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European Medicines Agency

Annual activity report 2017

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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 47 thereof,
- having regard to the 2017 work programme of the Agency, adopted by the Management Board at its meeting in December 2016,
- having regard to the annual report 2017 of the Agency adopted by the Management Board at its meeting in March 2018,
- having regard to the annual activity report 2017 of the Agency presented to the Management Board at its meeting of 7 June 2018,

GENERAL

1. 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.
2. Welcomes the results presented in the annual report 2017, as well as the considerable work programme delivered in 2017; notes that the Agency achieved its targets for the majority of the activities, but also notes that some of the activities were delayed or postponed due to Brexit or external circumstances.
3. Recognises the emphasis of the Agency that significant new tasks, over the years, were assigned to it without any increase in staff, leading to a critical dependence on external expertise. Notes with concern that the Agency, as a consequence of the relocation, requires significant resources to be redistributed for relocation tasks, and that such shortage of human resources may result in challenges for the Agency to fulfil its core and legislative responsibilities.
4. Welcomes the decision of 20 November 2017 of the General Affair Council (Art.50), on Amsterdam as EMA’s new location; this decision ended a long period of uncertainty and allows the Agency to start planning for a successful move in 2019.
5. Is pleased with the adoption of the EMA 2018 Multiannual Work Programme that suggests that the Agency will be able to maintain its core activities, but also signals that in other areas the Agency will have to temporarily reduce or suspend activities.
6. Highlights the importance of the work done in collaboration with the network and the creation of specific working groups to prepare the European regulatory network for the consequences of Brexit and ensure a coordinated approach within the network on the business continuity of the EMA and, in the end, the continuity of the network.

MISSION

7. Welcomes the work on marketing authorisations via the centralised procedure – both in human and veterinary medicines. In 2017, EMA recommended 92 new human medicines, including 35 new active substances and 18 new veterinary medicines, including 7 new active substances, for marketing authorisation. Many of these medicines include medicines for children, for rare diseases, and advance therapies and, in the veterinary field, out of 18 new medicines 10 were vaccines — a twofold increase from 2016.

8. Appreciates the first anniversary of the PRIME scheme and the enhanced support it provides to products that demonstrate a major therapeutic advantage in addressing patients' unmet medical needs, and notes that by the end of 2017, a total of 34 medicines were included in this scheme and expects the first marketing authorisation in 2018.

9. Notes the uptake of the marketing authorisation under accelerated assessment which allows faster assessment of medicines of major therapeutic interest. It is pleased to report that, thanks to this route, seven new medicines were recommended for marketing authorisation.

10. Is pleased with the results of the report on the experience with conditional marketing authorisation ten years after it was first introduced, which indicates that early access to medicines to patients who previously lacked or only had unsatisfactory treatment options has improved. During this period of time, 30 conditional marketing authorisations have been granted.

11. Recognises that medicine assessments employing regulatory tools to shorten assessment times are based on robust and sound evidence packages and should in future be designed to also address the needs of subsequent decision makers, like HTAs and payers.

12. Applauds the collaboration with HTA bodies, as close interaction with such organizations is critical to support medicine development programmes that allow a wider and faster access of new medicines to patients. Recognises the importance of the approval of a joint work plan 2017-2020 of EMA and EUnetHTA, and the creation of the joint platform for parallel consultation, and the new collaboration to support HTAs in their relative effectiveness assessment after CHMP opinion.

ACTIVITIES

13. Welcomes the collaboration with the Japanese Pharmaceutical and Medical Device Agency, and the United States Food and Drug Administration on supporting the development of new antimicrobial medicines, as this should stimulate the development of new treatments to fight antimicrobial resistance.

14. Welcomes the vital role of the Agency in fighting antimicrobial resistance (AMR), and especially its contribution in relation to the development and implementation of the One Health action plan against AMR, launched in 2017 by the European Commission, and the publication of the second version of the ECDC, EFSA, EMA joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report. Stresses that there are still important differences across the EU in the use of antibiotics in animals and humans.

15. Is pleased with the publication of the information guide for healthcare professionals on biosimilar medicines, as a response to the request from healthcare professionals on the need for information on both the science and regulation behind the requirements of biosimilars.

16. Notes with satisfaction the positive impact that the Paediatric Regulation has had on the life of children in the first 10 years of its implementation. Regrets that the overall positive impacts is not evenly spread across all therapeutic areas; while it works very well in areas where the needs of adult and paediatric patients overlap, major therapeutic advances have yet to materialise in

diseases rare and/or unique to children. The Paediatric Regulation allowed the authorisation of 260 medicines for children over this period of time.

17. Is pleased with the Agency's support of the CVMP strategy to encourage development for medicines for minor use/minor species or limited markets, as these medicines may otherwise not be developed under the current market conditions.

18. Encourages the Agency to continue facilitating the availability of new veterinary medicines, especially veterinary vaccines and products for minor species/uses and limited markets, and also the research and innovation.

19. Encourages the Agency to continue to provide support to the European Commission in relation to the new veterinary regulation, and calls for the Agency and the budgeting Authority to ensure that it can meet the increased demand on financial and human resources that is expected to arise from the new legislation.

20. Supports the work done by the EMA-HMA joint task force on the availability of authorised medicines for human and veterinary use in developing and coordinating the necessary actions to help guarantee increased availability and uninterrupted supply of medicines.

21. Appreciates the Agency's recognition of the need to respond to regulatory challenges in innovative fields of medicines, and welcomes the EU innovation office network (EU-IN) and its work and focus throughout 2017. Notes that 23 Innovation Offices established in NCAs voluntarily joined the network.

22. Applauds also the joint action plan with the Commission to foster the development of ATMPs, welcomes the joint workshop organised on personalised medicines and encourages works to continue in these fields.

23. Underlines the importance of identifying and meeting emerging trends in science and technology, thus welcomes the setup of the new Regulatory Science Observatory, which in 2017 surveyed key trends in science, technology and regulatory tools that can impact the operations of EMA.

24. Supports the establishment of the joint HMA - EMA big data taskforce created in 2017 to explore how big data can be used in medicines development to support research and innovation.

25. Is pleased with the extension of the multinational assessment team initiative to post-authorisation assessments in 2017, making the use of resources across the EU even more efficient.

26. Applauds the Agency's continued efforts in the transparency field, and particularly in the first anniversary of the ground-breaking initiative to publish clinical trial data after granting the marketing authorisation.

27. Notes with satisfaction the first EMA public hearing, establishing a valuable new tool for the PRAC to complement scientific evidence with the contribution of EU citizens.

28. Notes with satisfaction the improvement in operational efficiencies leading to the decrease in average assessment time for post authorisation and initial authorisation phase, signifying faster approval without compromising the rigorous evaluation of medicines.

29. Congratulates the Agency on its continued strengthening of international collaboration with other regulators, and specifically on the breakthrough EU-US mutual recognition agreement allowing for a better use of inspection expertise and resources.

30. Notes and supports EMA efforts to step up interaction with academia through a new framework and a detailed action plan promoting other initiatives for mutual education and training, staff exchange

programmes for mutual learning a research agenda, and the creation of EMA entry point for academia, to receive information on available support within the EU Regulatory Network. Also notes the launch of the action plan to support small and medium-sized enterprises (SMEs), to increase engagement with actors in the pharmaceutical innovation environment.

31. Applauds the increased number of courses offered in the EU Network Training Centre (EU NTC) during 2017 (100 courses offered) and the full implementation of the Learning Management System.

32. Notes and supports the work done to ensure patient safety through the lifecycle of medicines, including the revision of the guideline on first-in-human clinical trials and better labelling of excipients.

33. Supports further initiatives as a follow-up on the Commission report on shortcomings in the summary of product characteristics (SmPC) and the package leaflet (PL), and how they could be improved to better meet the needs of patients and healthcare professionals. Appreciates the work done by the joint EMA - HMA Working Group to improve SmPC and PL.

34. Supports the Data Gathering Initiative that was set up in 2014 to gather evidence needed by the European Commission to assist with the future re-draft of the legislation governing fees charged by EMA.

TELEMATICS/IT ISSUES

35. Applauds the launch of the new and improved EudraVigilance system simplifying reporting and data analysis.

36. Supports the decision to use cloud strategy to also facilitate the relocation by using location independent services and looks forward to its successful implementation.

37. Stresses the importance of continuing the implementation of the Telematics strategy.

38. Welcomes the Referentials and Organisations components of SPOR delivered in 2017. Looks forward to the completion of the SPOR programme.

39. Understands that several projects were postponed due to Brexit. Regrets that others were over time or over budget, in particular that the delivery of the fully functional system of the clinical trials programme was postponed. Suggests to keep close attention to the feasability, delivery and budgeting of future Telematics programmes.

40. Reaffirms the importance of the timely implementation of the EU clinical trial regulation, which is expected to significantly improve the European environment for the conduct of clinical trials. Supports all the work done and notes that there still are major challenges ahead.

FINANCES AND HUMAN RESOURCES

41. Is pleased that the European Parliament granted the discharge in respect of the implementation of the budget of the Agency for the financial year 2016.

42. Notes that the Agency's initial budget for 2017 amounted to EUR 322,103,000 (2016 initial budget EUR 324,711,000), but that the continuing weakening of the pound which started in 2016 resulted in exchange rate gains in salaries and rent and building payments; the budget was amended, bringing the final budget to EUR 331,266,000.

43. Notes that 87.96% of its 2017 revenue came from fees paid by the pharmaceutical industry for services provided (in 2016: 89.48%), 8.99% from the European Union budget (in 2016: 5.51%), and 3.05% from external assigned revenue as described in the work programme (in 2016: 5.01%).

44. Notes that at the end of 2017, the Agency achieved occupancy rate for temporary agents of 98% and that during 2017, the Agency recruited 149 members of staff and had 127 staff leaving the Agency.

45. Notes the Competency Framework mapping efforts of the Agency and the internal mobility policy aimed at business continuity arrangement, put in place and intimately interrelated to the relocation of the Agency to Amsterdam.

46. Commends the work of the Agency's Anti-Fraud Office and its collaboration with OLAF in fraud prevention and the review of the AFS in 2017, to reflect on its recent experiences and proactively anticipate a response to latest fraud related trends. It applauds the Anti-Fraud strategy action plan for 2017 and its full, successful and timely implementation.

INTERNAL POLICIES

47. Welcomes the implementation of the Agency's Code of conduct and the handling of declared interests of staff members throughout 2017. Compliments the adoption of the Policy on handling of information from external sources.

48. Expects the Agency to continue monitoring HR real time data to be able to rapidly assess and understand workforce capacity and be able to overcome any shortcoming, especially in view of the Agency's relocation.

49. Applauds the efforts of the Agency to provide stakeholders and partners with consistent, high-quality, timely, targeted, and accessible information on the Agency's work, outputs and medicinal products, while realising some stakeholder interactions had to be reduced or put on hold due to the business continuity plan. Welcomes the continuous emphasis on strengthening of the engagement with stakeholders, including civil society, and involving general practitioners in regulatory decisions.

AUDITS AND INTERNAL CONTROLS

50. Regrets that some audits planned for 2017 were cancelled/postponed due to the business continuity plans endorsed by the Management in June 2017, including the 'Request for access to documents' and the 'EU Clinical Trials portal and database'.

51. Welcomes the Internal Audit Service's final report on the New Pharmacovigilance Fees Regulation, which confirms that the Agency has an effective system for fee processing, and systematic planning and monitoring of the underlying activities. Is concerned with the identified weakness stemming from EMA's management of the deficit between the pharmacovigilance fees income and the related costs, and is satisfied with EMA's response and action plan to rectify the issue.

52. Acknowledges the results of the audit of the European Court of Auditors, confirming the reliability of the 2016 accounts and the legality and regularity of the transaction underlying the accounts of the Agency. It notes the resulting comments and the Agency's action plan to address them.

53. Is satisfied that no critical recommendations stemming from audits carried out by the Internal Audit Capability up to 31 December 2017 were open, and expects the closure of the very important recommendations within the agreed timelines.

54. Notes that the assessment on the compliance and effectiveness of internal control standards concluded that the system in place is generally compliant with the standards, and is calling on the Agency to implement the identified planned actions to further improve efficiency.

55. Acknowledges that in regard to ex-ante verifications, all transactions without exception were checked by applying appropriate checklists, in line with the financial regulations and the Charter of the Verifying Officer.

56. Notes the reduction of ex-post control activities in 2017 to 4, due to the launch of Brexit business continuity plan, and that the 2017 ex-post controls performed showed no significant weakness of the process analysed, although potential areas for improvement were highlighted.

57. Notes that a system to support the Executive Director's declaration of assurance was in place.

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

59. Thanks 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.

London, 7 June 2018

[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 2017.The EMA annual activity report 2017 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 2017 comprises four main parts and annexes, as follows:

Part I: Key achievements in 2017. 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 2017, 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 2017; 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. Its creation followed the decision by the EU Heads of State and Government on 29 October 1993, choosing London as the location for EMA's premises.

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, with respect to the authorisation, maintenance and supervision, in the following therapeutic areas: treatment of cancer, diabetes, neuro-degenerative dysfunctions, viral diseases and rare human diseases ('orphan' medicines). Also, 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 be submitted for assessment to EMA on behalf of the EU. To achieve this, EMA provides a single route for the evaluation of innovative medicines in the EU, hereby avoiding the duplication of the evaluation in each of the 28 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 made available in all EU languages at the same time, ensuring that consistent information on medicines is provided to all EU citizens.

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

On behalf of the EU, EMA hosts a number of databases, important for public health, such as EudraVigilance — the largest database 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.

EMA provides for a single scientific assessment, resulting in a scientific recommendation for the European Commission, which subsequently translates this scientific recommendation into a single

marketing authorisation decision, valid for the whole EU. 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 some 3,900 scientific experts, made available by the Member States to the Agency.

A robust scientific assessment process is pivotal in making safe, effective and good quality medicines available to patients, with the necessary guarantees ensuring the independence of EMA's work embedded in the way it operates.

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 (CAT, CHMP, COMP, CVMP, HMPC, PDCO, PRAC), 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] 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

1. Key achievements in 2017

The year 2017 was another challenging year for EMA. The impact of the UK's decision to withdraw from the European Union left its mark. As well as continuing with its day-to-day work and successfully delivering most of its work plan, the Agency worked with the national competent authorities to prepare the network for the impact of the UK's withdrawal. EMA and the Member States worked on identifying possible gaps in expertise, so that appropriate measures could be taken to fill these gaps. They also worked on a methodology to transfer the portfolio of medicines for which the UK is currently rapporteur or co-rapporteur to other Member States.

1.1. Human and veterinary medicines highlights

1.1.1. Human medicines

In 2017, EMA recommended 92 medicines for marketing authorisation. Of these, 35 had a new active substance, i.e. one which had never previously been authorised in the EU.

Many of these medicines represent a significant improvement in their therapeutic areas; they include medicines for children, for rare diseases, and for advanced therapies.

Seven new medicines were recommended for marketing authorisation following a review under accelerated assessment; a mechanism which allows for a faster assessment of medicines of major therapeutic interest by EMA's scientific committees (within 150 days rather than up to 210 days).

Three medicines received a recommendation for a conditional marketing authorisation. This tool enables the early approval of a medicine that addresses an unmet clinical need on the basis of less complete clinical data than is normally required. These medicines are subject to specific post-authorisation obligations that aim to obtain complete data on the medicine.

In addition, the CHMP issued negative opinions on 6 medicines in 2017. This means that the CHMP could not conclude that the benefits of the medicine outweighed the risks.

Some 90% of all opinions (positive and negative) were reached by consensus among the members of the CHMP, meaning that its experts were in agreement on all aspects of the marketing authorisations, following in-depth discussions.

Around 62% of the applicants who received a positive opinion for their medicine had received scientific advice from EMA during the development phase of their product. This is a procedure that allows EMA to provide early input on the kind of evidence that would be required for authorisation, and helps to reduce the risk of patients taking part in unnecessary or poorly designed clinical trials.

Product information for 397 medicines was updated on the basis of new safety data. The revised information is expected to help patients and healthcare professionals to make informed decisions when using or prescribing a medicine.

1.1.2. Veterinary medicines

New medicines to benefit animal health in Europe

In 2017, EMA recommended 18 new veterinary medicines for marketing authorisation; seven of these contain a new active substance. Among the 18 medicines recommended for marketing authorisation,

ten were vaccines – a twofold increase compared to 2016. Six of these vaccines were developed by means of biotechnological processes, such as recombinant DNA technology.

Product information for 17 medicines was updated on the basis of new safety data. The revised information is expected to help animal owners and healthcare professionals to make informed decisions when using or prescribing a medicine.

In 2017, MRLs were established for 4 active substances.

1.2. Advancing human health

1.2.1. Supporting development of promising or much-needed medicines for patients

First anniversary of PRIME

Our PRIority MEdicines (PRIME) scheme marked its first anniversary. By the end of 2017, a total of 34 medicines were included in this scheme, which provides early and enhanced support to products that can demonstrate a major therapeutic advantage in addressing patients' unmet medical needs. The first marketing authorisation applications for medicines receiving PRIME support were submitted during 2017, and we expect first recommendations in 2018.

Supporting development of medicines for children

10 years of Paediatric Regulation

The year 2017 also marked the tenth anniversary of the EU Paediatric Regulation. In its report to the European Parliament and the Council, published in October with the title 'State of Paediatric Medicines in the EU', the European Commission concluded that the progress made in the development of medicines for children, including the authorisation of over 260 new medicines, could not have been achieved without specific EU legislation and EMA's role in its implementation.

Despite the overall positive impact on the health of children, the report also acknowledges that the results from the paediatric legislation are not evenly spread across all therapeutic areas. While it works very well in areas where the needs of adult and paediatric patients overlap, major therapeutic advances have yet to materialise in diseases that are rare and/or unique to children. The report identified concrete areas for action which EMA and the European Commission are now working to address, initially by reflecting on the best way forward with a broad range of stakeholders, including patients/carers, academia, healthcare professionals, and industry.

Global research collaboration for the benefits of children

The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) held its ninth annual workshop in May 2017. Enpr-EMA is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children. Its aim is to foster high-quality ethical research in children, in order to provide knowledge and support regarding quality, safety, and efficacy of paediatric medicines. This year's workshop emphasised the need for global collaboration and provided a dedicated session on interaction between the EU and the US for global paediatric research.

Conditional marketing authorisation gives patients access to important new medicines earlier

Conditional marketing authorisation applies to medicines that target seriously debilitating or life-threatening conditions such as HIV infection, breast cancer, severe epilepsy in infants, or multi-drug resistant tuberculosis.

In 2017, EMA reviewed its experience with conditional marketing authorisation (CMA) ten years after it was first introduced. A report published in January 2017 showed the positive impact of this important tool. The report indicates that CMA has provided early access to such medicines for patients who previously lacked or only had unsatisfactory treatment options, and over a period of 10 years, no medicine with a CMA has had to be revoked or suspended.

Collaborating with HTA bodies and healthcare payers

Some new medicines that receive marketing authorisation fail to get reimbursed or fail to become accessible for patients. Close interaction between regulators, HTAs and other relevant decision-makers is critical to support medicine development programmes that generate data relevant for all these stakeholder groups, with the ultimate aim of ensuring patient access to important new medicines.

In November 2017, EMA and the European Network for Health Technology Assessment (EUnetHTA) finalised their new joint work plan 2017-2020, outlining key areas of collaboration. It foresees continued focus on areas in which major progress has already been made, including early dialogue and scientific advice. A joint platform for parallel consultation was created in July 2017 to provide developers of medicines with simultaneous, coordinated regulatory and HTA advice on their development plans and to facilitate alignment of data requirements.

EMA and EUnetHTA will also continue their information exchanges on the outcome of the regulatory assessment at the time when a new medicine is granted a marketing authorisation. In 2017, a new collaboration started to support the HTAs in their relative effectiveness assessment after CHMP opinion. EMA and EUnetHTA also committed to work to optimise tools for the generation of evidence post-authorisation, such as patient registries.

New areas of collaboration include a plan to explore possible synergies in how HTA bodies and regulators apply the concepts of unmet medical need and therapeutic innovation, and to understand the conceptual similarities and differences between the significant benefit of orphan medicines versus their added therapeutic value.

Supporting development of new antimicrobial medicines and treatment approaches

EMA, the Japanese Pharmaceutical and Medical Devices Agency, and the United States Food and Drug Administration reached an agreement in 2017 to align data requirements for certain aspects of the clinical development of new antibiotics. This is expected to stimulate the development of new treatments to fight antimicrobial resistance and protect global public health. Representatives from the three regulatory agencies held two tripartite meetings in 2017. The aim of this collaboration is to facilitate a single development program for new antibacterials that can satisfy the regulatory requirements of each of the three agencies. The three regulators agreed on a common approach for clinical trials, designed to study the effects of new antibiotics in certain indications, such as uncomplicated gonorrhoea or uncomplicated urinary tract infections. Stressing the importance of gathering meaningful clinical data in children, they also committed to working together to streamline paediatric development of new antibacterial agents. These talks took place under the terms of the respective confidentiality agreements of the three agencies.

