assessing these risks since the result of the UK referendum and developed a risk mitigation strategy.

The significant risks and respective mitigating actions are outlined in the table below.

These risks, should they have materialised and the consequences not had been appropriately managed, would have resulted in operational, reputational, legal or financial implications for the Agency.

Risk	Mitigating actions and controls
Loss of existing staff resulting in loss of professional competencies and knowledge	The Agency implemented staff support measures aiming to make the transition to Amsterdam as smooth as possible for colleagues who relocated with the Agency. Surveys to gauge staff intentions to relocate were conducted on a regular basis. The support measures included entitlements and allowances available in the Staff Regulations or already in place at the Agency, as well as additional provisions put in place for a transitional period. Several new recruitment procedures considering the criticality of skills and the risk assessment of staff loss were launched in 2018 and 2019 to replace possible loss of staff.
Loss of UK expertise in the scientific work	UK experts constitute 15% of the Agency's expert base and conduct around 20% of the scientific work. Losing these resources will lead to: – significant increase in workload for EU experts; – potential loss of specific expertise. A dedicated ORP subgroup was set up to evaluate the impact of Brexit on the Agency's core activities and proposed remedial actions. The group had been focussing the following remedial actions: • Redistribution of UK product portfolio. • Distribution of workload for initial marketing authorisation applications (human and veterinary medicines), including reassigning procedures not yet started but that had been originally assigned to the UK. • Distribution of workload for scientific-advice procedures. • Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning nationally authorised medicinal products. • Distribution of workload for maximum residue limits (MRLs). • Distribution of workload for pharmacovigilance procedures for centrally authorised products. • Operational adjustments.
Inability to relocate the Agency o the Netherlands by 29th March 2019	A joint governance structure between EMA and government authorities in the Netherlands was set up to enable close collaboration between our Agency and the Dutch authorities at national and local levels, and to monitor progress of the relocation.

Annex 9. Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2019

The table below lists those contracts signed during the reference period 01/01/2019-31/12/2019.

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 – Authorising Officer
EMA/2018/05/ST	Framework contract	Language Matters B.V.	Provision of interim services (1st priority)	EUR 15,400,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2018/15/CO_1	Framework contract	LM Tietopalvelut Oy	Books on demand (printed and digital format) – 1st priority	EUR 140,000	Negotiated middle value	Stakeholders & Communication Division – N. Wathion
EMA/2018/15/CO_2	Framework contract	Ebsco Information Services	Books on demand (printed and digital format) – 2nd priority	EUR 140,000	Negotiated middle value	Stakeholders & Communication Division – N. Wathion
EMA/2018/27/PE	Framework contract	EUROmediSAFE 2	Safety and efficacy studies on medicines: Lot 4 re-opening of competition	EUR 3,000,000	Open	Inspections, Human Medicines Pharmacovigilance & Committees – N. Wathion
EMA/2018/30/CO	Service contract	Springer Nature Customer Service Center GmbH	Drug pipeline database	EUR 550,000	Open	Stakeholders & Communication Division – N. Wathion
EMA/2018/36/LD	Framework contract	Intakt Law	Pre-litigation and litigation services in relation to EU staff matters	EUR 185,400	Negotiated 11.1(h)(ii) Annex I	Legal Department – T. Jablonski
EMA/2018/37/DED	Contractor's T&Cs	DHL International B.V.	Courier services	EUR 250,000	Negotiated 11.1(a) Annex I	Deputy Executive Director Office -Facilities Support Service –

						T. Freitas
EMA/2018/40/FI	Service contract	ABN Amro	Bank acoounts and online banking services for mainly EUR payments within the SEPA area	EUR 143,999	Negotiated middle value	Administration and Corporate Management Division – N. Steikunas
EMA/2018/41/FI	Service contract	ING Belgium NV/SA	Banking services - Deposit of surplus funds	EUR 143,999	Negotiated middle value	Administration and Corporate Management Division – N. Steikunas
EMA/2018/42/LD	Framework contract	Trilateral Research Ltd	Advisory and support services in relation to EU data protection matters - 1st priority contractor	EUR 140,000	Negotiated middle value	Legal Department – T. Jablonski
EMA/2018/46/LD	Framework contract	Ernst & Young Société d'Avocats	Advisory and support services in relation to EU data protection matters - 2nd priority contractor	See EMA/2018/42/LD	Negotiated middle value	Legal Department – T. Jablonski
EMA/2019/01/AUD	Framework contract	KPMG Advisory N.V	Provision of internal audit services (1st priority)	EUR 570,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/02/FI_1	Framework contract	ING Belgium NV/SA	Corporate bank accounts - Daily banking operations (Lot 1)	EUR 370,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/02/FI_2	Framework contract	ABN Amro Bank NV	Corporate bank accounts - Daily banking operations (Lot 1)	EUR 370,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/05/DED	Framework contract	EW Facility Services B.V.	Cleaning, Waste Management and Other Related Services	EUR 5,700,000	Open	Deputy Executive Director Office – N. Wathion
EMA/2019/06/DED	Framework contract	G4S Security Services B.V.	Provision of security services	EUR 9,000,000	Open	Deputy Executive Director Office – N. Wathion
EMA/2019/07/DED	Framework contract	BaxterStorey Netherlands B.V.	Provision of catering services	EUR 4,800,000	Open	Deputy Executive Director Office – N. Wathion
EMA/2019/09/DED	Framework contract	Xerox Nederland B.V.	Managed print and ancillary services	EUR 6,110,000	Open	Deputy Executive Director Office – N. Wathion