Fostering a constructive dialogue with the pharmaceutical industry and supporting innovation in SMEs

In 2017, EMA started a new platform to discuss research and development support for pharmaceutical industry stakeholders. The aim is to foster more integrated support activities through continuous improvement and mutual learning. EMA and industry associations will regularly meet to address all areas of product development support, including scientific advice, paediatric and orphan medicines and innovation support. This new platform provides an opportunity for both general updates, and more focused discussions on specific processes or issues, to foster a constructive dialogue with industry stakeholders. Because small and medium-sized enterprises (SMEs) are a motor of innovation in the pharmaceutical industry, EMA launched a new action plan to support SMEs in the development of new human and veterinary medicines. The plan covers the period up to 2020 and aims to increase awareness of EMA's SME initiative by increasing engagement with actors in the pharmaceutical innovation environment such as incubators, universities and investors. It also includes actions around training and education of SMEs and academia, actions to support the development of innovative medicines, and actions to support continued engagement with SMEs, EU partners and stakeholders.

1.2.2. Responding to regulatory challenges in innovative fields of medicine

EMA constantly reviews and improves its standards and guidance. This allows the Agency to respond to challenges particular to the development of innovative medicines in new fields, such as advanced therapies or personalised medicines, with the ultimate aim of providing patients with timely access to innovative treatments.

The EU Innovation Offices Network (EU-IN)

The EU Innovation Offices Network (EU-IN) is a joint initiative launched by EMA and the Heads of Medicines Agencies in October 2016 to support innovation in medicines. Its focus is on small and medium-sized enterprises and academic innovators. During 2017, 23 Innovation Offices, established in National Competent Authorities, voluntarily joined the network. The EU-IN held discussions on emerging areas of innovation, with expected impact on regulatory evaluation standards and practices in the pharmaceutical sector, namely nanomedicines and novel manufacturing strategies (including continuous manufacturing, point of care manufacturing and 3D printing), and borderline products.

Advanced therapies action plan

In October, EMA and the European Commission's Directorate-General for Health and Food Safety (DG SANTE) launched a new joint action plan to foster the development of advanced therapy medicinal products (ATMPs). The action plan contains 19 action points in different key areas. The main aim is to engage with a wide range of stakeholders and to facilitate the progression of ATMPs from early development to patients. This includes the streamlining of procedures to better address the specific requirements of ATMP developers.

One of the actions, a new guideline on good manufacturing practice for ATMPs, was completed in November 2017, when the document was published by the European Commission. The objective of the guideline is to ensure that these novel medicinal products are consistently produced and controlled according to high-quality standards, for the benefit and the safety of patients.

Personalised medicines

Personalised medicines are often seen as the next frontier in patient-centred health care. There is no common definition of the term, but it is often referred to as a medical model for tailoring the right therapeutic strategy for the right person, at the right time, on the basis of an individual's characteristics and genetic makeup. To discuss evolving concepts and regulatory challenges, as well as opportunities in the development of personalised medicines, EMA organised a joint workshop on personalised medicines with EMA's Patients' and Consumers' Working Party (PCWP) and Healthcare

Professionals' Working Party (HCPWP), in March 2017. The participants discussed how the Agency and the European medicines regulatory network approach and support the development and evaluation of personalised medicines. They also explored how patients and healthcare professionals can contribute to this process and what their priorities might be in this area. A report that summarises the main conclusions of the workshop was published in May 2017.

1.2.3. Ensuring patient safety throughout the lifecycle of medicines

EMA constantly strives to improve its regulatory standards to ensure the protection of patients throughout the lifecycle of medicines, from their development to their use across Europe.

Revision of the guideline on first-in-human clinical trials

In 2017, EMA finalised the revision of its guidance on first-in-human clinical trials. Developed in cooperation with the European Commission and the EU Member States, the revised guideline further helps clinical trial sponsors and regulators to identify and mitigate risks for trial participants. The revision took into account the comments received during a public consultation and a follow-up workshop.

The safety and well-being of trial participants should always be the utmost priority when designing early clinical trials. The guideline puts emphasis on the sponsor's responsibility to define the uncertainty associated with the medicine tested at each step of the development, and to describe how the potential risks that might arise from this uncertainty will be addressed by the design and conduct of the trial. The approach must be supported by a well-documented scientific rationale from the outset and be responsive to data emerging over the course of the trial.

Better labelling of excipients for safe use of medicines

EMA and the European Commission updated the annex to the European Commission guideline on excipients in the labelling and package leaflet of human medicines with new safety advice for 15 excipients. Excipients refer to everything in a medicine other than the active substance. While most excipients are considered inactive, some can have a known action or effect in certain circumstances. These must be declared in the labelling of the medicine.

The updated annex contains all excipients that must be declared in a medicine's labelling and package leaflet along with related safety warnings. The main aim of this update was to take into account safety concerns which were not addressed in the existing annex to the guideline. It also paid specific attention to, for example, the safety of these excipients when included in medicines used in children or pregnant women.

The updated annex, which took into account the comments received for each excipient during public consultations and is published, in all European Union languages, along with the relevant scientific reports, applies to both centrally and nationally authorised products. The updated document includes five new excipients and new safety warnings for ten existing excipients. The new safety information will help patients and healthcare professionals make more informed decisions about the medicines they take and prescribe.

New and improved EudraVigilance to simplify reporting and data analysis

On 22 November 2017, EMA launched a new and improved version of EudraVigilance, the European database and analytical system that holds reports of suspected adverse reactions to human medicines

that are authorised or being studied in clinical trials in the European Economic Area (EEA). EudraVigilance is a key tool for patient safety in Europe and the new system makes it easier for marketing authorisation holders and sponsors of clinical trials to report suspected adverse reactions and facilitates the analysis of this information.

The enhancements and expected benefits of the new EudraVigilance are:

- simplified reporting of individual case safety reports (ICSR) and reduced duplication of efforts. Marketing authorisation holders now report directly to EudraVigilance, rather than to individual national competent authorities, who instead access the ICSRs via EudraVigilance;
- better detection of new or changing safety issues, enabling rapid action by regulators to protect public health;
- better searchability and more efficient data analysis based on the use of the ISO/ICH agreed standard for ICSRs and new query functions;
- increased system capacity to support large volumes of users and reports;
- greater transparency in safety monitoring and much greater access to data and information for patients and healthcare professionals;
- more efficient collaboration with the World Health Organization (WHO), with EMA making all ICSRs originating in the EEA directly available from EudraVigilance to the WHO Uppsala Monitoring Centre (UMC).

Stakeholders were supported through the process with a change management plan developed through the PRAC. Support included regular webinars, an on-line training module, and the opportunity for system testing prior to the go-live. EMA also ensured all relevant guidance was updated, including Good Pharmacovigilance Practice on reporting suspected adverse drug reactions and the detection and management of safety signals.

1.3. Contributing to animal and human health in relation to veterinary medicines

EMA and the EU national competent authorities safeguard animal health in the 28 EU Member States, as well as in the European Economic Area countries, by ensuring that all medicines available on the market are safe, effective and of high quality.

In 2017, EMA's veterinary medicines activities focused mainly on the availability of new veterinary medicines, particularly for minor species, facilitating research and innovation for the benefit of animal welfare and the continued fight against antimicrobial resistance (AMR).

The Agency provided support to the European Commission in the drafting of the new veterinary regulation. One of the aims of the new legislation is to simplify administrative processes and this will have a considerable impact on the Agency operations. In preparation for this, EMA completed a review and streamlining of its major business processes, as a first step towards a leaner administration, and to ensure efficiency in meeting the increased demand that is expected to arise from the new legislation.

1.3.1. Facilitating availability of new veterinary medicines

New development guidelines for medicines for minor use/minor species or limited markets

In April 2017, EMA adopted a set of revised guidelines that clarify the data needed to support an application for a marketing authorisation for veterinary medicines intended for minor uses and minor species (the so-called MUMS) and limited markets. The revision is part of the overall strategy of the Agency's Committee for Medicinal Products for Veterinary Use (CVMP) to encourage development of veterinary medicines for diseases that occur infrequently or in limited geographical areas in major species and for minor species. These medicines may otherwise not be developed under the current market conditions.

Clarifying requirements for field trials for vaccines

At its November meeting, the CVMP accepted recommendations to help applicants understand cases in the authorisation of veterinary vaccines in which a justification to omit field efficacy studies (i.e. studies in animals under real-life conditions in the field) would be acceptable. Improving clarity on this topic will facilitate the availability of veterinary vaccines in the EU.

These recommendations were made by the joint EMA and HMA Steering Group on veterinary vaccine availability on the basis of the outcome of a joint EMA/HMA stakeholder focus group meeting, held in June 2017. They come in the context of a joint action plan to facilitate timely access to the EU market for new or improved veterinary vaccines, in the interest of animal and public health and animal welfare.

Supporting activities for development of medicines for fish

In July 2017, regulatory barriers and solutions for improving the availability of fish medicines were discussed in a meeting with the FishMed Plus Coalition. The topics covered ranged from the authorisation of new products, extension of use of already authorised products, and stimulation of interest in marketing medicines for fish.

1.3.2. Encouraging research and innovation in veterinary medicines

Interest and research activities into novel therapies for animals such as cell-based or gene therapy techniques have gathered speed over the last few years. The term 'novel therapies' in this context refers to therapies that are either genuinely new, or new only to the veterinary domain, although often well-known in the context of human medicines. Additional guidance from regulators is often needed in these areas to help stimulate development in these new fields.

Stem cell therapies – priority area for guidance

In June 2017, the Agency approved the first ever guidance at EU level for stem-cell based medicines for veterinary use. The guidance addresses the concerns raised by manufacturers and authorities in regard to the sterility (absence of bacteria, fungi and mycoplasma), tumorigenicity and management of extraneous agents of specific stem cell therapies in the veterinary sector. It was prepared by the CVMP's Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT).

First guidance for veterinary monoclonal antibodies

Another priority area for guidance is the monoclonal antibodies for use in animals. The first guidance document in this area was published in December 2017.

Monoclonal antibodies are bioengineered molecules that recognise and bind to a specific target protein, and have not been used in veterinary medicines until recently. In human medicine, these therapies have been authorised for many years for use against cancer and diseases affecting the immune system, such as rheumatoid arthritis. Therapies that are new to veterinary medicine face particular

challenges since regulatory guidance remains yet to be developed once more experience has been gained.

1.3.3. Fighting antimicrobial resistance – the holistic 'One Health' approach

Antimicrobial resistance (AMR) is an increasingly serious threat to global public health, affecting both people and animals. No country or organisation can face the challenge of antimicrobial resistance alone, so it requires coordinated action across all government sectors and society.

EMA supports a 'One Health' approach, promoting a close and integrated cooperation between the human and veterinary fields.

The Agency is collaborating with the European Commission (EC), the European Centre for Disease Prevention and Control (ECDC), and the European Food Safety Authority (EFSA), to develop and implement the initiatives set out in the European Commission's new 'One Health' action plan against AMR, launched in 2017. In recognition of this joint work, EMA together with its EU partners was shortlisted in the category 'Excellence in collaboration' for the first EU Ombudsman award.

An information session organised by EMA and ECDC was an opportunity to review the present challenges with AMR and the various ongoing initiatives at EU level to tackle the threat. The event brought together representatives of the WHO, the EC, EU Member States, patients' organisations, and healthcare professionals.

Promoting responsible use of antimicrobials in animals

In 2017, EMA launched a public consultation on a reflection paper on the use of aminoglycosides in animals, to critically review the current knowledge on the usage of these medicines and the potential impact on animal and human health.

A consultation was launched on the off-label use of antimicrobials in veterinary medicine. The purpose of this consultation was to define off-label use and to better understand the underlying reasons for existing veterinary practices in relation to the use of antimicrobials.

In January 2017, EMA and EFSA published a joint opinion on measures that the EU must take to reduce the use of antimicrobials in animals. The measures, recommended by the two agencies, include the setting of national targets to minimise the use of antimicrobials, implementing farming practices that help to prevent diseases, and considering alternative farming systems that could reduce the use of antimicrobials.

Collecting data for evidence-based policy-making

ESVAC report 2017

The 2017 results of the annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on the sales of veterinary antibiotics were encouraging. Between 2011 and 2015, the sales of antibiotics for animal use decreased overall by 13% in the 30 participating countries. The report also highlighted that the situation in the EU remains variable: despite an overall decrease in use, eight countries reported an increase of 5% or more. However, the report gives reasons for optimism that the substantial reduction of the sales of antimicrobials for food-producing species observed in some countries could serve as a model for other Member States.

Assessing progress regarding reduction of antimicrobial resistance and antimicrobial consumption

In October 2017, ECDC, EFSA and EMA recommended a set of indicators to measure progress of Member States in reducing the use of antimicrobials and combatting AMR. The indicators address both

the human and animal sectors and reflect antimicrobial consumption and antimicrobial resistance in the community, in hospitals, and in food-producing animals. The indicators are based on data already gathered through existing EU monitoring networks.

JIACRA report: more evidence on the link between antibiotic use and antibiotic resistance

In July 2017, ECDC, EFSA and EMA published an updated version of their Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report.

The report confirmed the link between antibiotic consumption and antibiotic resistance in both humans and food-producing animals. It highlighted that there are still important differences across the EU in the use of antibiotics in animals and humans.

Overall antibiotic use is higher in food-producing animals than in humans, but the situation varies across countries and classes of antibiotics.

In particular, a class of antibiotics called polymyxins – which includes colistin – is used widely in the veterinary sector. Recommendations were made to reduce animal use of such antibiotics, which are increasingly used in hospitals to treat multidrug-resistant infections.

Other antibiotics are more often used in humans than in animals. These include third- and fourth-generation cephalosporins and quinolones, antibiotics that are also considered critically important for human health.

1.4. Optimising the operation of the network

To ensure that the European Union's medicine system protects human and animal health, EMA works closely with more than 50 national competent authorities in the European Economic Area (EEA), with the European Commission, and a broad range of stakeholders, including patients and consumers, healthcare professionals, academia, and the industry.

It is essential that this network responds, in a timely and effective way, to technical and scientific developments as well as new public health challenges, such as shortages of medicines. Hence, the Agency makes steady efforts to strengthen the network and to engage better with all categories of stakeholders. This is now more important than ever as the EU medicines network has to prepare for the United Kingdom's withdrawal from the European Union and the consequent redistribution of work currently performed by the UK.

1.4.1. A stronger European medicines network for European citizens

By working closely together in a network, EMA, the European Commission and Member States reduce duplication, share the workload, and ensure the efficient and effective regulation of medicines across the EU. The Agency operates at the heart of this network, coordinating and supporting interactions between its members.

Joint task force to ensure availability of medicines in the EU

Shortages of medicines are an increasing problem in Europe and have been recognised by HMAs and EMA as an area of great concern, affecting all stakeholder groups.

Such shortages have an impact not only on the supply chain, but ultimately on healthcare systems, resulting in a significant impact on end users. They can lead to medicines rationing, delay of critical treatments, and the use of alternatives that may be less efficacious or that can increase the risk of medication errors and lead to adverse events. With respect to veterinary medicines, shortages may in addition cause concern for animal health and welfare, in cases where alternative medicines do not exist or are not marketed.

The causes of shortages vary and include economic factors (e.g. pricing differences leading to parallel distribution and depletion of medicine in one market; lack of reimbursement, or company decision not to market medicine), problems in manufacturing, and quality issues (e.g. non-compliance with good manufacturing practice).

To tackle this issue, EMA and the Heads of Medicine Agencies (HMA) created a joint task force in December 2016, to develop and coordinate the necessary actions to help guarantee uninterrupted supply of human and veterinary medicines. The work of the Task Force covers both human and veterinary medicinal products, regardless of their authorisation route (centralised, decentralised, mutual recognition or purely national procedure), in the following cases:

- when medicines are authorised but not marketed (or no longer marketed);
- when authorised medicines are affected by supply chain disruptions that directly prevent their availability. Such disruptions may occur due to GMP, GCP and/or GDP problems, quality defects, etc.

The Task Force is composed of three Thematic Working Groups (TWGs), tackling the problem from the three critical angles: marketing authorisation, supply chain disruptions and communication.

Its main purposes are:

- to assess why authorised medicines are not marketed in EU Member States;
- to establish causes of shortage / supply chain disruption and metrics for better shortage management;
- to develop communication strategies within the network and with other actors in the healthcare system during shortages.

The Regulatory Science Observatory

EMA set up its new Regulatory Science Observatory (RSO) to identify and meet emerging trends in science and technology and promote the strategic application of science in the regulation of the pharmaceutical products.

As one of its first major actions throughout 2017, the RSO surveyed key trends in science, technology and regulatory tools that can impact the operations of EMA. The aim was to better understand if and how these trends influence EMA operations, assess the current level of network engagement and make preliminary recommendations for future engagement. A report resulting from this exercise will be finalised in 2018. It will serve as a reference source to support the development of a Regulatory Science Strategy.

Use of big data to improve human and animal health

In 2017, EMA and the national competent authorities (NCAs) established a new task force to explore how big data can be used to support research, innovation and robust medicines development for the benefit of human and animal health. The task force kick-off meeting took place on 6 March 2017.

The term 'big data' refers to large sets of information which require specialised computational tools to enable their analysis and exploitation. These data might come from electronic health records from millions of patients, genomics, social media, clinical trials, or spontaneous adverse reaction reports, to name just a few.

The task force, chaired by the Danish Medicines Agency and EMA, is composed of experienced staff from medicines regulatory agencies in the network. Their efforts are complemented on an ad hoc basis by external experts in big data collection and analysis. A mandate for the group with a set of deliverables has also been agreed.

Strengthening safety monitoring through better use of real-world evidence

Analysis of data of medicines in the 'real world', i.e. in normal conditions of use, has the potential to support regulatory decision-making throughout the product life-cycle. Up until now, such use of real-world data has mainly focused on monitoring the safety of products on the market. In 2017, EMA continued to support benefit-risk evaluations of medicines made by the PRAC and other committees, by analysing data on the drug utilisation and safety of medicinal products in real-world clinical use. Such support included:

- A collaborative study on the utilisation of codeine for the treatment of pain in children to assess the effectiveness of risk minimisation measures introduced in October 2013; the collaboration included the Spanish Agency for Medicines and Medical Devices (AEMPS), the UK Medicines and Healthcare products Regulatory Authority (MHRA) and EMA.
- Several studies conducted in-house by EMA with databases of electronic health care records (the THIN database) and claims data (the IMS database) among which:
    - valproate: trends in prescribing in bipolar disorder in France, Germany and UK;
    - tramadol: patterns of drug utilisation in France, Germany and UK;

    - fluoroquinolones: nested case control study on tendon ruptures;
    - levonorgestrel-containing intra-uterine devices: cohort study on psychiatric adverse events
- Two EMA-funded studies assessing the effectiveness of the risk minimisation measures for diclofenac and hydroxyzine were launched in 2017 through procurements to academic centres.
- Five other studies were on-going.

A review of EU-funded initiatives linked to real-world evidence was performed to determine whether their outputs could be used as resources for the generation of real-world data able to support regulatory decision making on medicines. Of 171 initially identified EU-funded initiatives, 65 were selected and characterised.

In parallel, a review of electronic healthcare databases available in Europe was performed to identify the data sources considered adequate to respond to regulatory questions on the benefit-risk of medicines. Out of 77 data sources, 34 were retained for further investigation and fully described.

EMA has continued to support the registration of post-authorisation studies in the EUPAS Register, which included more than 1,200 studies by the end of 2017, and represents one of the largest inventories of observational studies in the world.

Increasing the utility of patient registries in regulation

Post-authorisation studies based on patient registries are frequently requested by the EMA Committees to support the monitoring of the safety or efficacy of marketed drugs in the real world. However, regulators and pharmaceutical companies often face challenges in using existing registries or establishing new ones. For this reason, in 2015, EMA launched a patient registry initiative to support a more systematic approach to the contribution of existing disease registries to the benefit-risk evaluation of medicines. In 2017, EMA defined a vision, strategy and workplan for the patient registry initiative and organised two workshops with concerned stakeholders on cystic fibrosis registries and multiple sclerosis registries.

In order to increase transparency on disease registries which are used or may be used for regulatory purposes, EMA also initiated the registration of multinational disease registries in the ENCePP resource database. By the end of 2017, the inventory included a total of 66 disease registries.

Optimisation of referrals as a regulatory tool to ensure best possible outcomes for public health at EU level

In 2017, HMA approved a proposal to initiate a strategic reflection on how to optimise the use of referrals amongst existing regulatory tools, to ensure the best possible outcome for public health at EU level, to better manage reputational aspects, and to ensure the best and proportionate use of EU network resources. This initiative is supported by CHMP, PRAC and CMDh.

The aim is to develop, with CHMP/PRAC/CMDh, mechanisms to support an early dialogue and to reinforce awareness throughout the Network through case studies and lessons learned. Topics will include triggering of referrals, their evaluation, and the subsequent implementation of the referral outcomes.

The EU Network Training Centre

Evolving science and technology requires the network to keep its knowledge and expertise continuously up to date in order to meet new regulatory challenges. The EU Network Training Centre (EU NTC) provides a central platform for the supply of scientific and regulatory training practices between EMA and national competent authorities in the EEA, to ensure the spread of good practices and improve the work done in the EU regulatory network.

This involves:

- using and coordinating the expertise in the network to create training curricula;
- supporting the organisation of training sessions to fill existing knowledge gaps;
- centralising training offers from EMA and the national authorities in the regulatory network into one training catalogue.

The offer in the EU NTC catalogue increased from 48 courses in 2015 to 100 courses in 2017. The EU NTC Learning Management System (LMS), a digital training platform, is available to network staff in all 28 Member States. Following a successful pilot phase, the LMS was fully implemented in January 2017.

Multinational assessment teams – broader involvement of national authorities in the work of EMA's scientific committees

A multinational assessment team, in which experts from several national agencies work together (rather than a single country being assigned with all the responsibility), allows wider involvement of national competent authorities in the work of the EMA scientific committees and optimises the use of national resources, whilst maintaining the high-quality scientific work of the committees.