EMA/2019/10/ST	Framework contract	Prescan B.V.	Medical services	EUR 3,000,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/12/DED	Framework contract	Spirit Hostess Services Promo Adviezen B.V.	Reception and Switchboard Management and Hosting Services	EUR 2,339,000	Open	Deputy Executive Director Office – N. Wathion
EMA/2019/17/SG	Contractor's T&Cs	Continuity Innovation B.V.	Work area recovery site	EUR 142,000	Negotiated middle value	Administration and Corporate Management Division – M. Lenihan
EMA/2019/22/ST	Framework contract	Adecco Nederlands Holding B.V.	Provision of interim services (2nd priority)	EUR 15,400,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/23/ST	Framework contract	Manpower B.V.	Provision of interim services (3rd priority)	EUR 15,400,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/33/AUD	Framework contract	Grant Thornton Bedrijfrevisoren CVBA	Provision of internal audit services (2nd priority)	EUR 570,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/34/AUD	Framework contract	BDO LLP	Provision of internal audit services (3rd priority)	EUR 570,000	Open	Administration and Corporate Management Division – N. Steikunas
EMA/2019/35/ED	Framework contract	Taxicentrale Amsterdam B.V.	Provision of executive driver services	EUR 77,476	Negotiated middle value	Deputy Executive Director Office -Facilities Support Service – T. Freitas
EMA/2019/36/DED	Service contract	Waternet	Provision of tap water at the Agency's new premises	EUR 40,000	Negotiated 11.1(b)(ii) Annex I	Deputy Executive Director Office – N. Wathion
EMA/2019/37/DED	Service contract	Nuon-Vattenfall	Provision of district heating at the Agency's new premises	EUR 450,000	Negotiated 11.1(b)(ii) Annex I	Deputy Executive Director Office – N. Wathion
G3-CO-1031102	Framework contract	Vodafone Global Enterprices Ltd	Mobile communication services	EUR 263,779.65	Open	Information Management Division – A. Nolte
PO/2018-02/A4	Framework contract	Consortium LUMIERE	Services related to audiovisual production, production of graphics, animation and digital media applications. 1st priority	EUR 800,000	Open	Stakeholders & Communication Division – N. Wathion

PO/2018-02/A4	Framework contract	Media Consulta International Holding AG	Services related to audiovisual production, production of graphics, animation and digital media applications. 2nd priority	EUR 800,000	Open	Stakeholders & Communication Division – N. Wathion
PO/2018-02/A4	Framework contract	Consortium WAV 360	Services related to audiovisual production, production of graphics, animation and digital media applications. 3rd priority	EUR 800,000	Open	Stakeholders & Communication Division – N. Wathion
DI/07790	Framework contract	SAP Belgium NV/SA	Software licences and maintenance	EUR 13,000,000	Open	Information Management Division – A. Nolte
EIOPA-OP-042-2018	Framework contract	VONQ B.V.	Provision of broker services for advertising related to recruitment	EUR 350,000	Open	Administration and Corporate Management Division – N. Steikunas
HR/R1/PO/2018/004	Framework contract	Deloitte Consulting & Advisory CVBA	Consultancy services for those staff dealing with human resources within institutions (1st priority)	TBC	Open	Administration and Corporate Management Division – N. Steikunas
HR/R1/PO/2018/004	Framework contract	Ernst & Young Special Business Service	Consultancy services for those staff dealing with human resources within institutions (2nd priority)	TBC	Open	Administration and Corporate Management Division – N. Steikunas
HR/R1/PO/2018/004	Framework contract	McKinsey & Company Inc. Belgium	Consultancy services for those staff dealing with human resources within institutions (3rd priority)	TBC	Open	Administration and Corporate Management Division – N. Steikunas
COM/19/ETF/0006	Framework contract	GOPA COM.SA	Provision of strategic communication services for media relations	EUR 304,000	Open	Stakeholders & Communication Division – N. Wathion
EAC/34/2018	Framework contract	Reprings Desk Inc	Supply of copies of articles in all formats	EUR 120,000	Open	Stakeholders & Communication Division – M.-A. Heine
COMM/2019/OP/0018	Framework contract	Telmaco S.A.	Provision of professional audio, video and photographic equipment and accessories and services related to this equipment	EUR 100,000	Open	Stakeholders & Communication Division – M.-A Heine
COMM/2019/OP/0018	Framework contract	VP Media Solutions S.P.R.L	Provision of professional audio, video and photographic equipment and accessories and services related to this equipment	EUR 100,000	Open	Stakeholders & Communication Division – M.-A Heine

Annex 10. Annual report 2019

Please see the Agency's 'Annual report 2019', publicly available on the EMA corporate website.

Annex 11. Administrative appropriations – Building policy

Financial Regulation, Article 87(3.a) Building(s) covered by the appropriation of the financial year

Name, location and type of building	30 Churchill Place, London, E14 5EU
The building is a multi-tenanted office premises. The lease covers parts of the basement, ground and promenade levels, and levels 1 through 10. As of March 2019, these premises are no longer used for the Agency's operations. The premises were sublet from 1 July 2019, with revenue from subletting implemented as internal assigned revenue (CL).	
Surface area (in square meters)	30,340
• of which office space	• 17,946
• of which non-office space	• 12,394
Annual rent	EUR 19.2 million: • Rent - EUR 15.1 million • Building insurance, service and estate charges – EUR 4.1 million
Type and duration of rental contract	Rental lease of 25 years duration with no break clause; term commenced on 1 July 2014
Host country grant or support	Reduction in business rates whilst used by EMA
Present value of the building	Not applicable

The Dutch government provided the Agency with a temporary building (SPARK building) at no rental cost to the Agency for the interim period from 1 January 2019, whilst the final premises were being constructed and fitted out. The Agency occupied the SPARK building from 4 March 2019 until the end of 2019. In January 2020 the Agency will move into its permanent premises in Domenico Scarlattilaan 6, 1083 HS, Amsterdam. The process of vacating the SPARK building will start on 6 January and finish 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

Evolution of surface area for Agency	2018	2019	2020 – 2039
30 Churchill Place, London, E14 5EU, UK			
Surface area (in square meters)	30,340	30,340	30,340 *Not used for Agency's operations*
• of which office space	• 17,946	• 17,946	
• of which non-office space	• 12,394	• 12,394	
Domenico Scarlattilaan 6, 1083 HS, Amsterdam, The Netherlands			
Surface area (in square meters)	n/a	n/a	33,411[1]
• of which office space			• 22,781[1]
• of which non-office space			• 10,630[1]

[1] The floor area was amended in line with the measuring of the actual building following construction; split between office and non-office space only indicative.

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 accordance with European Parliament and Council Regulation (EU) 2018/1718 the Agency's seat moved to Amsterdam from 30 March 2019. A positive opinion by the Budgetary Authority was provided in March 2018 for the lease of a building in Amsterdam, the Netherlands, offered by the Dutch Government. For the sub-letting of premises in in 30 Churchill Place, Canary Wharf, London/UK a positive opinion by budgetary authority was received in June 2019.

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

Annex 12. Environmental performance

Environmental management at the Agency

As a result of the UK decision to leave the EU and the subsequent business continuity situation at the Agency, the relocation to the Netherlands in early 2019 and the fact that the European Commission's Eco-Management and Audit Scheme (EMAS) is site-based, the registration to EMAS to receive certification was put on hold.

The Agency aims to use the prepared framework and adjust it to the Agency's new premises in Amsterdam once relocated and will pursue the EMAS registration once located in the final premises. EMAS is site-based and an updated EMAS version will be prepared with the environmental statement for the new permanent EMA offices in Amsterdam. The programme requirements include an aim for BREEAM Excellent.

The Agency's environmental footprint is impacted by running the office building, i.e., resource consumption, waste, carbon emissions, as well as by staff engagement and behaviour in regards to environmental consciousness. The Agency aims to pursue setting objectives and targets for the new final premises to be monitored and achieved over the course of 2020 onwards.