This initiative is available to all Member States, and it applies to:

- rapporteurs and co-rapporteurs;
- rapporteurs for maximum residue limit applications;
- coordinators for scientific advice procedures for both human and veterinary medicines.

As of April 2017, EMA expanded the multinational assessment team initiative to post-authorisation assessments, which means that these teams can be used for the assessment of extensions of marketing authorisations for existing medicines. In the first phase, it applies only to the multinational teams that were used for the initial marketing authorisation evaluation.

Data gathering initiative

The data gathering initiative concluded in 2017. The Management Board started this initiative in 2014 to gather evidence needed by the European Commission to support a future re-draft of the legislation governing the fees charged by the Agency. The Data Gathering Steering Group was set up with the primary objective to gather information on the time spent by staff, both within the EMA secretariat and across the network of national competent authorities regulating medicines, on the range of procedures and activities relating to the regulation of human and veterinary medicines. In adopting the final report from the group, the Management Board considered that the data collected were a useful insight into the work of the network and could inform the ongoing debate as to how the medicines regulatory system in Europe is resourced sustainably.

Crisis simulation exercise coordinated by EMA in October 2017

In October 2017, the Agency coordinated a crisis simulation exercise, together with the European Commission and NCAs, to test processes and procedures in place to deal with major incidents which could have a serious impact on public health. The simulation focused on a fictitious human medicines

safety issue and based on the findings, EMA will consolidate relevant procedures and guidance. The lessons learned from the running of the crisis simulation exercise cover areas such as: process streamlining, communications and interactions, memberships, technical considerations.

1.4.2. Management of the network technical systems

EMA looks after the IT systems connecting all parties in the network. They facilitate important exchanges of information on aspects such as safety monitoring of medicines, authorisation and supervision of clinical trials, and compliance with good manufacturing and distribution practices.

Management Board adopts new Information Management strategy to 2020

At its December 2017 meeting, the Agency's Management Board adopted a new Information Management strategy in the light of EMA's relocation. The strategy outlines the priority actions necessary for relocation, in order to maintain and improve operational excellence and deliver effective information services throughout the process.

EMA's Cloud strategy

In early 2017, EMA decided to adopt cloud computing as a core element of its Information Management strategy, after a period of extensive research and consultation with the network and with stakeholder groups. Cloud computing is the delivery of IT services – servers, storage, databases, networking, software, analytics and more – over the internet ('the cloud'), as opposed to being provided from an organisation's own servers.

EMA will only adopt cloud solutions where feasible and where they add value. The first cloud service implemented at the Agency is a document repository for individual case safety reports submitted via the new EudraVigilance system.

Towards better digital identification of medicinal products – the SPOR project

EMA is currently implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). The ISO IDMP standards provide data elements, formats, and terminologies to unambiguously identify medicines and exchange information about them.

To facilitate the implementation of these ISO IDMP standards, EMA is delivering a set of master data management services **for the four domains of master data in pharmaceutical regulatory processes:** substance, product, organisation and referential (attributes such as pharmaceutical form and route) data. These four domains, or areas, are known collectively as SPOR.

The first two services, the Referentials management service (RMS) and Organisations management service (OMS) were launched in June 2017 to cover two out of four SPOR domains. This did not immediately change any regulatory submission processes, apart from the use of OMS in electronic application forms for marketing authorisations holders. However, EMA is consulting stakeholders on the benefits of using the SPOR services to support different regulatory procedures (e.g. simplification of Type IA variations).

1.4.3. Always in touch with stakeholders

EMA's first public hearing

On 26 September 2017, EMA held its first ever public hearing. This new tool for citizen engagement was introduced by the EU's pharmacovigilance legislation. It enables the Pharmacovigilance Risk Assessment Committee (PRAC) to hold public hearings during certain safety reviews of medicines, to

support its decision-making by providing perspectives, knowledge and insights into the way medicines are used.

Public hearings are held on a case-by-case basis, where PRAC determines that collecting the views of the public would bring added value to its review, in addition to the other channels of stakeholder engagement, such as stakeholder submissions or through inclusion of patients and healthcare professionals in expert meetings.

EMA's first public hearing gave patients, carers, doctors, pharmacists and academia a chance to share their experience with valproate - a medicine that treats epilepsy, bipolar disorder and migraine. The public hearing was part of a review of the safety of valproate in women and girls who are pregnant or of childbearing age. Malformations and neurodevelopmental problems can occur in babies who are exposed to valproate in the womb and the review followed concerns that current EU-wide measures to reduce the risk were not sufficiently effective.

The hearing gave an opportunity to EU citizens to make their voices heard to complement the available scientific evidence in the evaluation of this medicine. The total number of attendees was 65, including 28 patients and patient representatives, 19 healthcare professionals and academics, 11 from the pharmaceutical industry, and 7 from the media. There were a total of 25 speaker contributions, grouped into 16 speaker slots.

The speakers came up with important ideas for new risk minimisation measures, such as including visual reminders of the risks on the outer packaging of valproate medicines and promoting the need for regular treatment reviews for all women receiving valproate long-term, to ensure that in future no woman taking this medicine is unaware of the risks.

All input received during the hearing was taken into account by the PRAC in its assessment of valproate.

EMA steps up interaction with academia

In April 2017, EMA launched its new framework and action plan with academia, to formalise, structure and further develop interactions with this important stakeholder group.

The framework's overall objectives are to:

- raise awareness of the mandate and work of the European medicines regulatory network, in order to increase academia's trust in and engagement with the regulatory system;
- encourage the translation of academic research into novel methodologies and medicines which meet regulatory standards and address needs of public and animal health;
- ensure that the best scientific expertise and academic research are available in time to support effective evidence generation, regulatory advice and guidance, as well as decision-making in regulatory processes;
- work with academia to develop regulatory science that embraces scientific progress in medicines development without compromising patient safety, such as the use of novel endpoints or novel methodologies.

Along with the framework, EMA has developed an action plan which includes, among other activities, initiatives for mutual education and training, staff exchange programmes to promote mutual learning, a strategic research agenda for regulatory science, and the creation of an EMA entry point for academia to receive information on available support within the EU Regulatory Network.

Involving young people in EMA activities

Young patients and consumers can make an important contribution to committee discussions on medicines by sharing their experience and perspectives of living with a disease or condition.

In 2017, EMA agreed on principles for involving patients and consumers under the age of 18 in the activities of its scientific committees and working parties. The principles define what input young people could provide, and suggest options on how best to capture their opinions. They also establish a process for identifying, supporting, and consulting with young people.

According to the new principles, involving young people in the Agency's activities will be considered on a case-by-case basis, when it is expected that their views could enhance scientific discussions related to the development and assessment of medicines for children and adolescents.

The key forum in which young people could participate in the Agency's activities would be its Paediatric Committee (PDCO), but experience has demonstrated that the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC) and the Scientific Advice Working Party (SAWP) can also benefit from young people's input when these groups review medicines for children.

New guide on biosimilar medicines for healthcare professionals

EMA and the European Commission published an information guide for healthcare professionals on biosimilar medicines. Biosimilars are biological medicines that are highly similar in all essential aspects to a biological medicine that has already been authorised. To date, the Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended 28 biosimilars for the use in the EU.

The objective of the guide is to provide healthcare professionals with reference information on both the science and regulation underpinning the use of biosimilars.

The guide was developed in collaboration with EU scientific experts, in response to requests from healthcare professionals. Organisations from across the EU representing doctors, nurses, pharmacists and patients contributed, to ensure that the guide adequately addresses questions relevant to healthcare professionals.

Access to clinical data - one year on

The 20 October 2017, marked the first anniversary of EMA's ground-breaking transparency initiative to publish clinical reports underpinning the market authorisation of new medicines for human use. This enables citizens, including researchers and academics, to directly access these reports via EMA's clinical data publication (CDP) website**.**

EMA is the first regulatory authority to provide such broad access to clinical reports.

As of the end of 2017, clinical reports on 55 medicines, including orphan, biosimilar and generic medicines, as well as medicines for use in children, are publicly available on the CDP website. This amounts to 3,583 clinical documents, totalling more than 1.3 million pages.

Published data have attracted a total of 2,361 new users (1,877 general and 484 non-commercial research users), resulting in 29,232 document views and 96,977 document downloads for non-commercial research purposes.

A 2017 survey of the users of the website, such as researchers, healthcare professionals, patients and industry, showed that three quarters of responders agreed that the publication of clinical data builds public trust and confidence in EMA's scientific and decision-making processes. Two out of three responders agreed that the data made available help researchers to re-assess the clinical data.

62% of the users said that the data are useful, and 87% confirmed that the data are presented in an understandable format, despite the redaction or anonymisation of certain information, in line with European legislation on commercially confidential information and personal data protection.

Outcome of the EMA survey on centralised initial marketing authorisation procedure 2016/2017

In September 2016, the Agency launched a tripartite survey (EMA-industry-rapporteurs) on the centralised initial marketing authorisation application (MAA) procedure, to collect feedback on the performance of the procedure and on the level of satisfaction. A similar survey targeting EMA and industry on centralised post-authorisation procedures was conducted in April 2015. The questions covered procedural- and content-related topics and queried stakeholder satisfaction.

Overall, the survey showed that there is a high level of satisfaction from respondents (CHMP (co)-rapporteurs, EMA staff and applicants) across all phases of the procedure in terms of quality and timeliness of interactions. In terms of content, the assessments reports, questions and major objections were considered clear, well-justified and of high quality, whilst submissions were in the majority of cases adherent to the scientific advices received.

The survey identified some areas that would benefit from optimisation from both a procedural point of view and for the applicants to improve the quality and presentation of their dossiers.

Reporting irregularities that may affect safety of medicines

At its March 2017 meeting, EMA's Management Board adopted a new policy to handle allegations of improprieties submitted by external parties, to complement the existing policy on whistleblowing applying to the Agency's staff.

The goal of the new policy is to create an environment where individuals from outside the Agency feel confident to raise their concerns on improprieties. The policy helps EMA assess these reports and co-ordinate any further investigation in a structured way, while protecting the identity of the reporter.

Since 2013, EMA has received a total of 43 reports that relate, for example, to the manufacturing of medicines or the conduct of clinical trials. Since March 2017, citizens can raise their concerns by sending a message or providing information to the address 'reporting@ema.europa.eu'. They can also send a letter to the Agency. Their identity is kept confidential.

1.5. Regulatory collaboration to improve global health

A central pillar in EMA's strategy to protect public health is the strengthening of collaboration with other international regulators. In 2017, the Agency continued to work with its partners in Europe and beyond, to contribute to the health of EU citizens and people around the world.

1.5.1. Bilateral interactions with non-EU regulators

The Agency has existing confidentiality arrangements with the Therapeutic Goods Administrations (TGA) in Australia, Health Canada (HC), the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, and the Food and Drug Administration (FDA) in the United States (US). Interactions with these authorities take place almost daily, partly structured around clusters of activities and partly *ad hoc*.

A new milestone in EU-US relations

On 1 November 2017, the mutual recognition agreement between the EU and the United States (US), recognising inspections of manufacturing sites for human medicines conducted in their respective territories, became operational. This agreement, which updates an agreement from 1998, allows for recognition of each other's inspection outcomes and hence for better use of inspection expertise and resources.

In June, the European Commission confirmed that the US Food and Drug Administration (FDA) has the capability, capacity and procedures in place to carry out good manufacturing practice (GMP) inspections at a level equivalent to the EU. The FDA confirmed the capability of eight EU Member States (Austria, Croatia, France, Italy, Malta, Spain, Sweden, and United Kingdom). The remaining EU inspectorates will continue to be assessed until 15 July 2019.

The new agreement allows EMA and the FDA to make decisions based on findings in each other's inspections. It is a major milestone towards closer cooperation which improves the use of available resources to safeguard quality and safety of medicines.

The agreement will avoid duplication, reduce costs and enable the regulators to focus on manufacturing sites in parts of the world where there is greater risk. Around 40% of finished medicines marketed in the EU come from overseas, and 80% of the manufacturers of active pharmaceutical ingredients for medicines available in the EU are located outside the Union.

New EMA-Japan fellowship programme

In 2017, EMA, MHLW and PMDA agreed to establish a fellowship programme based on the model of EMA's fellowships with the FDA. The first EMA fellow visited Japan in October. She focused on procedural aspects of the marketing authorisations, from the pre- to post-authorisation stages and aims to, among other aspects, improve understanding of the work and decisions taken by both agencies and deepen effective collaboration in strategic areas.

EMA also hosted a meeting with PMDA and FDA to discuss regulatory approaches for the evaluation of antibacterial agents. For more information, please see section on 'Contributing to animal and human health in relation to veterinary medicines'.

1.5.2. Multilateral work

In 2017, EMA continued to cooperate in a multilateral context with organisations such as:

- World Health Organisation (WHO)
- The International Council on Harmonization (ICH)
- International Coalition of Medicines Regulatory Authorities (ICMRA)/ICDRA)
- International Pharmaceutical Regulators Forum (IPRF)
- International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)

1.5.3. European cooperation as a model for Africa

A delegation from the East African Community (EAC) visited the Agency in May 2017 as part of EMA's ongoing collaboration with African regulators. The goal of the meeting was to gather information and experience to support the potential creation of a networking medicines agency for the EAC.

The delegation included the heads of national agencies from the EAC Partner States (Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda), as well as representatives from the World Health Organization and the World Bank Group. Participants discussed the structure and operations of EMA as a model for a regional networking agency that could coordinate the work of the national regulatory agencies in the assessment of human and veterinary medicines.

A workshop with the Committee for Medicinal Products for Human Use (CHMP) and African regulators in March 2017 looked at how to promote reliance on the scientific output of the CHMP, and in particular the Agency's 'Article 58 procedure' for global health products intended for use outside the EU. The workshop was organised with the support of the Bill and Melinda Gates Foundation.

1.5.4. Promoting awareness of the EU regulatory system

In September 2017, the Agency organised, for the first time, a two-day awareness session for international regulators and non-governmental organisations (NGOs) on the European medicines regulatory network and EMA's role. Sixty regulators from non-EU European, African, Asian and American countries and several international NGOs attended the session. Based on the positive feedback received, EMA will organise further sessions.

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 2017 forecast/target
	Results within +/- 10% of the 2017 forecast/target
	Results 10%~25% below the 2017 forecast/target
	Results more than 25% below 2017 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, or calls reopened due to incorrect handling, 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 1 to 0 (or rising from 0 to 1) 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.

To be noted that some of the activities listed in the following sections had to be delayed or postponed due to resource reallocation linked to the relocation of the Agency or external circumstances.

Evaluation activities for human medicines

Pre-authorisation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Scientific advice/protocol assistance pre-submission meetings	137	89	117	120	118
Scientific advice and protocol assistance requests, of which:	551	510	582	632	630
Parallel scientific advice with international regulators	2	3	6	5	3
Joint scientific advice with HTA bodies	11	30	23	30	29
Post-authorisation scientific advice	122	89	148	130	144
Scientific advice for PRIME products	n/a[1]	n/a [1]	4	22	28
Protocol assistance requests	113	137	126	144	159
Novel technologies qualification advice/opinions	22	20	14	20	19
PRIME eligibility requests	n/a[1]	n/a[1]	84	90	81
Scientific advice finalised	432	386	439	484	490
Protocol assistance finalised	101	139	122	144	156
Orphan medicines applications, of which:	329	258	329	277	260
Parallel orphan applications with international regulators	109	86	96	70	55
Submitted applications on the amendment of an existing orphan designation	0[2]	1	4	4	2
Oral explanations for orphan designation	-[3]	-[3]	87	90	80
Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	485	515	549	550	630
Finalised procedures for compliance check on PIPs	85	67	73	70	67
Annual reports on paediatric deferred measures processed	155	172	189	170	197
EMA paediatric decisions processed	345	319	369	350	402
Requests for classification of ATMPs	28	61	60	50	46
Innovation Task Force briefing/meeting requests	27	35	41	25	33
Innovation Task Force Art 57 CHMP opinion requests	5	0	2	0	

[1] PRIME initiative was launched in March 2016.
[2] New procedure established in 2014, following the revision of EC guideline on format and content of orphan applications.
[3] New indicator introduced in 2016 work programme.

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	Scientific advice/protocol assistance procedures completed within regulatory timeframes	99%	100%	99.5%	100%	100%
	Products included in PRIME scheme (percentage of applications)	n/a[1]	n/a[1]	17.9%	20%	23.5%
	Orphan designation opinions delivered within the legal timeframe	100%	100%	100%	100%	100%
	PDCO opinions sent to applicants within legal timelines	99.7%[2]	99.7%[2]	99.5%[2]	100%	99.75%
	Increase in scientific advice requests	17%	-8%	14%	0%	8%
	SME requests for scientific advice (percentage of total SA requests)	24%	32%	30%	30%	31%

[1] PRIME initiative was launched in March 2016.
[2] Slight delays incurred due to re-examination (1 opinion in 2014, 1 opinion in 2015, and 2 opinions in 2016).

Achievements

Objective	Activity	% complete	Achievements/results
Facilitate research and development of new medicines	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	80%	EMA provided continuous and structured input in IMI and H2020 funded research. The Agency published and implemented EMA approach to becoming involved with externally funded regulatory science, including signposting and structured input from ITF.
	Identify recurring questions in areas of highest potential benefit from science and innovation and develop the relevant Q&A or regulatory guidance documents	70%	The ambition to use the Business & Analysis Forecasting function more structurally, to support operational activities based on questions coming to, and issues identified at Business Pipeline meetings, is being achieved. There is still room to further streamline this activity and further improve awareness across the Agency. To some extent this is a moving target, especially in a Brexit situation, in the sense that the business requirements may change. Therefore, we foresee the need to further develop this activity over the next two years. Supporting the development of innovative medicines through the ITF, and signposting to

Objective	Activity	% complete	Achievements/results
			opportunities for more structured interactions with regulators, appears to be working: an increasing number of H2020 funded projects have come through ITF and scientific advice; CRISPR and gene editing have resulted in a workshop with follow up on guidance, classification and one company coming to SA. Topics identified in ITF intelligence gathering are being translated into concrete deliverables, e.g. concept paper for companion diagnostics and educational initiatives to help ensure regulatory preparedness for assessment (organ on a chip, gene editing). Additionally, enhanced interaction with the relevant stakeholders helped increase awareness of regulatory requirements.
	Based on the horizon scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, and involving NCAs, to address specific areas for innovation	50%	The seventh 'Framework Programme (FP7) small-population research methods projects and regulatory application' workshop (ASTERIX, IDeAl and InSPiRe projects) was held in March. EMA-FDA-Health Canada workshop on paediatric Pulmonary Arterial Hypertension was held in June. EMA co-lead the gene editing workshop with CAT and PGWP.
	Strengthen collaboration and integration across the Network and with academia to facilitate translation of innovation into medicinal products, including through the work undertaken by the Innovation Network	80%	The framework for interaction with academia was finalised and adopted in March 2017. Two ITF briefing meetings were held with academia and the 'Innovation in medicines' section of the EMA corporate website, available from the academia landing page, was updated in 2017. A webinar to support academia interaction with regulators is available online, and various online documents have been updated to reflect a more streamlined and visible interaction of EMA, EU-IN and academia. Some fine-tuning is still anticipated in terms of better using ITF in support of externally funded regulatory science projects.
	Use business forecasting and analysis tools to better inform the EU Network about past and prospective development and improve regulatory preparedness	90%	A three-year forecast for initial marketing authorisation applications was provided to the Agency's scientific committees and HMA. Dedicated reports for ATMP, biosimilars, and Art. 58 scientific opinion were prepared in 2017.
	Establish a platform to review	30%	Following a review of current opportunities for

Objective	Activity	% complete	Achievements/results
	and explore opportunities for optimising activities and procedures during the development phase		interactions during the development phase at the R&D platform meeting of 15 November 2017, it was agreed to identify concrete examples that can support discussions on the planning of development interactions. The follow-up discussion will occur in 2018.
Ensure that the needs of specific populations are met, including the elderly, children, patients with rare diseases, and others	Hold an industry platform meeting focused on changes to the interpretation of the orphan legislation due to the new Notice from the EC	100%	The industry platform meeting was successfully held on 25 April 2017. Report on meeting highlights was published on the Agency's corporate website in May. A post-meeting feedback survey was also conducted and the results were presented to the EMA medicines leadership team in May.
	Implement the revised interpretation of the orphan legislation (via the Notice), including update guidance documents and website	100%	Regulatory Q&A has been updated with the relevant information. An additional figure for clarification on the process for reassessment will be published on the corporate website. Presentations were given at Euro DIA in March and the industry platform meeting in April. The SOP on maintenance was also finalised in 2017.
	Optimise applicant submissions for maintenance of orphan designation through introduction of pre-assessment review meetings	100%	Pre-assessment has been implemented as standard for all maintenance procedures since last quarter of 2016. SOP on maintenance has been updated with this information.
	Implement EMA geriatric medicines strategy	100%	'Reflection paper on physical frailty: instruments for baseline characterisation of older populations in clinical trials ' was adopted.
	Provide feedback to the EC regarding their 10-year report on the paediatric regulation Ensure interaction with the FDA and other regulators regarding future scientific and regulatory challenges	40%	10-year report on paediatric regulation: Feedback to the draft report was provided to the EC. Emphasis was put on the development of the recommended areas for action which conclude the report. EMA participated at TOPRA conference on the 10 year report (11/2017 Brussels). US FDA interaction: At the end of 2017, EMA hosted a colleague from the FDA in the framework of fellowships. The Paediatric Cluster TCs continues to be organised on a monthly basis, work is being done to increase the participation of PDCO members. There is a strong cooperation with the FDA colleagues also with respect to the upcoming list of molecular targets in paediatric oncology.
	Contribute to the activities of	50%	INC activities continued via the PDCO

Objective	Activity	% complete	Achievements/results
	the International Neonatal Consortium (INC)		neonatology working group. EMA contributed to a paper on co-enrolment of neonates in several trials and to a paper on long-term outcome in neonates.
	Complete EMA contribution to FP-7-financed projects Inspire, Asterix and Ideal on small population research methodology, and foster dissemination and application of the project results	100%	EMA contributed to the Seventh Framework Programme (FP7). The activity is considered completed.
	Contribute scientifically to the methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders	50%	The Gaucher document was adopted and published in 2017. Further activities are ongoing, specifically via the orphan cluster with the FDA.
	Develop and provide up-to-date training in Paediatric Medicines development for the EU-NTC Develop and implement strategy for regular update of the training	100%	The full EU NTC Paediatric Curriculum is now fully functional and accessible to the Network. This activity is considered completed.
	Complete the pilot of rare disease cluster with the FDA and conduct lessons learned	100%	The pilot of rare disease cluster with the FDA finished at the end of the year. Following a review of the results and lessons learned, it was decided to continue the cluster.
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle	Contribute to the activities of EUnetHTA under Joint Action 3, particularly to selected activities in work packages 4 (WP4, joint production) and 5 (WP5, evidence generation), including exploring opportunities for collaboration through observership at relevant discussions	50%	The engagement in the respective work packages of EUnetHTA Joint Action 3 in 2017 worked as planned. Specific for WP4, all three requests for collaboration at market entry stage have been fulfilled; for WP5, following the launch of the new Parallel Consultation platform, new requests for scientific advice with EMA and HTAs have been managed accordingly. Furthermore, two engagements in therapeutic area-specific registries have been completed.
	Develop and deliver a joint EMA/EUnetHTA work plan, covering the areas from horizon scanning, pre-and post-licensing evidence generation, as well as market entry	40%	The EMA/EUnetHTA work plan 2017-2020 has been finalised and published in November 2017. The regular monitoring occurs through the EMA/EUnetHTA bilateral meetings, including the most recent one on 15 December 2017.
Reduce time-to-patient of medicines through	Build Network capacity to support accelerated development pathways	75%	Quality working party and biologics working party have been liaising with industry stakeholders regarding the quality support to

Objective	Activity	% complete	Achievements/results
the use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	(including PRIME), with a focus on quality aspects on critical development path		PRIME. In 2017, an agreement was also reached to support more comprehensively the quality aspects, and directly embed those in the PRIME process. An ad-hoc group of experts has been established to provide general support and expertise to cases where accelerated CMC development is proposed.
	Provide scientific leadership to the ADAPT-SMART project	85%	Input from IAB was successfully received. All planned deliverables/documents were completed or are in draft stage.
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	Analyse experience with legislative provisions, identify gaps in regulatory framework and provide technical support to the EC and the Network in relation to optimising existing regulatory framework, including development and/or implementation of new or amended legislation	80%	A report on the Agency's ten years of experience with conditional marketing authorisation was published on the EMA corporate website in January 2017, and subsequently presented to various stakeholders. Two regulatory intelligence analysis on (1) regulatory provisions on significant benefit and related concepts and (2) the Agency's experience with Commission Regulation (EC) No 847/2000 - assessment of similarity vis-a-vis orphan medicinal products had been well advanced, completing the collection of necessary data. The completion of the analysis, with report to the relevant scientific committees, will be finalised in early 2018. Support was provided in December 2017 to the EC on revision of comments received during the second public consultation on the proposed revision of the Commission Regulation (EC) No 847/2000, with regard to the definition of 'similar active substance'. Contribution was provided to ongoing EC initiatives.
	Develop implementation strategy on companion diagnostics legislation and related guidance documents for the industry	70%	Concept paper on predictive biomarker-based assay development in the context of drug development and lifecycle was released for public consultation in July by PGWP. In 2017 The Agency actively participated in the in-vitro diagnostic technical group, to prepare implementation of the new in-vitro diagnostic medical device regulation.
Provide high-quality, efficient and consistent support to	Perform an in-depth review of quality data, needed to support the development of a biosimilar medicinal product in a targeted	20%	In February 2017, a pilot project to test the added value and feasibility of tailored scientific advice for the development path of biosimilar medicines was launched. Through this new

Objective	Activity	% complete	Achievements/results
medicines development	way		initiative, EMA aims to provide developers of biosimilars with advice on the studies/tests they should be conducting, on the basis of the quality, and analytical and functional data they already have available for the medicine. The first two biosimilar applications were received in scientific advice in the first half of the year. No applications were received in Q3 and Q4. The lack of uptake is currently being investigated. It is expected that an in-depth review will be performed following the full assessment of six procedures.

In addition to the above activities, a multi- stakeholder paediatric oncology strategy workshop (cancers with anaplastic lymphoma kinase aberrations) was held in January 2017, as part of the activities of the ACCELERATE platform (paediatric oncology). The second paediatric strategy forum on medicine development for mature B cell malignancies in children took place in November 2017.

Initial evaluation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Number of MAA pre-submission meetings	57	102	85	50	63
Initial evaluation applications, of which:	100	111	114	111	90
New non-orphan medicinal products	38	36	41	46	32
New orphan medicinal products	21	25	27	29	19
Similar biological products	3	12	12	16	17
Generic products, hybrid and abridged applications	37	37	31	18	15
Scientific opinions for non-EU markets (Art 58)	1	1	0	0	1
Paediatric-use marketing authorisations	0	1	1	2	2
Number of granted requests for accelerated assessment	12	17	12	10	10
Number of consultations of SAGs/Ad-hoc expert groups in the context of MAAs	14	7	8	10	14
Reviews on the maintenance of the orphan designation criteria at MAA stage	-[1]	-[1]	20	30	24

[1] New indicator introduced in the 2016 work programme.

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	Applications evaluated within legal timeframes[1]	100%	100%	99%	100%	100%
	Average assessment time for new active substances and biosimilars (days)	197	200.7	197.2	205	175.7
	Average clock-stop for new active substances and biosimilars (days)	166	138.4	136.1	180	136.9
	Requests granted for accelerated assessment	80%	73%	48%	70%	63%
	MAAs initiated under accelerated assessment that have been completed as accelerated assessment	-[2]	-[2]	43%[3]	70%	58%
	Initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	-[4]	82%	63%	80%	69%
	Labelling review of the English product information annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	-[2]	-[2]	97%	90%	95%
	Percentage of comments on product information submitted during assessment procedure and taken on board by assessors	-[5]	-[5]	-[5]	90%	95%
	Therapeutic guidelines progressed to the next step or finalised (percentage vs planned)	-[5]	-[5]	-[5]	70%	60%
	Early background summaries drafted and sent to assessment teams (percentage vs planned)	-[5]	-[5]	-[5]	100%	100%
	Percentage of outcomes/results of workshops on therapeutic objectives published on EMA corporate website	-[5]	-[5]	-[5]	100%	90%

[1] Includes marketing authorisation and plasma master file applications.
[2] New indicator, introduced in the 2016 work programme.
[3] In 2016, 11 MAA procedures were started under the accelerated assessment (AA). By 31 December 2016, 3 of these were completed as AA, and 4 had reverted to standard timelines. Four procedures were still ongoing and are not counted towards the result of the indicator.
[4] New indicator, introduced in 2015.
[5] New indicator, introduced in the 2017 work programme.

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound and consistent	Continuously improve the tools (guidance and databases) available to EMA staff supporting scientific evaluation	100%	The work on the improvements of the tools continued in 2017. Some of the improvements implemented include: expanded scope of early background summaries, so more products will

Objective	Activity	% complete	Achievements/results
scientific assessments of marketing authorisation applications	activities of the committees		have these; capturing accelerated assessment in SIAMED; discussions on changes to improve the dashboard, as well as simplifying risk management plan process and updating templates accordingly.
	Monitor the conduct of pre-submission meetings and continue optimisation towards improved support for the later evaluation	100%	Based on the outcomes of the survey on initial marketing authorisation, the content and format of pre-submission meetings were positively rated.
Embedding pharmacovigilance planning in clinical guidelines and improve the quality of risk management review and better use of resources	Develop and maintain guidance and other tools (training material, checklist, metrics), embedding pharmacovigilance planning in clinical guidelines, supporting risk management planning and stakeholder interaction	100%	GVP V, XVI, and risk management plan template updates for industry were completed during 2017. GVP V was fully delivered, including training. ATMP guideline were adopted and released for public consultation.
Ensure and run highly effective and efficient processes to deliver initial evaluation activities	Streamline and strengthen the process of input by Quality Working Party and other quality of medicines working groups to the relevant parts of assessment report	90%	Biologicals working party pilot of the CHMP assessment report templates, via the BWP report to CHMP on procedures, was concluded in 2017. The QWP and BWP adopted the overview template, which has been published and is now being implemented in ongoing procedures.
	Optimise and embed in the Agency the process performance management system with strong customer focus on quality, simplification, and regulatory procedural excellence	100%	Process-focused communities were established in September 2016 for each regulatory evaluation procedure for human medicinal products (initial applications, quality variations, non-clinical - clinical variations, PSURs, referrals) under the lead of each process owner. Process owners and process champions are responsible for ensuring consistency in the way the Agency handles evaluation procedures and in the type of regulatory advice provided to MAHs and rapporteurs, identifying opportunities for simpler ways of working, knowledge sharing, and monitoring KPIs. Each process-focused community meets monthly and, so far, these communities have delivered multiple updates of Q&As, process simplifications, and template updates and checklists development. The Agency has now embedded these

Objective	Activity	% complete	Achievements/results
			communities in its operations. The preparation of a report on the experience gained has been deprioritised.
	Improve guidance and provide internal and external training to ensure regulatory procedural consistency	100%	Internal training on the new accelerated assessment process was delivered. Delegations from two Member States (SE and NL) were hosted in Q1 2017 to better understand the Agency's internal processes that support evaluation procedures and the interfaces with the Network.
	Establish an internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs	100%	Process-focused communities that were established in September 2016 continued to act as a knowledge sharing system. In 2017, monthly case studies were shared, and contributions were made to the internal knowledge sharing bulletin.
	Deliver workflow/case management solutions to reduce the Agency's and Network's administrative burden and to facilitate collaboration using online tools	0%	The project has been deprioritised.
	Develop regular interactions with industry, HTAs and HCPs to promote the operations of the evaluation activities and engage with industry in their optimisation	100%	Following a pilot of webinars with HTA in the first part of the year, the implementation of the production phase was rolled out in the second half of the year. Survey on initial marketing authorisation was analysed and presented to committees and industry at industry platform in July. The results of the survey were considered for improvement actions.
	Create a platform for collaboration with NCAs, to understand level of satisfaction and identify improvement opportunities	0%	This activity has been put on hold due to reprioritisation of other activities.
	Simplify the handling of generic applications, to increase the capacity while maintaining quality	10%	A survey on initial Marketing Authorisation Applications with applicants and the Network was conducted and based on the positive results, this activity was deprioritised and no further work has been undertaken.
Provide high-quality, robust,	Develop and maintain guidance and other tools (training	100%	The SmPC advisory group handled a number of Q&As and FAQs and organised 5 webinars which

Objective	Activity	% complete	Achievements/results
scientifically sound and consistent product information	material, checklist, metrics or labelling review guide) supporting SmPC review		enhanced the guidance in the area of labelling review, both for EMA staff and for the assessors, as part of the NCAs network. In particular, the following webinars and Q&As were delivered/prepared: Webinars: 1. Review of SmPC safety information; case studies before and after marketing authorisation (24/02/17); 2. Labelling and package leaflet - readability and consistency with SmPC (27/04/17); 3. Review of SmPC efficacy information (13/07/17); 4. Interpolation of interactions (22/09/17); 5. EudraSmPC website – What's new? (24/11/17). New FAQs: Based on experience gained in answering queries, 29 new FAQs were prepared and the FAQs on paediatric information in SmPC were completed. All were presented to the regulatory network during the November 2017 SmPC AG webinar. Q&As: 1. In-use stability studies for solid oral dosage forms; 2. SmPC paediatric information in indication not authorised in adults; 3. Expression of strength composition and dose recommendations - etirinotecan pegol; 4. Safety needle system; 5. Azithromicin article 46; 6. 4.6 information of product not indicated in women of childbearing potential; 7. Pregabaline – paediatric results; 8. Kalydeco-Symkevi – indications and cross-references to SmPCs of product to be used in combination. The 2017 SmPC AG annual report has been prepared; the report also includes a proposal for a product information review curriculum.
	Develop tools for improved oversight of labelling development during the lifecycle, supporting consistent and evidence-based reviews	0%	Activity has been postponed.

Objective	Activity	% complete	Achievements/results
	Analyse external requests regarding the contents of approved SmPC and provide consistent response	0%	No external requests were received in 2017.
Increase reliance of other regulators on European assessment and output	Implement collaborations with the FDA on pharmaceutical quality through setting up a new cluster, with a focus on innovation	70%	The EMA-FDA quality platform has been partly established in 2017, to liaise on innovative technologies via Process Analytical Technologies, Applications and Benefits Working Group, including the FDA and PMDA. In 2017, EMA hosted a FDA quality fellowship and confirmed ongoing interest in collaboration, with emphasis on continuous manufacture and accelerated access.
Ensure appropriate representation in relevant fora, to ensure convergence of standards	Contribute to ICH activities on starting materials (ICH Q11 Q&As on starting materials) and lifecycle management (ICH Q12 on lifecycle management guideline)	80%	ICH Q11 Q&A was finalised. In regard to ICH Q12 guideline, the ICH Expert Working Groups (EWG) signed them off in Q2 2017, but these have not yet been finalised as further analyses on the impact of these new guidelines needs to be assessed.
Reduce time-to-patient of medicines through the use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	Support activities stemming from Joint Action 3 / work package 4 by providing relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments	30%	The framework for collaboration in the context of joint relative effectiveness assessments production was established, and the first product-specific exchange occurred in June 2017. In total, three requests for collaboration at market entry stage were fulfilled.

Post-authorisation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Variation applications, of which:	6,006	5,999	6,204	6,257	6,267
Type IA variations	2,969	2,864	3,019	3,049	3,080
Type IB variations	1,886	1,980	2,000	1,985	2,054
Type II variations	1,151	1,155	1,185	1,223	1,133
Line extensions of marketing authorisations	16	14	25	17	21

Procedure		2014 result	2015 result	2016 result	2017 forecast	2017 result
	PASS scientific advice through SAWP	n/a[1]	1	2	2	1
	Number of consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	-[2]	-[2]	6	12	15
	Renewal applications	-[2]	-[2]	107	98	94
	Annual reassessment applications	-[2]	-[2]	25	26	19
	Transfer of marketing authorisation applications	-[2]	-[2]	35	49	47
	Article 61(3) applications	-[2]	-[2]	216	190	234
	Post-authorisation measure data submissions	-[2]	-[2]	1,016	900	795
	Plasma master file annual update and variation applications	-[2]	-[2]	19	17	22

[1] New procedure, pilot started in 2015.
[2] New indicator, introduced in the 2016 work programme.

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	Post-authorisation applications evaluated within legal timeframes	100%	99%	99%	99%	99%
	Average assessment time for variations that include an extension of indication	175	160	165	180	162
	Average clock-stop for variations that include an extension of indication	90	65.5	73	90	67
	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	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound and consistent scientific assessments of post-authorisation changes to marketing	Strengthen the support in clinical pharmacology and non-clinical aspects to centrally authorised products along their lifecycle	100%	All peer reviews for centrally authorised products requested in the course of 2017 were performed. In addition, proactive and ad hoc clinical pharmacology support was provided for other products during their lifecycle. Criteria for involvement in product team work have been defined and presented internally.

Objective	Activity	% complete	Achievements/results
authorisations			
	Develop/improve guidance and quality standards for each procedure and deliver internal training to ensure regulatory procedural consistency	100%	Multiple updates of the post-authorisation Q&As have been published, to clarify submission requirements and regulatory procedural aspects for variations. The type IA/IB and type II variation validation checklists have been published on the EMA corporate website, to help applicants prepare their submissions correctly, and to reduce the number of validation issues. A new, easy to use form to help marketing authorisation holders submit data generated to satisfy post-authorisation measures (PAMs) for centrally authorised products has been made available in 2017. Upon completing the form, the MAH is automatically informed of the category of PAM and the submission type and code for the eSubmission Gateway. The MAH also receives useful procedural information, including the timetable, the EMA committees involved, and the EMA resources assigned.
	Establish an internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs	100%	Process-focused communities that were established in September 2016 continued to act as a knowledge sharing system. In 2017, monthly case studies were shared, and contributions made to the internal knowledge sharing bulletin.
	Develop a knowledge sharing system, including for experts, to capture and share the knowledge gained through the initial evaluation and product lifecycle in order to harmonise approaches	0%	The project has been deprioritised.
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	Optimise and embed in the Agency the process performance management system with strong customer focus on quality, simplification, and regulatory procedural excellence	100%	Process-focused communities were established in September 2016 for each regulatory evaluation procedure for human medicinal products (initial applications, quality variations, non-clinical and clinical variations, PSURs, referrals) under the lead of each process owner. Process owners and process champions are responsible for ensuring consistency in the way the Agency handles evaluation procedures and in the type of regulatory advice it provides to

Objective	Activity	% complete	Achievements/results
			MAHs and rapporteurs, identifying opportunities for simpler ways of working, knowledge sharing and monitoring KPIs. Each process-focused community meets monthly and, so far, these communities have delivered multiple updates of Q&As, process simplifications, and template updates and checklists development. The Agency has now embedded these communities in its operations. The preparation of a report on the experience gained has been deprioritised.
	Implement identified improvements to handling procedures for CAPs and NAPs	0%	Activity has been delayed due to optimisation of the operating model of the responsible division at the Agency.
	Develop and implement a simplified work-sharing procedure for the evaluation of active substance master files used in submissions in centralised and decentralised procedures	50%	A request to start developing a process for the simplified work-sharing procedure was presented to HMA, by the Chair of CMDh active substance master files working party, at the Maltese presidency meeting on 22 February 2017. Impact assessment on current legislation is expected to be prepared and discussed at the CMDH WP in January 2018.
	Optimise processes that include interactions among multiple committees	100%	Explanatory note and a Q&A for assessors on the requirements of GVP Module VII were published in April 2017. New timetables, that allow weekly submission slots for PRAC-led variations, were introduced in March 2017, together with a user guide that helps applicants select the appropriate timetable for all type II variations and work-sharing procedures.
	Create a platform for collaboration with NCAs ,to understand levels of satisfaction	0%	Activity has been delayed.

Objective	Activity	% complete	Achievements/results
	and to identify improvement opportunities		
Further promote the 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)	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indication	0%	Activity has not started due to resource limitations.
Foster research and data generation in the areas of public health needs	Promote research activities in the area of direct oral anticoagulants (DOACs), thereby using high-quality data, information, and knowledge, to enhance benefit-risk monitoring of the authorised DOACs	50% For observational study: 80%	An observational study, to explore the relationship between DOACs and bleeding in special populations, and to explore the adherence to recommendations included in the approved product information, continued in 2017. The results are expected in 2018. The feasibility of a PK/PD research project has been explored, and the study has not been initiated because of concerns over the feasibility of the project.

Referrals

Workload indicators

Procedure		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Pharmacovigilance referrals started	7	5	8	8	7
	Non-pharmacovigilance referrals started	11	16	10	10	3

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	Referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound and consistent scientific assessments of referrals	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency	30%	The need to develop a common understanding within the Network on the best use of referrals was discussed and agreed with Committee chairs (CHMP, PRAC, CMDh) and EMA management in Q1 and Q2 2017. As a result of these discussions, a roadmap to develop a common understanding within the Network on the best use of Referrals was adopted at the HMA meeting in November 2017.
Ensure and run highly effective and efficient processes to deliver assessment of referrals	Optimise and embed in the Agency a process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	100%	A performance management system, including pharmacovigilance performance indicators, is in place since 2014. The performance of referrals is supported by a strong system of knowledge sharing that relies on monthly review meetings between team members dealing with referrals, to ensure consistency in the regulatory advice provided to the Network and industry.
	Create a platform for collaboration with NCAs to understand levels of satisfaction and to identify improvement opportunities	0%	The activity has been delayed.
	Review and rationalise the involvement of multiple committees in the evaluation of safety issues in the post-authorisation phase	30%	The need to develop a common understanding within the Network on the best use of referrals was discussed and agreed with Committee chairs (CHMP, PRAC, CMDh) and EMA management in Q1 and Q2 2017. As a result of these discussions, a roadmap to develop a common understanding within the Network on the best use of referrals was adopted at the HMA meeting in November 2017.
	Implement identified improvements to handling procedures for CAPs and NAPs	100%	Administrative simplifications such as removal of wet signatures from Opinion documents were implemented in 2017.