Annex 13. Project implementation

Project progress and delivery as of 31 December 2019 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

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)

The traffic lights reflect the change to the overall project timeline, budget and scope that has taken place during 2019, in comparison to what was planned and approved at the end of 2018 (i.e. as noted in the work programme 2019).

In cases where the project start or end dates foreseen in the work programme 2019 were revised during the year, the current dates are added in the relevant cells, with the original date from the work programme 2019 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. The status of the projects is indicated in the report under 'Results 2019' as *continues*, *reduced* or *suspended*, according to the decisions taken on these projects at the time of adopting the work programme 2019. Of note, this status indication is not linked to the results delivered in 2019, but only reflects the BCP status of a given project.

During the first half of 2019, EMA Portfolio Board supported the CTIS project in restructuring its fixed-price contract; on-boarded 4 new projects - DIMSIS II, E-recruitment and learning management systems optimisation, Staff on-boarding, and Information classification; managed the funding of the EvVet3 and NVR activities and closed 3 projects: Corporate website, the Data centre relocation, and the IT application maintenance transition. Project prioritisation for 2020 was drafted and subsequently approved by EXB and MB.

During the second half of 2019, PB approved the start of 3 new projects: Real-world evidence rapid analytics; Travel management and delegate reimbursement; SAS (Statistical Analysis System) stabilisation & performance; and Information classification.

PB also advised the roadmaps for Administration digitalisation, Data analytics, and the new CTIS delivery model, supported funding of the NVR programme and approved a number of project change requests. No projects were closed during the second half of 2019.

Projects in human medicines evaluation activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2019
				Time	Budget	Scope	
Clinical trials programme							
Clinical Trial Information System (CTIS) (previously EU portal and clinical trials database)	• Regulation (EC) 536/2014, art.80-82 • Regulation (EC) 536/2014, art.40-43	Q1 2018 (Q3 2014 for the old CTDB project)	2021				CONTINUES A new delivery model has been put in place to promote direct and continuous feedback by the product owners and EMA staff to the contractors in charge of delivering the solution for the independent audit due at the end of 2020. Due to the size of the backlog, the change of contractor and introduction of a new way of working, involving more the stakeholders, the project is facing some delays and is now in the re-planning phase for the independent audit.
EudraCT & EU Portal (EudraCT legacy)	• Regulation (EC) 536/2014, art. 80-82,98	2018	2020				CONTINUES Due to the delay in the CTIS project, delivery of this project has been delayed and the activities planned for 2019 will start in 2020.
e-Submission programme							
eCTD4 pre-project	n/a	2020	2021				SUSPENDED
Single submission portal	n/a	Q3 2016	2018				SUSPENDED

Projects in veterinary medicines evaluation activities

Programme / project	Legal basis	Start date	End date	Project delivery against Time	Budget	Scope	Results 2019
Veterinary change programme							
EudraVigilance veterinary v3.0	• Regulation (EC) 726/2004, art.57(d)	2017	~~2019~~ To be redefined in light of the NVR				CONTINUES, subj to budget availability Due to the introduction of the new Veterinary legislation, some resources had to be diverted to analyse the impact of the new legislation on this project and the limits on the budget slow down the execution. Integration and data migration modules delivered. Funding availability issues have been managed and their impact mitigated.
New veterinary legislation	• Regulation (EU) 2019/6	~~Q1 2019~~ Q4 2019	2022				CONTINUES, subj to budget availability Project started Q4 2019 with the implementation of the Union Product Database.

Projects in horizontal activity areas

Programme / project	Legal basis	Start date	End date	Project delivery against Time	Budget	Scope	Results 2019
Data integration programme							
Substances and products management	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26	2017	~~2020~~ 2024				REDUCED temporarily Staff shortage during the relocation demanded strict management of priorities within the project; nevertheless

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2019
				Time	Budget	Scope	
services (including veterinary Union database)	• Draft veterinary regulation, art.51 • 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						it delivered phase 1 which includes integration and support to several systems and data migration. Furthermore, the project had rescheduled its delivery plan for 2024.
Online programme							
Extranet	n/a	Q1 2014	2021				SUSPENDED
Intranet	n/a	Q1 2014	2021				SUSPENDED
European medicines web porta	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, Art.26	Q1 2014	2021				SUSPENDED
Standalone projects							
S-REPS, phase 3 – SIAMED with Knowledge Management	n/a	2019	2020				CONTINUES SIAMED roadmap has been approved, but due to the Agency's relocation the project priorities were adjusted and implementation started with ITF management processes and analysis of the scientific advice.

Projects in corporate support and governance activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2019
				Time	Budget	Scope	
Administration digitalisation							
E-Recruitment and LMS Optimisation	n/a	2019	2020				CONTINUES Delivered under budget in Q3 2019 (formal project closure planned in Q1 2020)
On-boarding	n/a	2019	2021				CONTINUES Staff, contractors' and interims' on-boarding is planned for Q1 2020
Standalone projects							
Data centre relocation	n/a	2017	2019				Project was delivered on time and under budget Q1 2019
EMA move to permanent building	n/a	2019	2019				Project was taken over by Dutch authorities
Application Maintenance and Development (AM&D) sourcing project	n/a	2019	2021				CONTINUES Tender for the new Framework contract was ready for Q3 2019 and selection procedure to be started in Q1 2020.
Information classification	n/a	2019	2019				Project was delivered on time and under budget Q4 2019
General Data Protection Regulation	• Regulation (EU) 2016/679	2019	2019				SUSPENDED

Programme / project	Legal basis	Start date	End date	Project delivery against			Results 2019
				Time	Budget	Scope	
(GDPR)							
Upgrade of the Data Analytics infrastructure	n/a	2019	2021				SAS (Statistical Analysis System) stabilisation & performance optimisation started Q4 2019.
Real world evidence	n/a	2019	2021				Real World Evidence rapid analytics started Q4 2019.

Annex 14. Pharmacovigilance Fee Regulation: Key Performance Indicators and performance information for the calendar year 2019

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.

Part 1 of this report presents these key performance indicators (KPIs) for the calendar year 2018, and part 2 presents the more detailed performance information required by the regulation.

Part 1: Key Performance Indicators

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

Pharmacovigilance activities financed by PhV fees	2019 actual
Number of PSURs and PSUSAs procedures started	788
Number of imposed PASS protocol procedures started	11
Number of imposed PASS report procedures started	2
Number of pharmacovigilance referral procedures started	8
Number of pharmacovigilance annual fee chargeable units invoiced	157,853

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	2019 estimated %	2019 actual procedures	2019 actual %
MAHs invoiced for PSURs and PSUSAs procedures started involving CAPs only:		593	
· Micro sized enterprises	2.25%	4	0.67%
· Small and medium sized enterprises	7.50%	29	4.89%
MAHs invoiced for PSURs and PSUSAs procedures started involving NAPs or CAPs/NAPs:		4,245	
· Micro sized enterprises	2.50%	44	1.04%
· Small and medium sized enterprises	7.50%	201	4.73%
MAHs invoiced for Imposed PASS protocol procedures started for CAPs only:		11	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	0	0.00%
MAHs invoiced for Imposed PASS protocol procedures started for NAPs or CAPs/NAPs:		0	
· Micro sized enterprises	2.50%	0	0.00%
· Small and medium sized enterprises	7.50%	0	0.00%
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:		30	
· 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:		3	
· 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:		275	
· Micro sized enterprises	2.50%	1	0.36%
· Small and medium sized enterprises	7.50%	21	7.64%

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	2019 estimated %	2019 actual	2019 actual %
Pharmacovigilance annual fee chargeable units invoiced		157,853	
· Micro sized enterprises	2.50%	1,106	0.70%
· Small and medium sized enterprises	7.50%	9,141	5.79%
· Generics (non-SME)	36%	68,026	43.09%
· Authorised homeopathic, authorised herbal, and well-established use products	0%	26,744	16.94%

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	Invoiced in 2019 [14]	Cash collected in 2019	Percentage [15]	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	14,055	13,595	97% (89% in 2018)	9,412
Income recovered for imposed PASS protocol procedures started	283	283	100% (63% in 2018)	120
Income recovered for imposed PASS report procedures started	53	26	49% (93% in 2018)	11
Income recovered for pharmacovigilance referral procedures started	1,342	1,340	100% (100% in 2018)	896
Income recovered for pharmacovigilance annual fee chargeable units invoiced	9,305	9,249	99% (99% in 2018)	n/a

Part2: 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 2019

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

[14] The figures in this table differ from the ones in tables 4,5,6 and 9 below due to adjustments and corrections related to 2019 and processed in 2020, whereas the amounts shown in the tables below show only the value of the invoices related to the applications received between January and December 2019. In addition, some of the applications received at the end of the year were processed in the financial system in January 2020.

[15] Invoices are issued with 30 days credit which means that the payment of the invoices issued in November and December 2019 were paid for in 2020. The final 2019 cash recovery rate as of April 2020 is 100% for PSURs and PSUSAs, PASS, Referrals and Annual fees.