Pharmacovigilance activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Number of signals peer-reviewed by EMA	2,030	2,372	2,372	1,800	2,062
Number of signals validated by EMA	34	61	61	35	82
PSURs (standalone CAPs only) started	520	512	518	557	551
PSUSAs started	-[1]	268	243	370	372
Number of imposed PASS protocol procedures started	32	31	12	20	6
Number of imposed PASS result procedures started	-	2	3	5	6
Number of emerging safety issues received	19	34	21	15	21
Number of notifications of withdrawn products received	132	160	118	220	302
Cumulative number of products on the list of products to be subject to additional monitoring	203	261	301	320	336
Number of incident management plans triggered	-[2]	-[2]	7	9	4
Number of non-urgent information or rapid alert notifications submitted through EPITT	-[2]	-[2]	49	55	61
Number of external requests for EV analyses	-[2]	-[2]	34	40	32
Number of MLM ICSRs created	-[2]	-[2]	8,495	11,000	14,193

[1] New procedures, established in 2015.
[2] New indicator, introduced in the 2016 work programme.

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 target	2017 result
Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	99.2%	100%	100%	100%	100%
Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	-[1]	98.5%	100%	95%	100%
Protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	98.4%	100%	100%	100%
Percentage of reaction monitoring reports supplied to the lead Member State monthly	100%	100%	97%	100%	97%
PRAC recommendations on signals and	-[2]	-[2]	100%	100%	100%

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	translation of labelling changes in EU languages published					

[1] New procedures, established in 2015.
[2] New indicator, introduced in the 2016 work programme.

Achievements

Objective	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes and services	Coordinate data collection and analysis to measure pharmacovigilance impact as feedback to improve processes, and to provide input into the EC report on EU network pharmacovigilance tasks in 2018	90%	Collaboration with ENCePP and PRAC groups on measuring the impact of regulatory decisions continued in 2017 with three studies and two manuscripts. Of the three product-specific impact studies, one is final and two are ongoing. A review of methods for measuring impacts was published in November 2017. An additional study on the methods used by Industry, to measure the effectiveness of risk minimisation, was published by the Agency on 7 November 2017. The revised PRAC strategy on measuring the impact of pharmacovigilance activities was published in Q4 2017. The activities of the PSUR roadmap were concluded with a joint industry and national competent authority assessors' training. The aim of the training was to achieve a common understanding of the role of periodic safety assessment reports (PSUR) in the product lifecycle. The training took place in Sept 2017. It identified key issues encountered by industry and regulators in the preparation of PSURs and best practices on ways to address them.
	Support ECDC in the delivery of the vaccine risk/benefit blueprint, as anticipated in the IMI ADVANCE project, by providing governance and code of conduct for such studies and regulatory support, as required	80%	ADVANCE code of conduct and governance models have been submitted and published on the public ADVANCE website (www.advance-vaccines.eu). Support to ECDC on the vaccine blueprint will continue in 2018 as part of the ADVANCE project.
	Present learnings from codeine study to PRAC as a proof of concept for the collaborative approach on collection and analysis of real-world data, and initiate further network studies	80%	Final results from codeine study were received and were compiled for presentation to the PRAC in 2017. A draft report on the feasibility of collaborative studies with involvement of the EU Regulatory Network for data collection and analysis was drafted and sent to PRAC in

Objective	Activity	% complete	Achievements/results
			December 2017. PRAC discussion will take place in 2018, based on the collaborative approach taken for the codeine study, to prepare a final version of the report.
	Revise guidance and Q&As on medication errors, as necessary	100%	Following the review of comments received on the Q&A and guidance on medication errors, it was identified that there is no need for an update of the guidance document.
	Conduct a lessons-learned exercise after one year experience of public hearings	100%	The draft report is pending internal agreement and endorsement by PRAC and Management Board. Publication of the report will follow.
	Publish the final ADR and signal management GVP module and prepare for public consultation on GVP modules on pregnancy, paediatrics, PSURs, and geriatrics	70%	Guideline on good pharmacovigilance practice (GVP) Module VI on 'Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev. 2)' was published in August 2017, and GVP Module IX on 'Signal Management (Rev. 1)' was published in October 2017. These two updates focused on the requirements needed to support the new EudraVigilance System, launched in November 2017. GVP Module on 'Product- or Population-Specific Considerations IV: Paediatrics' was released for public consultation in August 2017 and is foreseen to be finalised in Q2 2018. GVP Module on 'Product- or Population-Specific Considerations V: Geriatrics' is foreseen for public consultation in Q2 2018. GVP Module 'Product- or Population-Specific Considerations III: Pregnancy and breastfeeding' is currently being drafted.
	As part of the implementation of the PSUR Roadmap, conduct a consultation with the pharmacovigilance stakeholders on the Explanatory note for the GVP VII on PSURs, and deliver a joint NCA/industry training on preparing and assessing PSURs	100%	Explanatory note and a Q&A for assessors on the requirements of GVP Module VII were published in April 2017. New timetables, that allow weekly submission slots for PRAC-led variations, were introduced in March 2017, together with a user guide that helps applicants select the appropriate timetable for all type II variations and work-sharing procedures. The activities of the PSUR roadmap were concluded with a joint industry and national competent authority assessors' training. The aim of the training was to achieve a common understanding of the role of periodic safety assessment reports (PSUR) in the product lifecycle. The training took place in Sept 2017.

Objective	Activity	% complete	Achievements/results
			It identified key issues encountered by industry and regulators in the preparation of PSURs, and best practices on ways to address them.
	Optimise administration of the EURD list by moving it to an appropriate IT platform, developing close collaboration with the network, and developing risk-based criteria to determine periodicity and granularity of PSUSA scope of procedures	35%	The activities of the Granularity and periodicity advisory group (established in 2015) have been embedded in the Agency's operations. The group meets quarterly. A workshop with the Network took place in December 2017 to initiate the discussions on how to develop risk-based criteria for the definition of the granularity and scope of PSUSA procedures.
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through the use of high-quality data, information and knowledge	Build capacity for EU Network analysis of epidemiological data	50%	A document on capacity building for the EU Network on analysing of epidemiology data was drafted and public workshops on data anonymisation, Big Data, statistics for observational studies, and common data models was held. The output of these workshops is being analysed in the finalisation of the capacity building document, in addition to individual reports from these workshops.
	Develop inventory to facilitate access to real-world data	95%	The inventory was finalised and endorsed by the ENCePP Steering Group in December 2017. It will be submitted for publication in January 2018.
	Consult on mechanism for joint industry funding of studies Initiate at least 4 EMA studies on real world evidence data	50%	A document on industry funding of studies was discussed at the ENCePP Steering Group in September 2017. The ADVANCE proposal for governance models, including industry funding, was reviewed by the ECDC Expert review panel and proposals for improvements have been made. A new proposal on industry funding will be drafted in 2018, based on the comments from the ENCePP Steering Group, the revised ADVANCE Governance models, and the revised ENCePP Code of Conduct. EMA launched two of the four EMA funded studies foreseen in the 2017 work programme.
	Review the scientific advice process for post-authorisation studies to identify possible process improvement opportunities	50%	Post-authorisation methodology experts participated in several Scientific Advice meetings.
	Continue leadership of work package for WebRADR on	100%	The IMI WEB-RADR guidelines 'Framework for use of social media in pharmacovigilance' and

Objective	Activity	% complete	Achievements/results
	governance aspects of social media monitoring		'Framework for ethical considerations for the use of social media in pharmacovigilance' were finalised, and the main results presented at the project closing meeting and at the ISOP conference in Liverpool. Publication on the WEB-RADR website has been put on hold by the consortium until manuscripts for publication have been submitted.
	Evaluate the options and feasibility to provide increased support to use of registries for targeted products on the EU market from learnings from the pilot process	60%	Reports on workshops for registries in cystic fibrosis and multiple sclerosis with recommendations were published on the EMA corporate website. Methodological guidance on registries is under development, with a view to go for consultation in 2018. A workshop on CAR T-cell products registries is planned for Q1 2018.
	Implement business process to receive and manage industry reported safety signals	100%	GVP module IX on Signal management (Rev 1) was published in October 2017. A one-year pilot of the business process to manage industry reported safety signals from EudraVigilance was agreed with the European Commission and the European Medicines Regulatory Network (to start on 22 February 2018), and this was communicated to stakeholders on 22 November 2017.

Other specialised areas and activities

Workload indicators

Procedure		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Herbal monographs, new[1]	11	14	8	5	4
	Herbal monographs, revised	5	3	9	12	8
	List entries	1	0	2	1	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	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Implement the Clinical Trials Regulation (EU) No 536/2014*	Finalise the new and revised guidelines related to the implementation of the Clinical Trials Regulation, considering the comments received during public consultation, as applicable	95%	The document on 'Risk-proportionate approaches in clinical trials' was finalised and published by the Commission in Eudralex Volume 10. The revision of the GCP inspections-related guidelines was finalised, and the publication in Eudralex Volume 10 is expected in Q1 2018. The 'Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol' and the 'Guideline on good clinical practice compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials' were launched for public consultation in August and July 2017, respectively. Comments received during the public consultation are being reviewed and are planned to be finalised and published on the EMA corporate website in the second half of 2018. The 'Procedure for the management of serious breaches by the EEA Member States, including their assessment and the appointment of a lead Member State' is planned to be finalised and published on the EMA corporate website in the second half of 2018. For status update on the progress of the development of the EU Portal and Database and Safety Reporting, please refer to Annex on projects.
High level support of coordinated, cross-European	Issue-specific working procedures on handling emerging health threats, in line	95%	The plan has been completed. However, due to pertinent comments and suggestions from the management, some further fine tuning is

Objective	Activity	% complete	Achievements/results
preparedness to act upon public health threats	with the new structure and plan		needed. Completion and adoption expected by the end of Q1 2018.
Facilitate the development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	Provide scientific support to writing a new guideline on paediatric aspects of new antibiotics and to the revision of SmPCs for already approved antibiotics	60%	Draft guideline on paediatric clinical development of antibacterial agents was reviewed at IDWP and PDCO and it is expected to be sent out for consultation in Q1/Q2 2018. A workshop is planned to be organised jointly with the FDA and PMDA on paediatric development of new antibacterials in June 2018.
Strengthen the quality of the scientific review processes	Establish a pragmatic approach to setting European standards for herbal combination products	65%	The work has begun to identify herbal substances, preparations and combinations from non-European traditions that fulfil minimum data requirements for establishing EU herbal monographs. The approach to set European standards for herbal combination products (monographs), including solution for tea combinations, has been progressed. The first case 'Species diureticae' was adopted in March 2017. Three other herbal tea combinations were started by the rapporteurs in the course of the year. First discussions on the draft monographs took place at the MLWP. Non-European and combination substances were specifically included in a public call to interested parties and NCAs in September 2017, and subsequent proposals are currently under review by HMPC/MLWP.
Promote application of harmonised international standards	Provide technical and scientific contribution to the development of an addendum to the ICH guideline E9 on statistical principles in clinical trials and the finalisation of the ICH guideline E17 on multi-regional clinical trials	100%	The ICH E9 (Rev.1) draft addendum on estimands and sensitivity analysis in clinical trials was published by EMA in August 2017. Support was provided to ICH E17 that was published in December 2017.
	Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S1)	70%	Over the course of the reporting period, the Agency organised monthly teleconferences and contributed to progress the work related to the ICH S1 guideline revision.
Ensure needs of specific populations	Develop and implement EMA strategy for medicine safety in	25%	Progress has been made with drafting of the GVP content; further progress is anticipated for

Objective	Activity	% complete	Achievements/results
are met, including the elderly, children, patients with rare diseases, and others	pregnancy		2018, especially in view of the meeting planned for input regarding long-term pregnancy outcomes.

* For information on the IT systems required by the Clinical trials regulation, please see Annex 1, Projects in human medicines evaluation activities.

In addition to the above activities, public consultation on the draft revised guideline on first-in-human clinical trials, to ensure safe and effective performance of Phase I trials as integrated protocols, and to ensure correct implementation of the updated framework, ended in February 2017. A workshop with stakeholders, to further expand on the comments received, was organised, and the issues discussed formed part of the revision process of the draft. The draft guideline was adopted at the July CHMP.

Evaluation activities for veterinary medicines

Pre-authorisation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 target	2017 result
Innovation Task Force briefing requests	2	2	4	4	7
Scientific advice requests received	31	27	18	25	17
Requests for classification as MUMS/limited market	29	30	25	25	25
Of which reclassification requests	-	1	6	-	8

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 target	2017 result
Scientific advice procedures completed within set timeframes	97%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide support and incentives to the development of new medicines for MUMS/limited markets	Publish annual report on MUMS/limited market activities	100%	Report on 2016 MUMS/limited market activities was published in March 2017.
	Inform stakeholders of the revised MUMS guidelines	100%	The final guideline on MUMS/limited market data requirement for immunologicals was adopted and published on the Agency's corporate website in April 2017. Targeted communication to stakeholders that provided comments on that specific guideline was sent out at the same time. A news item was also published to mark the completion of the revision of this guideline. A talk was given at an assessor training, held under EU NTC on 18-19 December 2017 in Madrid (ES).
Promote innovation and the use of new approaches in the development of veterinary medicines	Promote access to the Agency's Innovation Task Force through presentations to industry and as part of existing pre-authorisation procedures	100%	In March 2017, ITF was one of the topics of the EMA Veterinary Info Day stand on pre-submission advice procedures and was promoted during presentations at the meeting. Additionally, ITF briefing meetings have been promoted in all suitable early contacts with companies, either during meetings, or when answering written or telephone queries.
	Implement any improvements identified as a result of 2016 evaluation of the impact of measures recently put in place to support innovation (ADVENT, ITF)	100%	An internal report on measures in place to support access was prepared in 2016 and finalised in Q1 2017, with an action plan for further development. The next step will be feedback and evaluation of impact of ITF and SA procedures through a stakeholder survey in Q1 2018. Guidance to applicants requesting scientific advice was revised and published in Q4 2017. An infographic to summarise currently available support has been published Q4 2017.
	Publish Q&A developed by ADVENT in priority areas for technologies that are new to veterinary medicine (including cell-based therapies, monoclonal antibodies for veterinary use)	100%	In 2017, the ADVENT published the following Q&A documents: Q&A on allogenic stem cell-based products for veterinary use: specific questions on sterility; Q&A on allogenic stem cell-based products for veterinary use: specific questions on extraneous agents; Q&A on allogenic mesenchymal stem cell-based products for veterinary use: specific questions

Objective	Activity	% complete	Achievements/results
			on tumorigenicity, and Q&A on monoclonal antibodies for veterinary use. Q&A about target animal safety studies in stem cells is expected to be finalised Q1-Q2/2018.
	Explore the scope for developing specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials to control infectious disease in animals	100%	A plan on specific actions in the area of alternatives was discussed with CVMP in November 2017 and is foreseen to be finalised in Q1 2018. Arising from the OIE meeting on alternatives in 2016, drafting of a paper on regulatory pathways has been initiated in cooperation with the FDA in Q1 2017 and completed in Q4 2017. The article will be published in Biologics Journal after the official review by both Agencies (Q1 2018). The Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) point 3.7 on alternatives to antibiotics was discussed in June and November.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice	100%	Parallel scientific advice with the FDA is being actively promoted in early contacts, business meetings with companies, pre-submission meetings, and ITF meetings. Analysis of the existing pre-authorisation procedures was conducted, and recommendations concerning parallel scientific advice were developed in 2016. In 2017, the action plan was further evaluated, based on the feedback received from the Agency's human medicines' scientific advice team and the EMA-FDA liaison. Several constraints have been identified, including the companies' limited interest to use the parallel scientific advice procedure. Companies are informed about the option to request parallel scientific advice in published guidance and when responding to enquiries.
Support development and availability of veterinary medicines	Implement EMA contribution to the EU Network Strategy 2020 in the area of promoting availability of vaccines within the EU, with particular emphasis on vaccines against transboundary diseases and diseases with limited markets	100%	In January 2017, EMA organised a stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines, authorised to EU standards. A summary of the meeting containing some recommendations and the presentations were published on the EMA corporate website in Q1 2017. The recommendations fed into the vaccine availability initiative. A reflection paper on the availability of epizootic

Objective	Activity	% complete	Achievements/results
			vaccines is now being developed. As part of the Network action plan on availability of veterinary vaccines, the HMA Steering group on availability of veterinary vaccines and the CVMP ad hoc group on veterinary vaccine availability (CADVVA) organised, in June 2017, a focus group with invited stakeholders on field efficacy trials, in the context of EU authorisation for veterinary vaccines. A meeting with stakeholders on the availability of vaccines also took place in Q2 2017. A report with the conclusions of the meeting was published in Q4 2017, together with the Steering Group recommendations based on the meeting. The SG recommendations were reviewed by CVMP in November 2017, and follow up was included in the 2018 IWP work plan. The Member States survey on needed EU vaccines was concluded and the outcome reported to the Steering Group in December 2017. Ongoing contribution to the Steering Group and CADVVA groups is being provided, as appropriate.

Initial evaluation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Initial evaluation applications	12	10	21	18	17
New MRL applications	4	4	6	3	3
MRL extension and modification applications	2	3	1	4	3
MRL extrapolations	2	1	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		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Procedures completed within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality and consistent scientific outputs of EMA	Finalise the development of a revised guideline, procedures, and templates for CVMP assessment reports, and provide training on these	100%	Since April 2017, the training on the pharmaceuticals template and guidance has been made available on the EU NTC learning management system (LMS) platform, to reach a wider audience in the Network. The template guidance for immunological products, adopted in December 2016, has been implemented for use since March 2017. Training has been developed and published on the LMS platform in December 2017. Feedback of user experience is being collected.
Ensure that the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	Provide technical support to the European Commission in drafting implementing acts specified in Regulation 470/2009	100%	Support to the EC has been provided. The implementing measure concerning extrapolation of MRLs was adopted by the EC in May 2017. The CVMP recommendation on principles for risk assessment and risk management were forwarded to the EC in March 2017 and presented to the relevant Standing Committee in June 2017. A draft implementing regulation based on the CVMP recommendations was published for consultation in November 2017. The outcome will be discussed at a Standing Committee meeting in January 2018. Further support may be requested by the EC before finalisation of the final implementing measure, in order to address issues raised in the public consultation or at the Standing Committee meeting. The CVMP recommendation on MRLs for residue control was previously submitted to the EC in July 2013. The EC then expressed hopes that a corresponding implementing measure would be adopted in early 2018. Related to this, in September 2017, the EC requested EMA advice on the basis of existing 'other provisions' included in Reg 37/2010. EMA aims to provide a

Objective	Activity	% complete	Achievements/results
			final response to the request in February 2018. Further support may be required for the discussion with Member States on the implementing measure.
	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products	100%	The approach on genotoxic substances in the establishment of MRLs was addressed in the context of the development of the principles for risk assessment and risk management (revision of Volume 8), incorporated in the recommendation, submitted to the Commission in March 2017, and incorporated into the draft implementing regulation published for consultation in November 2017. The draft guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products was adopted for consultation by CVMP in February 2017. Consultation ended on 31 August 2017. The final guideline is expected to be published in Q4 2018.
	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)	0%	The European Commission has initiated a review of the procedure for the establishment of MRLs for biocides, with a particular focus on the workshare between EMA and ECHA within the procedure. The reflections/discussions continue at the EC level. The Agency will progress on the issue once the EC has finalised its approach.

Post-authorisation activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Variations applications, of which:	340	373	410	355	446
Type IA variations	175	196	243	185	238
Type IB variations	118	116	126	120	130
Type II variations	47	61	41	50	78
Line extensions of marketing authorisations	6	3	3	5	5

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Ensure efficient delivery of post-authorisation procedures	Implement improvements identified in the review of post-authorisation procedures	100%	Implementation of several improvements in post-authorisation procedures has been incorporated in the Veterinary change programme, and partly executed by the completed Veterinary business streamline project. The new assessment report template for type II variations has been drafted to support consistency in scientific output, and was implemented in Q3 2017.

Referrals

Workload indicators

Procedure		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Arbitrations and Community referral procedures initiated[1]	7	7	8	2	1

[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		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Facilitate prudent and responsible use of	Engage with the EC and Member States to identify and, where possible, prioritise	100%	The revision of the prioritisation of referrals of antimicrobials continued in 2017. The new proposal was presented to CVMP (November)

Objective	Activity	% complete	Achievements/results
antimicrobials and other classes of products	referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues		and finalised before the end of 2017. A second step is now needed, in which a specific proposal with the ranking of referrals is adopted by the CVMP before being sent to the EC (Q2 2018).