Note: the Agency has made every effort to meet 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 2019, pending the development of additional IT reporting functionality. In these cases the relevant fields are left blank.

1) Number of Agency staff (FTEs) involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees	Full Time Equivalence (FTEs)
Periodic safety update reports	10
Post-authorisation safety studies	1
Referrals initiated as a result of the evaluation of pharmacovigilance data	3
TOTAL	14

2) Number of hours outsourced to third parties with specification of the activities concerned and costs incurred		2019	
		Units	Cost €'000
Identifying and managing duplicates	Number of duplicate couples assessed	176,736 (177,811 in 2018)	1,433
	Number of 'master' reports generated based on duplicated data	92,480 (121,929 in 2018)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded	101,388 (61,202 in 2018)	
	Number of adverse reaction reports recoded	79,552 (56,756 in 2018)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review	123 (237 in 2018)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected	136,848 (292,367 in 2018)	
Monitoring of substance groups and selected medical literature[1]	Number of literature references screened and reviewed (July-December)	546,439 (521,495 in 2018)	1,040
	Number of individual case safety reports (ICSR) entered into Eudravigilance database and made available to NCAs and MAHs (July-December)	9,635 (13,275 in 2018)	

[1] EMA is responsible monitoring 400 substance groups (300 chemical & 100 herbal) and selected medical literature to identify suspected adverse reactions with medicines authorised in the European Union, and for entering the relevant information into the EudraVigilance database.

3) Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees	Staff costs €'000	Non-staff costs €'000
Cost for assessment of periodic safety update reports	1,004	9,764
Cost for assessment of post-authorisation safety studies	144	182
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	391	1,033
Annual cost for information technology systems and literature monitoring		7,702
Overall pharmacovigilance costs	20,219	

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[16]	Number of joint submissions[17]	Number of MAHs who submitted joint report[18]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
788	n/a	1,579	n/a	38,625	241	4,296	144	4	36	1	15,416,693

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	Number of (parent) MAHs[19]	Total number of MAHs[15]	Number of joint submissions	Number of (parent) MAHs in case of joint submission[20]	Total number of MAHs in case of joint submission[16]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
11	n/a	11	11	0	0	0	0	0	0	0	195,140
2	n/a	31	75	36	30	74	0	0	0	0	53,200

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	79	482	3	0	1	0	296,413

[16] Total number of CU generated for the products falling into the scope of the procedure - total number of CU (to be) invoiced
[17] Number of received joint submissions
[18] Total number of MAHs in received joint submissions
[19] Number of (parent) MAHs and total number of MAHs
[20] 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) Number of marketing authorisation holders involved in each procedure, that have claimed a small and medium-sized enterprise status or micro enterprise status	SME status		Micro status	
	Claimed	Denied	Claimed	Denied
Fee for assessment of periodic safety update reports	144	4	36	1
Fee for assessment of post-authorisation safety studies	0	0	0	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	21	0	1	0
Annual fee for information technology systems and literature monitoring	465	8	169	4

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2019
Generic application (Article 10(1) of Directive No 2001/83/EC)	2,050
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,851
Authorised homeopathic medicinal product	82
Authorised herbal medicinal product	262

9) Performance information relating to the 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 (€)
3,830	157,853	465	8	169	4	73,284	26,041	2,996	1,735	9,304,660	58.95

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started			
Member State	PSUR	PASS	Referral
Austria	41	0	0
Belgium	21	0	1
Bulgaria			
Croatia	15	0	1
Czech Republic	15	0	1
Denmark	48	1	0
Estonia	9	0	0
Finland	32	0	0
France	68	0	2
Germany (BfArm)	40	2	1
Germany (PEI)	65	2	1
Greece	4	0	0
Hungary	9	0	1
Ireland	42	0	0
Italy	37	0	1
Latvia	10	0	0
Lithuania	14	1	0
Malta			
Netherlands	79	3	3
Norway	12	0	0
Poland	39	2	2
Portugal	55	0	0
Romania	1	0	0
Slovakia	5	0	0
Slovenia	1	0	0
Spain	50	1	1
Sweden	76	1	1
United Kingdom			
Total	788	13	16

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							
NCAs	PSUR and PSUSA			PASS		Referrals	
	No. of proc.	Total hours	Average per proc.	No. of proc.	Total hours	No. of proc.	Total hours
Austria	37	2,108	57				
Belgium	20	2,836	142				
Bulgaria							
Croatia	12	972	81			1	200
Denmark	31	3,624	117	1	300		
Estonia	11	846	77				
Finland	31	2,365	76				
France	110	13,104	119	6	362	2	92
Germany (BfArM)	54	6,349	118	3	362	2	2,223
Germany (PEI)	31	2,546	82	1	74		
Greece	2	280	140				
Hungary	12	1,558	130			1	204
Ireland	21	1,716	82				
Italy	39	3,126	80			1	715
Latvia	6	539	90				
Lithuania	5	550	110				
Malta	1	200	200				
Netherlands	28	1,397	50				
Norway	12	592	49				
Poland							
Portugal	29	1,238	43	1	41		
Romania	1	58	58				
Slovakia	3	284	95				
Slovenia	1	167	167				
Spain	25	2,093	84				
Sweden	78	4,463	57	1	0	1	0
United Kingdom							
Grand Total	600	53,011	88	13	1,138	8	3,434

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

Not all NCAs were in a position to provide data for 2019.

Terms and abbreviations

Term / abbreviation	Definition
ACPC	Advisory Committee on Procurement and Contracts
AD	administrator function group
ADR	adverse drug reaction
ADVENT	Ad-hoc Expert Group on Veterinary Novel Therapies
AER	adverse event reports
Agency	European Medicines Agency
AMR	antimicrobial resistance
AMRH	African Medicine Regulatory Harmonisation Programme
ANVISA	Agência Nacional de Vigilância Sanitária, Brazilian Health Regulatory Agency
API	active pharmaceutical ingredient
Art.	article
AST	assistant function group
AST/SC	secretaries and clerks' function group
ATD	access to documents
ATMP	advanced therapy medicinal product
BCP	business continuity plan
BE	bioequivalence
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
BIO	Biotechnology Innovation Organization, host of BIO International Convention
the Board	EMA Management Board
BREEAM	building research establishment environmental assessment method
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
CO_2	carbon dioxide
CoI	conflict of interest
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
CTIS	clinical trials information system
CTR	Clinical Trials Regulation
CV	curriculum vitae
CVMP	Committee for Medicinal Products for Veterinary Use

Term / abbreviation	Definition
DA	delegating act
DG	Directorate-General of the European Commission
DG DEVCO	European Commission Directorate-General for International Cooperation and Development
DG GROW	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG SANTE	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
DIMSIS II	development, implementation and maintenance support of information systems II
DNA	deoxyribonucleic acid
DoI	declaration of interests
DPIA	data protection impact assessment
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
ECHA	European Chemicals Agency
eCTD	electronic common technical document
e-CV	electronic curriculum vitae
e-DoI	electronic declaration of interests
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFPC	European Forum For Primary Care
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMAS	European Commission's Eco-Management and Audit Scheme
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
ENVI	Committee on the Environment, Public Health and Food Safety of the European Parliament
EP	European Parliament
EPAR	European public assessment report
EPITT	European pharmacovigilance issues tracking tool
ERA	environmental risk assessment
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
etc.	*et cetera*, and so forth
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
EU NTC	EU Network training centre
EU TMB	EU Telematics Management Board
EudraCT	European Union Drug Regulating Authorities clinical trials database
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice database

Term / abbreviation	Definition
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance, system for managing and analysing information on suspected adverse reactions to medicines
EUnetHTA	European network for health technology assessment
EUR	euro
EU-SRS	Europe-wide substance registration system
EV	EudraVigilance
EVMPD	Eudravigilance Medicinal Product Dictionary
EVVet	EudraVigilance veterinary
EWP-V	efficacy working party (veterinary)
EXB	EMA Executive Board
Executive Board	EMA Executive Board
FDA	United States Food and Drug Administration
FTE	full-time equivalent
GCP	good clinical practice
GDPR	General Data Protection Regulation
GLP	good laboratory practice
GMDP	good manufacturing and distribution practice
GMP	good manufacturing practice
GP	general practitioner
GVP	good pharmacovigilance practice
GxP	good practice (e.g. laboratory, clinical, manufacturing)
H&V	human and veterinary
Health Canada	department of the government of Canada that is responsible for national public health
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
Horizon 2020	EU Research and Innovation programme
HR	human resources
HPRA	Health Products Regulatory Agency, Ireland
HTA	health technology assessment
i.e.	*id est*, that is
IA	implementing act
IAC	internal audit capability of EMA
IALN	inter-agency legal network
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
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	individual case-safety report
ID	identification
IDMP	identification of medicinal products
IGDRP	International Generic Drug Regulators Programme
IHI	Institute for Healthcare Improvement
IMI	Innovative Medicines Initiative
IMI PREFER	Innovative Medicines Initiative project on Patient Preferences in benefit risk assessments during the drug life cycle