Pharmacovigilance activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Periodic safety-update reports (PSURs)	158	159	175	160	161
Total adverse-event reports, of which:	28,404	31,467	38,162	31,000	50,885
Adverse-event reports (AERs) for CAPs	11,878	14,387	18,419	14,000	26,671
Adverse-event reports (AERs) for NAPs	16,526	17,080	15,257	17,000	24,214

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 forecast	2017 result
PSURs evaluated within the established timelines	97%	99%	98%	90%	98%
Adverse event reports for CAPs monitored within the established timelines	95%	98%	96%	95%	98%

Achievements

Objective	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance, by providing the necessary guidance and systems and delivering high-quality processes	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	60%	EMA involvement in product data submission was scaled back from pro-active organisation of meetings with MSs (2015 - February 2017) to on-request support by Member States (February 2017 - on-going). Product data are now available for IT, ES, NL, IE, LV, UK, FR, FI and NO. SE, CZ, DE, DK, PL and AT are in the process of setting up the actual transfer of data. BE and LT have initiated the process with the

Objective	Activity	% complete	Achievements/results
			setup of the Gateway. Linking of product data to adverse event data for new product data was delayed due to re-prioritisation and re-allocation of IT resources to the ongoing ADR project. The updated mapping tool enabling data transfer was deployed on 17 June however, the necessary linking of new product data to adverse event reports was put on hold in 2017, in view of the ongoing work for the ADR project. The mapping is now foreseen for Q1 2018.
	Revise the surveillance strategy for centrally authorised products to link signal detection and PSURs and to ensure better use of pharmacovigilance resources	65%	The revised recommendation for basic surveillance was released for public consultation in February 2017. A pilot exercise to test the recommendation started in July and will run until the end of February 2018. This includes voluntary participation from 8 MAHs, involving 26 centrally authorised products. Finalisation of the recommendation is estimated for Q4 2018 and will be based on the feedback from the pilot exercise and the comments received from the public consultation.
	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	100%	Following the focus group on promotion of pharmacovigilance reporting for food-producing animals in 2016, a reflection paper was drafted and subsequently adopted by the Pharmacovigilance working party (veterinary) at its May 2017 meeting. The reflection paper has been adopted at the July CVMP meeting and subsequently published on the Agency's corporate website.
	Revise the process for incident management plans in light of the lessons learned from a simulation exercise and recent experience	100%	In order to take into account the lessons learned from the simulation exercise on the Incident management plan and four real cases, revision (Rev.2) of the Incident management plan was initiated in 2017 and presented to the European Surveillance Strategy group in June 2017. Agreement by European Surveillance Strategy group was granted in October 2017, followed by CVMP and HMA endorsement in November 2017.
Provide consistent, high-quality information on pharmacovigilance topics to	Publish the veterinary pharmacovigilance annual bulletin	100%	Veterinary pharmacovigilance public bulletin on 2016 activities was published in February 2017.

Objective	Activity	% complete	Achievements/results
stakeholders and partners			

Other specialised areas and activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Support increased availability of veterinary medicines	Set up a pilot project to evaluate how existing data on antimicrobials can be extrapolated to promote retention on the market	75%	The expert group working on the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) met 5 times in 2017. The group is preparing a report to CVMP on the possible extrapolation of doses of antimicrobials that could be used for the harmonisation of the SmPCs of antimicrobials in future. Two more meetings and a focus group meeting will take place during 2018 before the report can be finalised.
	Provide CVMP feedback on gap analysis from the FishMed Plus coalition on availability of fish medicines	100%	In June 2017, the FishMed Plus coalition provided to CVMP a gap analysis and a list of recommendations to increase the availability of fish medicines. A meeting with CVMP took place in July, to exchange views and to provide feedback on the information provided. A final gap analysis and recommendations, as agreed in the bilateral with CVMP, was provided to FishMed Plus coalition in September 2017, which in turn provided very positive feedback.
	Finalise reflection paper on anthelmintic resistance	100%	The reflection paper on anthelmintic resistance was adopted by CVMP on 12 April 2017 and subsequently published on the EMA corporate website. As a consequence of this reflection paper, work has started on an action plan on the recommendations for CVMP.
	Develop a reflection paper on resistance in ectoparasites	50%	Work on the reflection paper continued in 2017. CVMP provided extensive comments on the first

Objective	Activity	% complete	Achievements/results
			draft and asked the veterinary Efficacy working party (EWP-V) to review the document further. Due to changes in EWP-V composition, rapporteurs were reappointed and the document revised in view of CVMP comments. The revised draft was discussed at the November 2017 EWP-V meeting; further discussion is foreseen via Adobe meeting in January 2018 and at the February 2018 EWP-V meeting. Adoption of the document for public consultation is foreseen for the May 2018 EWP-V meeting.
	Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	50%	Work on the draft guidelines continued throughout 2017. The substantial EWP (veterinary) activity in supporting this revision requires significant participation from the EU Network. Revision of the nine VICH GLs is staged in three different topic groups; EU comments on changes proposed in regard to topic 1 were endorsed by CVMP in December 2017; topic 2 and 3 are still under discussion. Work at the VICH Expert working group will continue in 2018 and the publication of draft guidelines for consultation is now expected for Q4 2018. Extensive contribution by EWP-V is foreseen throughout the whole 2018.
	Provide necessary input to the European Commission during the co-decision process (now called ordinary legislative procedure) for new veterinary legislation	100%	Throughout 2017, EMA provided technical advice and support to the EC during the Council Working Party discussions on new veterinary legislation, by attending meetings and providing comments to the draft Council WP documents received. EMA also participated in a workshop, exploring the development of monographs for environmental risk assessment of active substances used in veterinary medicinal products.
	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	5%	Due to the extended decision of the Council Working Party discussions on the draft new veterinary legislation and uncertainties of outcome with regard to the provisions for SmPC harmonisation, considerations for the establishment of the ad hoc CVMP-CMDv Task Force have been delayed until sufficient progress has been made on the legal proposals. A mandate for the group has been drafted.

Objective	Activity	% complete	Achievements/results
	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	100%	In June 2017, an agreement was reached on the organisation and working practices for the task force, including how initiatives related to availability of veterinary medicines will be integrated within the wider work plan of the task force, to ensure there is no duplication with existing groups, such as the European Surveillance Strategy (ESS) group and the Task Force on Availability of Veterinary Vaccines.
	In cooperation with the European Surveillance Strategy Group, finalise revision of the Incident Management Plan for veterinary medicines, develop systems to facilitate management of shortages, and ensure adequate supply of essential veterinary medicines	100%	The scope of the Incident Management Plan (IMP) was extended in early 2016 to cover also the incidents arising as a result of supply shortages. The endorsed revision of the IMP was published in December 2017. Proposals developed within the joint EMA/HMA Task Force on availability of authorised medicines by the group working on measures to improve management of shortages of medicines would be also considered by the ESS. The Agency is contributing to these discussions from the perspective of centrally authorised medicines.
Promote uptake of harmonised standards at international level	Contribute to training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	100%	EMA participated in the 8th and 9th VICH Outreach Forum meetings in February 2017 in Buenos Aires, and in November 2017 in Tokyo respectively. The 8th VOF meeting involved representatives from the seven VICH regions, as well as nine non-VICH countries and one international organisation, while the 9th VOF meeting involved seven VICH regions and ten non-VICH countries. In December 2017, CVMP/EWP-V commented on draft training slides on bioequivalence intended for publication on the VICH website and aimed at non-VICH countries. EMA also participated at the DIA Global Animal Health Workshop, organised in Nairobi in June 2017. The aim of the workshop was to share knowledge and understanding of good regulatory practices, and to promote close cooperation among regulatory agencies.
	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes	100%	A teleconference was held between JECFA and CVMP experts in March 2017 to discuss the calculation of the microbiological acceptable daily intake (ADI) in relation to the potential for

Objective	Activity	% complete	Achievements/results
			antibiotic resistance development at sub-minimal inhibitory concentrations. Further meetings will be organised as and when considered necessary.
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins	100%	The draft 'Reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health' was adopted for consultation by the CVMP Antimicrobial working party in May 2017, and by CVMP in July 2017. The end of the consultation period was mid-October 2017. Revision of the reflection paper is expected to be finalised in Q1 2018. This reflection paper provides important recommendations on the classification of aminoglycosides, as a class of antimicrobials classified by the WHO as critically important. It was agreed by CVMP and AWP in September 2017, and endorsed by CVMP, that since the focus of the reflection paper is on aminopenicillins and their beta-lactamase inhibitor combinations, the title should be changed accordingly to 'Reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health'. The adoption by AWP and CVMP for release for consultation is foreseen for the second quarter of 2018, after the review by the AMEG. This reflection paper provides important recommendations on the classification of aminopenicillins as a class of antimicrobials classified by the WHO as critically important.
	Work with the European Commission on publishing the outcome and follow up to the joint EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species	100%	The opinion on the 'Reduction of the need to use antimicrobial in food producing animals' (RONAFA) was finalised and adopted by EMA and EFSA scientific committees in December 2016 and sent to the EC. The opinion provides an extensive list of recommendations on how to reduce the use of antimicrobials in animals, which are used for recommendations and reports on the fight against antimicrobial resistance. In 2017, the recommendations of the RONAFA opinion are being taken into account when

Objective	Activity	% complete	Achievements/results
			developing or revising relevant documents at the Agency.
	In collaboration with EFSA and ECDC, prepare a second report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals	100%	The second joint inter-agency antimicrobial consumption and resistance analysis (JIACRA) report, analysing the sales and resistance to antimicrobials in animals and humans, was prepared and sent to the EC at the end of June 2017 and published on the EMA, ECDC and EFSA websites in July. Following the well-received publication of the first JIACRA report, this second report provides further analysis of the sales and resistance of antimicrobials with increased quality of the data of the 5 networks involved and a more detailed analysis.
	Prepare an opinion on indicators with regards to surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals	100%	Work on the joint EMA/EFSA/ECDC opinion on indicators with regards to surveillance of antimicrobial resistance and consumption in humans and animals continued during the first half of the year. The opinion was adopted by the CVMP at its September 2017 meeting, and sent to the EC and published in October 2017. The opinion was prepared in collaboration with the WHO.
	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine and publish the outcome in the ESVAC annual report	100%	The draft 7th ESVAC report was circulated to the ESVAC experts' network for initial consultation in June 2017. The final report was circulated to the EC, Member States and CVMP, and published on the Agency's corporate website in October 2017.
	Publish a harmonised methodology for measurement of the use of antimicrobials per species	90%	Guidance on collection of data on antimicrobial use by animal species from national systems was published for a 6-month public consultation on 24 March 2017. The final revised guidance will be published in Q1 2018.
	Publish reports on existing systems within the EU for collection of data on the use of antimicrobials in chickens and cattle	95%	A review of the existing data collection systems in poultry started at the end of 2016 and continued throughout the first half of 2017. The review has been finalised and is currently being drafted as a scientific paper, expected to be submitted in Q1 2018. A review of the data collection systems for cattle started in Q2 2017 and a working document has been completed.

Objective	Activity	% complete	Achievements/results
Minimise the use of animals in medicines research and development activities	Improve the guidance available on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches	80%	A reflection paper, providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs, was being finalised. The consultation on the reflection paper, providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs, ended on 31 May 2017. Guidance for individual laboratories for transfer of quality control methods, validated in collaborative trials with a view to implementing 3Rs, was being finalised following the end of consultation on 31 January 2017. A report on the actions taken, concerning a review and an update of EMA guidelines to implement best practice with regard to 3Rs in regulatory testing of medicinal products, was being prepared. These documents were expected to be finalised in 2017, taking into account the comments received. Following requests from WPs to update their respective sections, rather than just confirm content of versions from the consultation, the revised target date for finalisation is Q2 2018. The new joint 3R working group held its first annual meeting in June 2017; an annual report was drafted in Q3 2017 and will be published in Q1 2018, following endorsement by CHMP and CVMP.
	Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch testing of veterinary vaccines and other relevant areas	100%	The VICH guideline GL50 'Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use' and the VICH guideline GL55 'Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use' were finalised in the first half of 2017 and published in June.
Effectively manage risks to the environment arising from the use of veterinary	Develop a guideline on risk assessment of veterinary medicinal products in groundwater	80%	The draft guideline was published for a 6-month consultation in February 2017 (ending August 2017). A review of comments took place in Q3-Q4 2017 and a final guideline is now under development and will be adopted by CVMP in

Objective	Activity	% complete	Achievements/results
medicines			Q1-Q2 2018.
	Provide advice to the European Commission to assist the preparation of their strategy on managing pharmaceuticals in water	0%	In November 2017, the Commission published for consultation a survey, seeking comments on 30 possible policy options related to the development of a strategic approach to managing pharmaceuticals in the environment (human and veterinary). EMA and CVMP are developing comments in response to the consultation (which closes in February 2018).
	Develop a strategic approach to persistent bioaccumulative and toxic (PBT) substances within the authorisation procedure for veterinary medicinal products	100%	A reflection paper on how to authorise veterinary medicinal products containing PBT/vPvB substances was adopted by CVMP and HMA in May 2017, and subsequently published on the EMA corporate website.

Horizontal activities and other areas

Committees and working parties

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Number of reimbursed meetings	397[1]	437[1]	441	500	529
Committee meetings	-[1]	-[1]	71	71	71
Training[2]	-[1]	-[1]	21	73	30[3]
Workshops	-[1]	-[1]	66	62	32
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	-[1]	-[1]	283	294	396
Number of teleconference meetings (audio, video and web)	3,215	4,273	4,969	7,375	4,802
Number of reimbursed delegates	7,488	8,226	7,972	8,500	8,743

[1] Detailed split by types of meeting available from 2016. For previous years, all meetings counted under a single, overall entry.
[2] includes EU Network training centre meetings
[3] of these, 14 were EU NTC events

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Delegate satisfaction with the service level provided by the secretariat	n/a	93%	n/a	90%	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	100%	99%	99%	100%	100%
	First-stage evaluations of competing interests for committee members and experts completed prior to their participation in the first meeting after the submission of a new or updated declaration of interests	100%	100%	100%	100%	100%
	Ex-ante verifications of declarations of interests for new experts completed within two weeks after upload of the DoI in the experts' database	94%	100%	100%	90%	99%

[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	Activity	% complete	Achievements/results
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	Explore opportunities for collaboration and work with HTA organisations by providing support to the development and revision of methodological and disease-specific guidelines	0	No requests to revise or develop methodological or disease-specific guidelines were received in 2017.
	Improve alignment of committee work plans with the EMA work programme	100%	The adopted committee work plans for 2018 took into consideration the EMA work programme and business priorities in line with the Agency Relocation Business Continuity Plan. Common interest areas for future work have been identified across committees and will be considered for future committee work plans.
	Implement policy on coordination between committees with particular focus on coordination between scientific committees and the SAWP	75%	Common sessions between CHMP and PDCO initiated early in 2017 have been established as a standard operation in the course of the year. Regular interactions between PRAC and PDCO have continued in 2017. The ongoing regular interactions between SAWP and PDCO were further improved.

Objective	Activity	% complete	Achievements/results
	Implement transparency initiatives relating to committee communications, including agendas, minutes, and meeting highlights	100%	Following process improvements agreed in 2016, agendas, minutes, and other related committee communications are being published according to these revised procedures. Contribution has been provided to the initiative on streamlining communications across committees, in collaboration with the public engagement team. Beyond this initiative with regard to transparency, further work in collaboration with the public engagement team has been initiated with regard to optimisation of meeting minutes.
	Conduct a survey to capture the needs and expectations of stakeholders (committee members, NCA support staff) regarding the committee secretariat	100%	A survey was carried out with committee members and NCA support staff in January 2017, and the results were presented to all committees in Q1. Outcomes of the survey and feedback received during discussions will form the basis for improvements in committee secretariat support.
	Optimise automatic population of agendas and minutes using available databases, and design business intelligence reports to respond to the needs of the Network	100%	The work on automatic population of agendas and minutes, using available databases including Business Intelligence (BI) reporting, has been completed within the limitation of the available tools.
Ensure 'fit-for-purpose' scientific capability of the network	Establish an EMA regulatory science observatory and develop a horizon scanning process and methodology	75%	The observatory has been established as a collaborative matrix structure across the Agency, and the horizon scanning methodology has been designed in terms of sources, windows of observation, and main stakeholders.
	Develop a regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines	45%	Baseline report on science, technology, and regulatory tools feeding into regulatory science strategy was completed in December 2017. Additional trends were identified in December and an addendum report is due in Q1 2018. Development of the regulatory science strategy will begin once the baseline report is completed. Target for completing the strategy has been rescheduled to Q2 2019.
Improve collaboration and communication between committees,	Analyse involvement of scientific advisory groups in evaluation activities to identify gaps and improve guidance	25%	This activity has been deprioritised and postponed until Q1 2018.

Objective	Activity	% complete	Achievements/results
working groups and SAGs to increase quality, efficiency and consistency of outputs			
Provide up-to-date, timely, state-of-the-art guidance documents on relevant topics of medicines' development	Provide administrative and scientific support to the drafting/revision of Biostatistics Working Party guidelines on clinical and quality topics	60%	The final EMA guideline on multiplicity issues in clinical trials and the EMA draft reflection paper on statistical methods for the comparative assessment of quality attributes in drug development were released for public consultation on 1 April 2017.

Inspections and compliance

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
GMP inspections	420[1]	567[1]	672[1]	328	314
GLP inspections	0	1	0	1	0
GCP inspections	66	86	121	125	136
Pharmacovigilance inspections	20	14	8	13	15
PMF inspections	-[1]	-[1]	-[1]	45	83
Notifications of suspected quality defects	147	164	181	200	161
Notifications of GMP non-compliances[2]	-[3]	18	17	70	23
Number of medicinal products included in the sampling and testing programme	46	48	48	58	58
Standard certificate requests	3,338	3,221	3,787	3,750	4,023
Urgent certificate requests	535	785	487	480	531
Parallel distribution initial notifications received	2,492	2,838	2,850	2,850	2,639
Parallel distribution notifications of change received	1,295	2,096	1,847	2,200	1,975
Parallel distribution notifications of bulk change received	9	13	8	11	6
Parallel distribution annual updates received	2,339$_4$	3959[5]	3,815[6]	5,100	3798[6,7]

[1] PMF inspections included in GMP inspections results.
[2] Previously: 'Other GMP inspections related notifications'.
[3] Previously included under suspected quality defects.

[4] Excludes 560 received in 2014 but processed in 2015.
[5] Excluded 31 received in 2015 but processed in 2016.
[6] Excludes 1,323 received in 2016 but processed in 2017..
[7] Excludes approximately 1,900 notifications received in 2017 but will be processed in 2018.

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 target	2017 result
	Inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%
	Standard certificates issued within the established timelines	30.4%	91%	91.6%	90%	64.2%
	Average days to issue standard certificate	13.7	7	7	10	10.3
	Urgent certificates issued within the established timelines	100%	100%	100%	100%	100%
	Parallel distribution notifications checked for compliance within the established timeline	97%	99%	99%	90%	96%
	Additional GCP inspections addressed through information exchange on inspections carried out by international partners	29%	46%	34%	35%	39%
	Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	8%	14%	19%	10%	12%
	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%

Achievements

Objective	Activity	% complete	Achievements/results
Increase efficiency, consistency, quality, and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	Strengthen collaboration on GCP and pharmacovigilance compliance and inspections activities in areas of particular interest, based on mutual reliance with trusted international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan)	100%	Within the EMA-FDA GCP initiative, regular teleconferences and specific product-related teleconferences took place in 2017. One joint EMA-FDA GCP inspection and four observational inspections were coordinated. As of June 2017, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) is an observer to the EMA/FDA GCP initiative.
	Continue to provide support to EC on negotiations work to establish a mutual reliance framework with US FDA	100%	The mutual recognition agreement (MRA) on GMP inspections between the EU and the US was signed in early 2017, and published on 2 March. Implementation of MRA articles covering good manufacturing practice inspections, came

Objective	Activity	% complete	Achievements/results
			into force in November 2017. FDA confirmed the capability of eight EU Member States (Austria, Croatia, France, Italy, Malta, Spain, Sweden, and United Kingdom). The remaining inspectorates continue to be assessed and should all be recognised by 15 July 2019.
	Set up a pilot phase with FDA on sharing information on pharmacovigilance inspections	20%	Information on pharmacovigilance inspections is shared on an ad hoc basis.
	Implement EudraGMDP instruction rules for planning module to enable increased cooperation with Member States in coordinating third-country inspections	100%	Instruction on EudraGMDP planning module (registered users only) was finalised in the first part of 2017 and is now being implemented.
Minimise risk and impact of shortages due to manufacturing problems and quality defects	Implement the new form for reporting quality defects/suspected falsified medicinal products and start compiling information received, to analyse root causes for quality defects	95%	An electronic reporting template has been developed by EMA for reporting falsified and stolen medicines and was discussed in a meeting of experts from NCA's and PIC/s authorities held in November 2017. Participants agreed to start implementation of the new electronic template which will be published on the EMA public web site. This template and user guide cover quality defect and falsified medicines, including notification of suspicious offers for sale of medicinal products within the supply chain.
	Provide regulatory support to the work of the EU Observatory to facilitate the transition from high-enriched uranium to low-enriched uranium	25%	Support continued throughout 2017 by participation at meetings organised by the EU Observatory.
	Support and collaborate with HMA on the availability of medicines initiative	25%	Support continued throughout 2017 by participating in task force meetings and by chairing meetings of Thematic Working Group 2 - Supply Disruptions.
	Develop a new procedure within the Compilation of Union Procedures, for issuance of warning letters by Member States in case of non-compliance issues through the GMDP IWG	100%	The procedure for compliance management was adopted in 2017 by the Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG) and submitted to the European Commission for publication.
Ensure quality of medicines wherever they are	Monitor and report on the use of EudraGMDP planning module by inspectorates	10%	The use of EudraGMDP planning module has been monitored. A report on the use of the module by inspectorates has been postponed to

Objective	Activity	% complete	Achievements/results
manufactured			gather more information.
	Publish risk-based approach to GMP inspection for plasma master file inspections	50%	A drafting group on risk-based approach on GMP inspections for plasma master file inspections was formed in the first half of 2017. The work of the drafting group is ongoing and it will be presented to GMDP IWG in first half of 2018.
Improve application of equivalent standards of good manufacturing and clinical practice throughout the world	Support training activities in India and China, including the establishing of a panel of European inspectors available to participate in capacity building workshops in these countries	On-going	The Agency supported training activities in India and China; participated in the FDA–EMA–CDSCO–DIA GCP Workshop and the 2nd IPA annual conference 'Towards Excellence in Quality', in India; contributed to a series of workshops on advanced GMP in four cities in India, organised by Indian Pharmaceutical Alliance (IPA) and the FDA for the pharmaceutical industry and regulators from the CDSCO and local GMP inspectors; and contributed to two workshops on advanced GMP, organised by the China Pharmaceutical Association of Plant Engineering (CPAPE) in two cities in China, aimed at pharmaceutical industry and regulators in China.
Improve knowledge and understanding of data integrity and implications for regulatory decision making	Develop a draft guidance for industry on data integrity with the GMDP IWG and in collaboration with PIC/s	10%	The GMDP IWG 2018 work plan foresees drafting a proposal to amend the current GMP guidance Annex 11, in order to assure Data Integrity in GMP in collaboration with PIC/s.
Address the threat posed by illegal supply chains of medicines	Review the practical use of the existing Rapid Alert mechanism for transmission of information related to stolen and falsified medicines	75%	An electronic reporting template has been developed by EMA for reporting falsified and stolen medicines and was discussed in a meeting of experts from the NCA's and PIC's authorities held in November 2017. Participants agreed to start implementation of the new electronic template which will be published on the EMA public web site. This template and user guide cover quality defects and falsified medicines, including notification of suspicious offers for sale of medicinal products within the supply chain.
Support capacity building of non-EU regulators	Deliver training and capacity-building for inspectors and assessors, including international regulators	100%	GMP inspectors training for EU MS and pre-accession countries, as well as the GCP, bioequivalence and pharmacovigilance inspection training for EU and non-EU participants were held in 2017. In addition, the

Objective	Activity	% complete	Achievements/results
			online basic GCP (for EU and non-EU regulators) was provided in the first half of the year.
Strengthen collaboration with EDQM	Review collaboration with EDQM to enable the updated contract to be signed	100%	Updated contract for collaboration with EDQM was signed in December 2017.