Term/abbreviation	Definition
INC	International Neonatal Consortium
IVDR	In Vitro Diagnostics Regulation
IVD WG	in vitro diagnostics working group
INT	interim contract
IPA	informal network of EU agencies working with pre-accession
IPRF	International Pharmaceutical Regulators Forum
IPRP	International Pharmaceutical Regulators Programme
IRCH	International Regulatory Cooperation for Herbal Medicines
IRIS	Regulatory and Scientific Information Management platform
IT	information technology
ITF	Innovation Task Force, EMA platform for early dialogue with medicine developers
JIACRA	Joint Interagency Antimicrobial Consumption and Resistance Analysis working group
KPI	key performance indicator
LMIC	low- and middle-income countries
LMS	learning management system
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
Management Board	EMA Management Board
MAWP	multiannual work programme
MB	EMA Management Board
MDR	Medical Device Regulation
MEDDEV	guidance documents on medical devices
Member State	member state of the European Union
MFDS	Ministry of Food and Drug Safety, South Korea
MHLW	Ministry of Health, Labour and Welfare, Japan
MLM	medical literature monitoring
MLT	Medicines Leadership Team
MRA	mutual-recognition agreement
MRL	maximum residue limit
MS	member state(s) of the European Union
MUMS	minor use minor species/limited market policy
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NGO	non-governmental organisation
NITAG	national immunization technical advisory groups of WHO
NMPA	Chinese National Medical Product Administration
NVR	new veterinary regulation
OIE	World Organisation for Animal Health
OLAF	European Anti-Fraud Office
ORP	Operations and Relocation Preparedness Task Force at EMA
P3i	EMA's methodology for portfolio, programme, project management and IT delivery lifecycle
PASS	post-authorisation safety study
PB	EMA Portfolio Board

Term / abbreviation	Definition
PBT	persistent bioaccumulative and toxic substance
PDCO	Paediatric Committee
PEI	The Paul-Ehrlich-Institute
PhV	Pharmacovigilance
PIC/S	the pharmaceutical inspection cooperation scheme
PIM	pharmacological, immunological, metabolic
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PMF	plasma master file
PPHOVA	pilot project on harmonisation of old veterinary antimicrobials
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicines – a scheme to foster development of medicines with high public-health potential
PSUR	periodic safety update report
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
RAPS	Regulatory Affairs Professionals Society
REA	relative effectiveness assessments
RFI	request for information
RWE	real-world evidence
SAG	scientific advisory group
SAHPRA	South African Health Products Regulatory Authority
SAP	Systems, Applications & Products (budgetary system)
SAP HR	human resources module of SAP
SAWP	Scientific Advice Working Party
SCoMRA	Scientific Conference on Medical Products Regulation in Africa
SEPA	the Single Euro Payments Area
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	small or medium-sized enterprise
SmPC	summary of product characteristics
SNE	seconded national expert
SOP	standard operating procedure
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
S-REPS	scientific and regulatory evaluation procedure support
SRA Collaborative Registration Procedure	collaborative procedure in the assessment and accelerated national registration of pharmaceutical products approved by stringent regulatory authorities, a WHO-EMA collaborative registration pilot
Swissmedic	Swiss Agency for Therapeutic Products
T&C	terms and conditions
TA	temporary agent
TBC	to be confirmed
TFAMR	Ad-hoc Intergovernmental Task Force on Antimicrobial Resistance

Term/abbreviation	Definition
TATFAR	The Transatlantic Taskforce on Antimicrobial Resistance
TOPRA	The Organisation for Professionals in Regulatory Affairs
TR	trainee
Type IA	A minimal variation/change to the terms of a marketing authorisation with impact or no impact at all, on the quality, safety or efficacy of the medicinal product
Type IB	A minor variation that is neither a Type IA variation nor Type II variation nor an Extension
Type II	A variation/change to the terms of a marketing authorisation with significant impact on product quality, safety & efficacy
UEMO	European Union of General Practitioners
UK	United Kingdom
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Fund
Union	European Union
US	United States
VAT	value added tax
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	veterinary medicinal product
WHO	World Health Organization
WHO PQ	World Health Organization prequalification programme
WLA	WHO listed authorities
WONCA	World Organization of Family Doctors
xEVMPD	Extended Eudravigilance Medicinal Product Dictionary