Partners and stakeholders

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Requests for SME qualification	499	793	582	650	553
SME status renewal requests	813	994	1,185	1,400	1,335
Number of cases of patient/consumer engagement[1] in EMA activities	633	743	750	700	916
New scientific, regulatory and telematics curricula developed		1	8	1	0
Number of training events advertised to the EU Network		105	140	90	100[2]
Number of reimbursed training events to the EU Network		7	25	25	20[3]
Number of messages circulated via 'Early Notification System'		310	380	400	383
Number of EMA communications pro-actively sent to stakeholders		138	172	160	144
Number of EPAR summaries and EPAR summaries updates published		340	283	300	299
Number of summaries of orphan designation published		230	240	250	168
Requests for access to documents	416	701	823	850	865
Documents released following requests for access to documents	1,771	2,972	2,876	2,500	2,807
Requests for information	4,625	4,573	4,843	6,000	6,735
Number of documents published on the EMA corporate website	4,858	7,154	7,369	7,000	6,736
Number of pages published and updated on the EMA corporate website	2,201	2,911	4,790	4,000	3,754
Number of press releases and news items published	224	190	187	150	181
Requests for interviews and comments by media representatives	2,384	2,268	2,149	2,000	1,862
Number of reports, brochures and leaflets	2	7	25[4]	40	60

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
produced					

[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] Lower forecasts than in previous years due to the change in the system used to promote training events
[3] Including 14 events by EU Network training centre
[4] Sharp increase in 2016 due to high demand for graphic representation of reports, for posters and infographics

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 target	2017 result
Satisfaction level of patient and consumer organisations	95%	n/a	97%	n/a	n/a
Satisfaction level of SMEs	80%	92%	94%	80%	93%
Percentage of responses to ATD requests provided within set timelines	-[1]	94%	97%	90%	96%
Percentage of responses to RFI requests provided within set timelines	-[1]	97%	100%	97%	98%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	-[1]	81.7%	77%	70%	81%
Number of NCAs that have opened their training for inclusion in EU NTC learning management system		6	14	9	8
Number of users registered to the EU NTC Learning Management System		n/a	2,117	3,500	3,583
Number of NCA experts[1] registered to the EU NTC Learning Management System		n/a	1,225	2,600	2,668
Satisfaction level of partners/stakeholders with EMA communications	-[2]	80%	n/a	80%	82%
Key messages included in media articles generated by EMA press releases:					
At least one key message	-[1]	100%	100%	95%	100%
At least two key messages	-[1]	100%	51%	70%	57%[4]
Quote included	-[1]	60%	0%[3]	60%	57%
Average rating of pages on EMA corporate website during the year	-[5]	-[5]	3.6	3.0	3.3

[1] New indicator, introduced in 2015
[2] The survey, first conducted in 2015, is done every two years.
[3] No monitoring was done for quotes.
[4] This figure is based on spot sample and overall result may be different if checked on regular basis.
[5] New indicator, introduced in the 2016 work programme

Achievements

Objective	Activity	% complete	Achievements/results
Enhance cooperation within European medicines regulatory network	Conduct horizon scanning to identify emerging trends at an early stage and to ensure appropriate expertise is available, and improve regulatory preparedness, including through supporting the work undertaken by the Innovation Network and EU Network Training Centre	70%	Baseline report on science, technology and regulatory tools feeding into regulatory science strategy, was completed in December 2017. Additional trends were identified in December and an addendum report is due in Q1 2018. The EU Innovation Network agreed the contents of a survey to analyse Horizon Scanning activities across the network. A mapping of competencies across the network was completed for use in planning the EU Network Training Centre's activities.
	Complete the data gathering initiative for non-fee generating activities	100%	Final report on the outcome of the data gathering exercise was presented to the Management Board in March 2017. Addendum report on inspections was completed and adopted by the Management Board via written procedure in July 2017.
Strengthen stakeholder relations, focusing on patients and consumers, healthcare professionals, industry associations and academia	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	100%	The framework for interaction with academia was finalised and adopted by EMA Management Board in 2017. Dedicated audience landing page and web pages were also launched in 2017.
	Conduct a survey to monitor the interaction with industry associations	0%	The activity was postponed as the interactions with industry associations focused on Brexit-related activities in 2017 and will continue in 2018.
	Publish an annual report on EMA's interaction with industry associations	100%	The 2016 annual report was presented to the EMA Management Board at its 2017 June meeting and subsequently published on the EMA corporate website.
	Publish an annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations	100%	The 2016 annual report was presented to the PCWP/HCPWP and the EMA Management Board at its June 2017 meeting and subsequently published on the EMA corporate website.
	Implement recommendations to promote GPs' interactions with EMA	85%	Joint position statement between EMA and UEMO/EFPC/WONCA finalised from EMA side. Document is currently reviewed by the organisations. Publication is expected in 2018.

Objective	Activity	% complete	Achievements/results
			The level of involvement of GPs in EMA activities was consistent with that of 2016 and included participation in two important stakeholders meetings organised in the context of safety referrals
	Propose and agree additional processes to capture patient views and preferences within benefit/risk evaluations at CHMP, following the outcome of the pilot phase of patient involvement in CHMP oral explanations and the research projects on elicitation of patient preferences	100%	CHMP pilot report and recommendations were published in May 2017. Research project on elicitation of patients' preferences (follow-up on previous study on the same topic) was finalised, and a paper on the outcome of the research project was submitted for publication to a relevant journal.
	Explore the most optimal ways to report patient input and values in the relevant assessment reports, in line with the EMA AddValue project	100%	The most optimal ways to report patient input and values in the assessment reports were identified in 2017, and the CHMP assessment report template were updated accordingly.
Further develop support to and strengthen stakeholder relations with SMEs	Implement an action plan arising from the 10-year report on the implementation of the SME Regulation	87.5%	SME action plan was finalised and published on 31 May 2017. The implementation of the action plan is progressing. Completion is expected in 2020.
	Deliver high-quality guidance and systems for optimal use of available regulatory tools for SMEs (EU e-SME application), to facilitate efficient and effective access to support measures	10%	The activity was postponed until 2018 due to resource constraint.
Further strengthen the Agency's transparency and open data commitments	Complete the reflection paper on providing access to individual patient data	0%	No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
	Publish the clinical data under phase I of the policy on publication of clinical data	100%	In 2017, 58 publications were published, corresponding to over 3,500 documents.
	Assess the implementation of the policy on publication of clinical data and publish a report	75%	The activity started in October. Report is being prepared and planned to be finalised Q1 2018.
	Establish a technical group on anonymisation of patient data and hold regular discussions	100%	Public call for experts in anonymisation, to be part of the Technical Anonymisation Group, was launched in April 2017, and the first meeting of the group was held on 29 and 30 November 2017.

Objective	Activity	% complete	Achievements/results
	Finalise the transparency road map following public consultation on the draft roadmap	0%	No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
	Conduct public consultation and finalise the revised policy on access to documents	70%	Draft policy was published for public consultation in February 2017. The consultation closed in May and comments received were assessed. The draft policy and both output tables were revised to take account of these comments. It is planned to submit the policy to the MB in March 2018.
Ensure a more optimal organisation of the available expertise within the network for services provided to EMA	Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation	0%	No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
	Implement the first phase of the multinational assessment team approach post-authorisation	100%	Preparations for the launch took place over the first half of the year. The first phase of the MNAT approach in pre-authorisation was implemented as of 1 September 2017.
Ensure 'fit-for-purpose' scientific capability of the Network	Work with NCAs to include training courses in NTC learning management system and promote the use of NTC courses, to maximise the use of the EU NTC learning management system	85%	Work with the NCAs continued to include training courses in the EU NTC. The use of EU NTC courses is routinely promoted through the EU NTC newsletter and other relevant channels.
	Review and update existing curricula to ensure provision of up-to-date training, and further develop new curricula in various areas of identified needs	100%	Development of a curriculum in the non-clinical area continued and consideration is being given to the development of a curriculum on product information. Three additional curricula were adopted (Regulatory, Pharmacovigilance and Veterinary Efficacy). Training has been delivered under the existing EU NTC curricula. The necessity to review and update 6 out of 9 curricula was not deemed necessary.
Provide stakeholders and partners with consistent, high-quality, timely, targeted and accessible information on the Agency's work,	Review and improve the format and content of EMA information on medicines for patients and healthcare professionals (i.e. EMA summaries in lay language)	20%	Following feedback received from patients during reviews and from the patient training session held at EMA in November 2016, changes have been made to the EPAR summary template, mainly to improve how these documents appear in search engine results and to reduce 'patient unfriendly' regulatory details. The updated template will be used to produce summaries of medicines receiving a positive

Objective	Activity	% complete	Achievements/results
outputs and medicinal products			opinion from January 2018. Further changes to the EPAR summary template will be explored (e.g. introduction of a key facts section) in the context of the action plan related to the European Commission report and its recommendations to improve the EU product information, which were issued in March 2017. The EMA action plan related to the European Commission's recommendations on product information was published on the EMA corporate website in November 2017. Regarding academic collaboration on benefit-risk communication, the public call for tender for scientific studies, EMA/2017/09/PE – 'Efficacy and safety studies on medicines', was actively disseminated to researchers working in the field of benefit-risk communication. Work on the glossary of medical terms for the general public also continued throughout the second half of 2017, with the view of publishing the glossary during the second half of 2018.
	Implement and maintain up-to-date 'product-related communication guidance' on 'what' and 'when' EMA publishes with regards to information on products	100%	The updated product-related communication guidance was published in June 2017 and is regularly updated.
	Implement a framework for communicating the scientific output of EMA scientific committees	90%	The framework for communicating the scientific output of EMA scientific committees has been drafted, but not yet finalised, due to BCP reallocation of resources.
	Implement user-testing for EMA communication products which target the general public	15%	Feasibility and resources implications of implementing user-testing for EMA communication documents for the general public have been agreed. The EMA action plan related to the European Commission's recommendations on product information was published on the EMA corporate website in November 2017.
	Run a pilot to test and improve the crisis communication plan	10%	The activity was put on hold due to resource constraints.

Objective	Activity	% complete	Achievements/results
	Organise workshop with HCIN to explore additional ways to assess impact of EMA communications	100%	HCIN workshop took place on 27 and 28 April 2017.
	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	40%	The EMA perception survey was carried out in May 2017. The responses have been analysed and a report is in preparation, which is expected to be published in Q1 2018. The report will include recommendations on how to improve the Agency's communication products and tools.
	Improve the EMA corporate website by adding new tools and features, such as tools to improve search, search-engine optimisation, accessibility, analytics and others	60%	The EMA corporate website project continued with the migration to a new publishing system (EUROPA Next platform) in cooperation with DG DIGIT. Project completion is scheduled for Q3 2018.
	Develop new digital and multimedia communication tools	100%	Workshop on data visualisation and infographics took place in September 2017. 15 infographics and info-sheets were also published during the reporting period, including on the 10 years of conditional marketing authorisation; 10 years of Paediatric regulation; one year of PRIME; human medicines and veterinary medicines highlights; pharmacovigilance in the EU; vaccines hesitancy, and others. Two videos were produced and published (on AMR and patient engagement); a series of 3 animations were produced.
	Develop and implement an annual communications plan, in line with the framework strategy for external communication	100%	Annual communications plan was developed in Q1 2017 and implemented throughout the year.
	Implement a social media strategy	50%	Planning tool for Twitter is in place and implemented; follower analysis was performed on the basis of sample checks. Full analysis is delayed due to Brexit-related Business Continuity Plan.

International activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Ensure best use of resources through promoting mutual reliance and work-sharing	Implement and review the IGDRP information-sharing pilot to the centralised procedure	70%	One company is in the pilot scheme and has submitted a MAA, which is still under assessment.
	Optimise Article 58 scientific opinion activities, including by enhancing collaboration with WHO and concerned regulators and developing additional communication tools	100%	EMA and WHO agreed Article 58 eligibility for 3 products. Three scientific advice procedures for Article 58 products in 2017. There were no CHMP opinions for Article 58 products in 2017. Two ongoing CHMP evaluations for Article 58 products in 2017 (opinions expected 2018). One withdrawal of an Article 58 product in 2017. Revised guidance for sponsors, revised application forms for scientific advice, pre-submission meetings and scientific opinion. New branding for the Article 58 procedure was chosen in September 2017, following a staff competition. EU-M4all is now the new name. Reflection on constraints and barriers for future success of the procedure included a brainstorming exercise in December 2017 and interactions with industry (EFPIA June 2017 and IFPMA November 2017). Following on from the 2-3 March 2017 meeting of the CHMP and African regulators, Bill & Melinda Gates Foundation agreed to the use of

Objective	Activity	% complete	Achievements/results
			the remaining budget to organise up to 2 assessor training workshops in Africa in 2018. Extension of the Business Pipeline Meeting facility to NGOs and Product Development Partnerships. WHO-EMA Stringent Regulatory Authority Collaborate Registration Pilot: the fifth product entered the pilot in October 2017. This allows participating authorities to rely on the EMA scientific assessment in the approval of new medicines, in the context of a process facilitated by the WHO.
Promote convergence of global standards and contribution to international fora	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	50%	Involvement of the participating NCA representatives increased throughout 2017 and participants underlined the usefulness in terms of knowledge and relationship building. Overall, the outcome of the project has been rather positive and objectives based on enhancing information exchanges, liaison and collaboration with the EMA and the Member States were achieved. Due to Brexit related Business Continuity Plan, the IPA programme will not continue in 2018. The final report based on experience to end of 2017 is under preparation.
	Finalise the guideline on dementia	90%	The guideline publication was slightly delayed. The guideline will be adopted at the January 2018 CHMP plenary.
	Contribute to global dementia activities/programme in collaboration with other partner agencies, the EC, and international organisations	100%	The CNSWP/FDA Neurology TC took place as planned, as well as other regular bilateral interactions on this topic. This ensured good mutual understanding and alignment between EMA and the FDA. The OECD group is closing in January 2018 and the good multilateral cooperation between regulators will be acknowledged on that occasion.
Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	100%	EMA participated in workshops organised by the China Pharmaceutical Association of Plant Engineering in Taizhou (18-19 September 2017) and Jinan (21-22 September) in China. A list of GCP and GMP inspectors available for training and capacity building activities in China and India was drawn-up.

Objective	Activity	% complete	Achievements/results
Assure product supply chain and data integrity	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%	The ICMRA document has been adopted during the Kyoto meeting in November 2017. It is the first regulatory document which explores possibilities for technical alignment and interconnection of Track and Trace systems globally.
Support training and capacity building of non-EU regulators	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	100%	In 2017, the first awareness session for international regulators and NGOs was organised. Several visits of representatives from international regulators were organised, including a visit of the FDA staff member, of the East African Community, of a TGA staff member, and of NIPH (Japan).
	Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	100%	Organisation and participation in the EU Network Regulatory Awareness Session on International Collaboration and Article 58 with EMA Regulatory Affairs Office.
	In collaboration with the WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO training platform	20%	Discussions continued with the WHO, to enable greater collaboration in order to increase awareness of non-EU regulators on scientific and regulatory training opportunities offered by the EU Network.

In 2017, in addition to the above activities, the Agency participated in the DIA EU and US meetings, TOPRA meeting and BIO meeting, as well as programme committee planning and advisory council. It also participated in the launch of the twinning project between Moldova, Lithuania, and Poland, and organised East African Community visit to the EMA in May 2017. The Agency also provided support with the completion of the ICH reforms that were initiated in September 2015; provided technical coordination for the EC delegation chairs of the ICH sub-committee on communications, and supported the EC in the task force for the consolidation between IPRF and IGDRP. Preparations for the 8th Joint Working Group EU-India (specific cooperation mechanism) took place in July.

Data-management support

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
Number of Telematics information services provided by EMA	16	20	22	23	23
Number of ongoing Telematics IT projects where EMA is the delivery organisation	19	18	13	11	11
Number of ongoing non-Telematics IT projects where EMA is the delivery	15	11	6	4	6

Procedure		2014 result	2015 result	2016 result	2017 forecast	2017 result
	organisation					

Performance indicators

Performance indicators related to core business		2014 result	2015 result	2016 result	2017 forecast	2017 result
	Satisfaction of external customers of Telematics information services provided by EMA (% satisfied or very satisfied)	-[1]	-[1]	94%	80%	94%
	Satisfaction of EMA internal customers of information services (% satisfied or very satisfied)	-[1]	-[1]	94%	80%	94%

[1] New indicator introduced in 2016.

Achievements

Objective	Activity	% complete	Achievements/results
Share information on medicines within the Network and with stakeholders	Improve and establish systems and processes to ensure timely access to clinical data	80%	Publication of dossiers, in line with EMA Clinical data publication policy, continued throughout 2017. Support is being provided to the companies with a pilot for their first dossier to be published. Quarterly webinars are held with industry, in order to exchange information, receive their views, and explain EMA's position regarding the scope and application of the policy. Two webinars were held in Q1 and Q2 2017. A 2017 survey of the users of the EMA corporate website showed that three quarters of responders agreed that the publication of clinical data builds public trust and confidence in EMA's scientific and decision-making processes. Two out of three responders agreed that the data made available helped researchers to re-assess the clinical data. Integration of SIAMED to the workflow and case management tool were deployed in February 2017. Version 12 of the workflow and case management tool were deployed in March 2017. Automatic publishing process of the redacted clinical study reports, involving the workflow tool and the automatic publishing tool, started in March 2017. Change request 083 was approved in March 2017 for additional development work to the workflow and case management tool. Use cases

Objective	Activity	% complete	Achievements/results
			to support change request 083 were finalised, and the request for services was prepared. Further work has been suspended due to the need to prioritize Brexit preparedness and upcoming Agency's relocation.
Establish and improve EMA information services	Finalise implementation of the enterprise architecture function, including processes and artefacts	100%	During 2017, the established Enterprise Architecture function has contributed to the delivery of the new Information Management Strategy 2018-2020 and the Strategic Plan. The artefacts and related processes have been further integrated with portfolio processes in order to align with the Agency's planning and reporting cycle. Therefore, the creation of the Enterprise Architecture function and its underpinning processes and artefacts has been successfully finalised. This activity has been completed.

Support and governance activities

Workload indicators

Procedure	2014 result	2015 result	2016 result	2017 forecast	2017 result
n/a					

Performance indicators

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 forecast	2017 result
Posts on the Agency establishment plan filled	97%	98%	98%	97%	98%
Revenue appropriations implemented	96%	98.7%	100%	97%	96%
Expenditure appropriations implemented	94%	95.8%	96%	97%	93%
Payments against appropriations carried over from year N-1	97%	94%	96%	97%	89.9%
The maximum rate of carryover to year N+1, of total commitments within the title:					
Title 1	1.2%	0.9%	0.9%	1%	1%
Title 2	22.5%	7.6%	7.9%	15%	11.8%
Title 3	28.0%	23.1%	25.9%	25%	28.1%
Payments made within 30 days' time	98%	99.7%	99%	98%	97.3%

Performance indicators related to core business	2014 result	2015 result	2016 result	2017 forecast	2017 result
Availability of Telematics IT systems (% of time)	n/a[1]	99.4%	100%	98%	99.3%
Availability of corporate IT systems (% of time)	n/a[1]	100%	100%	98%	99.8%
Availability of EMA corporate website (% of time)	n/a[1]	99.7%	100%	98%	99.9%
Change in energy consumption (per workstation)	-[2]	+5.1%	-19.6%[3]	-1%	-5%
Change in water consumption (per workstation)	-[2]	+2.9%	-52.8%[3]	0%	+13%[4]
Change in paper consumption (per workstation)	-[2]	-38.2%	-22.7%[3]	-2%	-13%
Change in non-recyclable waste produced in restaurant and kitchenette (per workstation)	-[2]	-12.9%	-46.0%[3]	-5%	+13%[5]
Change in recyclable waste produced (per workstation)	-[2]	n/a	-26.3%[3]	-1%	+10%[5]
Change in recycling rate (per workstation)	-[2]		-5.2%[3]	+1%	-4%
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	-[2]	+1.0%	+1.4%	0%	n/a[6]
Overall net CO_2 emissions (per workstation)	-[2]	+0.2%	-10.2%[3]	0%	n/a[6]

[1] 2014 results not comparable due to change of indicator (a single combined indicator replaced with three more detailed ones).
[2] new indicator, introduced in 2016
[3] in 2016, the number of workstations increased, following the addition of the 10th floor
[4] fault in the grey water re-use system increased the need of fresh water
[5] increase in recyclable waste due to increase in Agency' activity and disposal of equipment in preparation for the relocation
[6] no data available since July 2017, as the new travel agent does not provide such information

Achievements

Objective	Activity	% complete	Achievements/results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Implement identified actions to align the Agency's quality management system with the new ISO 9001:2015 standard	0%	The activity has been postponed due to the need to prioritise EMA Brexit preparedness project.
	Develop and implement a framework for integrated planning and monitoring activities	0%	The activity has been postponed due to the need to prioritise EMA Brexit preparedness project.
	Review corporate support processes to identify opportunities for	60%	Review of workflows, review of number of delegated approvals necessary for certain workflows, increasing paperless processes as well

Objective	Activity	% complete	Achievements/results
	efficiency gains		as removing repeated workflows for different parts in the processes by improving templates that are used.
	Develop a competency management framework, including necessary processes and systems	100%	A proposed two-phase approach to developing and implementing a competency framework was presented to and endorsed by the Executive Board at the beginning of 2017, and integrated as a key component of the EMA HR Strategy. The first phase, focusing on short-term preparedness phase, included working with managers to map key jobs and competencies. This is expected to support the Brexit-related preparedness activities and help in addressing the risk of unexpected turnover and succession planning issues due to the upcoming relocation. A more comprehensive medium/long-term preparedness phase of implementing a full EMA competency and career framework will follow, involving engagement with all staff. The methodology for the first phase was developed in Q2 2017. The first phase successfully concluded with an approval by the Executive Board at the end of Q3 2017, ahead of the foreseen deadline. The mapping of jobs and competencies will also serve, in the context of Brexit preparedness, to support succession planning and recruitment strategy in 2018.
	Implement a competency management framework	30%	The first phase of implementation – carrying out a key jobs and competency mapping exercise – started in Q2; the output of the first phase was already used to develop an approach to prioritise development and recruitment for 2018 based on criticality, and to support decision-making accordingly. Implementation of the second phase commenced in Q4 2017, following the development of a project plan and endorsement by the Executive Board. In Q1/Q2 2018, the output of the initiative will be used to prepare a first draft of job families as a basis for the career development framework, which will be further elaborated during the year, both from a content/structure perspective and in alignment with other functions, and from a

Objective	Activity	% complete	Achievements/results
			process/IT tool perspective to ensure harmonisation in connection to the HR processes and tools in 2019.
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	Conduct the annual review of the Agency's handling of independence	0%	Due to the need to prioritise the EMA Brexit preparedness project, it was decided to delay the finalisation of the annual review of independence covering 2016 to March 2018.
	Implement the antifraud action plan	100%	All the actions have been fully implemented within the assigned deadlines.
	Review and update the Agency's antifraud strategy	100%	In December 2017, the EMA Management Board adopted a revised version of its anti-fraud strategy and a related action plan for the years 2018-2020.
Align the Agency with the highest European standards in environmental performance	Receive EMAS certificate and conduct external audit of the implemented standard	50%	Environmental management system was completed in December 2016, following the EMAS standards. Improvement actions following from the internal audit were implemented in January and February 2017. External verification audit has been put on hold and will be deferred until the Agency has relocated to its new premises in 2019.
Ensure continuity and quality of the Agency's operation	Conduct an impact assessment of the outcome of the UK referendum on EU membership	75%	Impact assessment as well as the budgetary consequences are being finalised, taking into account the European Council decision of 20 November 2017 to relocate the EMA to Amsterdam.
	Prepare business continuity scenarios and relevant action plans	100%	EMA published its plan to ensure operational continuity in October 2017. First phase of the BCP was launched in May 2017 and a decision was taken at the December Management Board to start the second phase of the BCP as of January 2018.

In addition to the above activities, a new policy on how EMA handles allegations of improprieties received from external parties was adopted in March. These improprieties may include allegations of departures from standards of good practices that could have an impact on the evaluation and supervision of medicines. A dedicated inbox has been created for external sources to report improprieties (reporting@ema.europa.eu).

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. Brexit

On 29 March 2017, the United Kingdom invoked Article 50 of the Treaty on European Union. This step formally started a two-year countdown to the UK's departure from the EU (Brexit).

After the EU referendum in the UK in June 2016, the Agency started to prepare for its eventual relocation. Most importantly, it began to develop plans to ensure that the assessment and safety monitoring of medicines would not be disrupted and that patients in Europe would continue to have access to high-quality, safe and effective medicines.

In the course of 2017, EMA initiated the first phase of a business continuity plan, aimed at preserving the Agency's ability to protect public and animal health, and took the decision to suspend or scale back some EMA activities in order to provide the necessary resources to prepare for the consequences of Brexit. The freed up resources were directed to divisions working on EMA preparedness.

Towards the end of the year, the Agency received the long-awaited decision on its new home: on 20 November 2017, the General Affairs Council (Art. 50) decided on Amsterdam as EMA's new location. Amsterdam's was one of 19 offers to host EMA, submitted by the Member States at the end of July 2017. The decision ended a long period of uncertainty and allowed the Agency to begin more concrete decision-making on how to ensure a successful move and retain majority of the existing staff.

Operations and Relocation Preparedness task force (ORP)

In order to address the challenges presented by Brexit, EMA established an Operations and Relocation Preparedness (ORP) task force to plan and prepare for the upcoming change, and to ensure that the Agency takes all the necessary steps to maintain continuity of its business operations, both during and after this period of change.

The work of the ORP task force is organised into 4 work streams:

- Relocation preparedness, which includes activities enabling the scientific experts from the Network to continue attending scientific meetings at EMA; retaining staff, including a smooth relocation of staff and their families, as well as working with the Netherlands on the timely availability of the new premises and the required facilities, including telecommunication.
- Operational and financial preparedness, which focuses on the preparedness of the scientific committees and working parties, in particular with respect to how the scientific assessment and monitoring of medicines will be shared between the Member States in view of the UK's withdrawal from the EU. It also includes the necessary activities to be undertaken to enable an undisrupted supply of medicines. This work stream also elaborates on the Agency's Brexit preparedness business continuity plan (BCP) which covers prioritisation and delivery of EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss.
- Human resource-related matters. This work stream encompasses the work to address HR-related aspects of the EMA preparedness and its implementation.
- Communication activities, covering both internal and external communication to EMA's staff, its key stakeholders and the wider public.

The task force is supported by ORP subgroups, devoted to specific activities and deliverables within these 4 work streams.

During 2017, the Agency has undertaken considerable work to prepare for the relocation, including but not limited to:

- Completing an impact assessment, identifying also the key risks that the Agency would be facing in this environment;
- Preparing Agency's requirements for the new location, including infrastructure requirements, technical specifications for the new premises, and other factors critical to operations of the Agency, and sharing this information with the interested Member States as well as the EU institutions;
- Member State visits to EMA and EMA site visits to candidate host countries upon request from a Member State;
- Conducting several staff surveys to gauge the potential staff losses in view of their impact on the Agency's operations, and assess potential remedial actions;
- Developing a dedicated Brexit recruitment and selection strategy to address the potential staff loss, including a job and competency mapping to support succession planning;
- Reviewing current contracts for goods and services and preparing a procurement plan to ensure the necessary contracts are in place at the time of the Agency's move to the new host Member State, including those for staff support during the transition;
- Developing support measures to maximise staff retention;
- Working with the Member States to address the workload issues arising from the loss of UK expertise;
- Issuing communications and preparing guidance for pharmaceutical industry to ensure companies have the correct information and take the necessary steps to be able to operate in the EU 27, ensuring continued availability of their medicines to EU citizens;
- Developing a dedicated EMA Brexit preparedness BCP to address situations where a 'business as usual' scenario is no longer possible;
- Beginning preparation for relocation of the Agency's data centres;
- Beginning liaison with representatives from the new host city of Amsterdam and the government of the Netherlands, following the Council decision of the new EMA seat on 20 November.

3.2. EMA governance

European Medicines Agency' governing body

The Management Board is the Agency's governing 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 Management Board takes strategic decisions and oversees corporate activities of the Agency, such as setting the EMA budget and approving its annual work programme. It does not give recommendations on marketing authorisations of medicines.

The Management Board consists of 36 members who are appointed to act in the public interest and who do not represent any government, organisation, or sector.

In 2017, the Management Board undertook several important activities which had a major impact on the work of the Agency.

Some of the most significant items, adopted or endorsed by the European Medicines Agency's Board, are listed below:

- **EMA preparedness for Brexit**
  - Regulatory preparedness

    On 27 April, an information meeting was held between the European Medicines Agency (EMA), members of its Management Board, and heads of the National Competent Authorities (NCAs) of the EU/EEA Member States to discuss how work related to the evaluation and monitoring of medicines will be shared between Member States, in view of the UK's withdrawal from the EU. At its June meeting, the Board endorsed the mandates of two working group — one focusing on human medicines, and one on veterinary medicines. These working groups were set up to explore options for a robust allocation of the workload across the European medicines regulatory network, and ways to streamline work and further increase capacity in the network.
  - Business continuity plan

    In June, the Board adopted the principles of EMA's business continuity plan to ensure operational continuity while the Agency prepares for its relocation and the UK's withdrawal from the EU. The plan classifies EMA activities into three categories of priority according to their impact on public health and the Agency's ability to function. It enables EMA to deliver its highest priority activities and temporarily scale back or temporarily suspend lower priority activities, if required.
- **Adoption of the framework for reinforced collaboration with academia**

  At its March meeting in London, the Management Board adopted a framework for collaboration between EMA and academia. The framework aims to reinforce and further develop the collaboration between the Agency and academia by clarifying the scope, and by formalising and structuring interactions in the wider context of the European medicines regulatory network.
- **Adoption of the EMA Multiannual Work Plan to 2020**

  The Board adopted the Multiannual Work Plan to 2020. This plan supports the implementation of the Joint Strategy to 2020 for the European medicines regulatory network developed by EMA and the Heads of Medicines Agencies (HMA) in 2015. The multiannual work plan outlines the key initiatives and activities to be undertaken by the Agency in the coming years, so as to support the achievement of common goals.
- **Adoption of the EMA Stakeholder Relations Management Framework**

  The Board adopted the European Medicines Agency stakeholder relations management framework, developed to streamline the interaction with the Agency's main stakeholder groups. The working methodology is based on the EC's Better Regulation Guidelines which foresees four levels of interactions: 'inform', 'consult', 'consult and involve' and 'cooperate and participate'. The framework's overarching principles apply across the key stakeholder group: patients, healthcare professionals, industry, and academia.
- **Adoption of the criteria to be fulfilled by Industry Stakeholders organisations involved in European Medicines Agency's (EMA) activities**

The Management Board adopted the criteria to be fulfilled by Industry Stakeholders organisations involved in Agency activities, which were developed taking into account existing criteria for other EMA stakeholder organisations and applicable when an organisation seeks to be consulted and involved directly by the Agency, or to cooperate jointly in specific areas.

- **Adoption of the rules on the protection of the dignity of the person and the prevention of the psychological and sexual harassment**

  At its June meeting, the Board adopted new rules on the protection of the dignity of the person and the prevention of psychological and sexual harassment.

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.

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 strategy implementation; 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; KPI and risk monitoring; audit reporting; and staff-related matters.

The Executive Board is chaired by the executive director (deputy executive director in his absence). It is composed also by all heads of division, head of the portfolio board, head of the legal department, head of international affairs, and the senior medical officer.

Other management 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, or regulatory matters. The MLT is comprised of heads of human and veterinary medicines divisions and heads of departments within the above 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 initial phase of all Agency projects. The PB has particular responsibility for improved quality, efficiency, and effectiveness of the Agency's procedures and processes, and ensures strategic alignment of projects. The PB reports to the Executive Board, which retains responsibility for decisions about inclusion of initiatives (programmes or projects) in the portfolio, the 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 board.

The 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 board, created to ensure the strategic coordination between the scientific committees of the Agency. Its members comprise the chairs of the seven Agency's committees.

3.3. Budgetary and financial management

Financial highlights of 2017

The European Medicines Agency is a fee-funded agency, with 87.85% of its 2017 revenue stemming from fees paid by the pharmaceutical industry for services provided.

The weakening of the pound, which began in 2016 following the referendum on the UK's membership of the EU, continued in 2017 and resulted in exchange rate gains on payments made in Sterling, in particular salary and rent and building maintenance payments.

In order to comply with the provisions of the Financial Regulation and in particular with Articles 69 and 70, the Agency, in late 2016, started committing operational expenditure (title III) fully at the point of entering into a legal commitment, even where the contract length extended beyond one year. As a result, commitments made in 2016, totalling EUR 2.9 million, expired in 2017 and had to be re-committed on new appropriations. It is expected that there could be similar impact in future years, increasing the amount of cancellation of carry-forward.

The Agency managed to comply fully with the ceilings/KPIs for the amounts carried forward: title I (10%), title II (20%) and title III (30%), with the following percentages achieved for the automatic carry-forward: title I: 1.04%, title II: 11.80%, title III: 31.05% (automatic and non-automatic carry-forward).

Budget overview

Authorised appropriations in the European Medicines Agency's initial budget for 2017 totalled EUR 322,103,000, representing a 0.8% decrease compared to the 2016 initial budget (EUR 324,711,000).

One amending budget was processed in 2017, bringing the final budget to EUR 331,266,000.

This increased external assigned revenue from the inducements received from the landlord for the Agency's new headquarters. The additional budgetary income covered the majority of rent payments for 2017.

A summary table of the evolution of the budget can be found in Annex I, while Annexes II and III provide detailed information, and Annexes IV and V details of the Amending Budget and transfers carried out in 2017.

Revenue (income from evaluation activities and EU contribution)

As stipulated in the Financial Regulation, budget revenue is based on cash received for 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 2017 amounted to a total of EUR 317,360,425.30.

Of the total income, 87.96% derived from the evaluation of medicines and other business-related activities; 8.99% from the European Union budget to fund various public health and harmonisation activities, including positive outturn of previous year; and 3.05% from external assigned revenue as described in the work programme (2016: 89.48%/5.51%/5.01%).

Expenditure (commitments and payments)

Commitments totalled EUR 307,824,585.74, or 92.92% of final appropriations (2016: 96.30%). Payments totalled EUR 259,988,515.04, or 84.46% of commitments entered into (2016: 85.51%).

Appropriations carried forward from 2017 to 2018

Automatic carry-forward

Automatic carry-forward to financial year 2018 totalled EUR 47,836,070.70, or 14.44% of appropriations (total carried forward from 2016 to 2017: EUR 43,032,304.83 or 13.71%).

Non-automatic carry-forward

The Management Board was requested to approve a non-automatic carry-forward to 2018 of EUR 6,181,000.00 to cover the cost related to key IT projects, resulting from delays in executing contracts for reasons outside the Agency's control.

Implementation of appropriations carried forward from 2016 to 2017

Automatic carry-forward from financial year 2016 to 2017 (fund source C8) totalled EUR 43,032,304.83. Payments against the C8 appropriations equalled EUR 38,681,396.97, or 89.89% of appropriations (2016: 95.54%) and EUR 4,350,907.86 were cancelled.

There was no non-automatic carry-forward (fund source C2) from financial year 2016 to 2017.

Appropriations from external assigned revenue

The Agency introduced assigned revenue (fund source R0) in 2014 in order to manage the inducements received in the context of the project to construct, fit-out and occupy its new headquarters.

In 2017, an amount of EUR 9,583,354.55 was recognised as assigned revenue from landlord inducements related to the project for the new headquarters. This amount contributed to the payment of rent cost incurred in 2017. No further inducements remain to cover future rent payments.

Budget transfers

In line with Article 27(1) 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 are not an indicator of deficiencies in financial management per se but are a necessary tool for adjusting the

budget in a changing environment as illustrated, for example, by the use of interim staff instead of contract staff, increased expenditure due to exchange rate fluctuation, etc. Only if and when the changes also relate to changes in the work programme might they indicate shortcomings in the planning process.

During 2017, eleven transfers were made. Ten were adjustments within the limits of Article 27(1) of the Financial Regulation (transfers within titles), and therefore approved by the Executive Director. One transfer required Management Board approval in accordance with Article 27(2) of the Financial Regulation, since it involved transferring more than 10% of budget line appropriations between titles. It totalled EUR 7,800,000, or 2.35% of final appropriations. Ten transfers involved expenditure appropriations and one revenue appropriations.

The transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development and project-related hardware investment, to provide appropriations for expenditure related to the fitting out of the building.

Cancellation of appropriations

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

In budget 2017, expenditure appropriations totalling EUR 23,441,414.26 remained unused, corresponding to 7.08% of final appropriations (2016: EUR 11,409,294.44, or 3.70%).

The underuse of commitment appropriations is largely due to the exchange rate gains realised in 2017 and the revised priorities implemented as a result of the business continuity plan (BCP) imposed on the Agency’s activities in preparation for its departure from the UK ('Brexit'), which led to lower commitment of appropriations.

This unused amount must be seen in conjunction with collected revenue being EUR 13,905,574.70 (4.20%) below budget revenue appropriations, while still resulting in a positive overall outturn balance (before adjustments for exchange rate, cancellations of carry-over, etc.) of EUR 9,535,839.56, or 2.88% of final appropriations (2016: 7,970,017.09, 2.58%).

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%[2]. 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 2017, 228 payments out of a total of 57,802 (0.39% of all payments) were made later than 30 days after receipt of a valid invoice (2016: 0.81% of all payments). This resulted in default interest of EUR 2,805.00 being paid to suppliers and contractors (2016: EUR 1,208.00).

[2] in accordance with Article 92 of the Financial Regulation applicable to the Budget of the Union and Articles 83(2) and 111 of its Rules of Application

Exchange rate impact on the budget

Whereas the revenue of the Agency is in Euro (EUR), administrative expenditure is mainly paid in Pounds Sterling (GBP). Throughout 2017, there was an overall decrease in the value of Sterling expressed in Euro, compared to the exchange rate used for the establishment of the budget, resulting in a drop by 5.6% in Euro terms for expenditure incurred in Sterling, when comparing the average exchange rate for 2017 (0.872) against the rate applied for the establishment of the budget (0.826).

3.4. Human resources management

The allocation and recruitment of staff is based on the Agency's objectives and priorities. Throughout the year, a number of Senior Management meetings are dedicated to resourcing, reporting, planning and strategic prioritization, in order to align the staff allocations with the planned activities, priorities and to prepare for future needs.

During 2017, a competency mapping was performed with assessment of the skills and competency needs for the various job titles.Tthis will help with the business continuity arrangements linked to the relocation of the Agency to Amsterdam.

The Agency has a policy for internal mobility of staff, and a new model was announced in February 2017. The new system has been used frequently during the year and is appreciated by staff and management.

During 2017, the Agency recruited 149 new members of staff (15 TA, 21 CA, 16 END, 50 interims and 47 trainees) and had 127 staff (18 TA, 18 CA, 15 END, 38 interims and 38 trainees) leaving the Agency.

The occupancy rate for temporary agents was 98%.

3.5. Assessment by management

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.

Work on the management dashboard continued in 2017 – this is intended to provide key performance information to senior management on, e.g. work programme implementation, budget and HR resource consumption, application volumes and other significant indicators. This is expected to replace quarterly reports done previously, and possibly merge information currently reported in several other management reports.

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

The supervision of activities involving potentially critical risks is adequately documented through the risk management system.

In 2017, all divisions drafted an annual activity report for the previous year (2016), reinforcing management oversight and assurance of sound management and efficiency of internal control systems throughout the organisation. In 2017, due to resources being diverted to Brexit activities, it was decided not to burden Heads of Division with divisional AAR and only draft such report for the Authorising Officer, as required by the Financial Regulations.

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

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.

Environmental analysis is performed annually to confirm the strategy or identify necessary adjustments. These are implemented through the update of the multiannual work programme, setting the priorities, and the development of the annual work programmes. Annual work programmes go through two iterations to 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. 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 2017 planning cycle was conducted in line with the requirements of the regulation.

Project management controls

2017 was the first full year that the new P3i methodology ran end-to-end. The project budget approval process remained unchanged. The Executive Board (EXB) has overall responsibility for the portfolio of

programmes and projects deciding on priorities and making available budget and resources; changes to the portfolio have to be approved by the EXB. The Agency's Portfolio Board (PB) 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. The PB reports to the EXB, while the latter retains responsibility on taking decisions concerning initiatives (programmes or projects) to be included in the portfolio; the allocation of the portfolio budget at any time; the 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.

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 ex-post evaluations are conducted by the Agency in line with 'EMA internal notice on project-related ex-post 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 Implementing Rules. The follow-up actions (i.e. Gate 3 and project closure milestones) are also identified.

Ex-post 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 Implementing Rules.

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

3.6. Fraud prevention

During 2017, the Anti-Fraud Office endured its close and proactive cooperation with OLAF, in relation to both spontaneous reporting and the development of targeted anti-fraud training. Within the Inter Agency Legal Network (IALN), EMA is chairing the Anti-Fraud Working Group, created with the aim to harmonise the approaches to anti-fraud matters among EU agencies. A report on anti-fraud practices was elaborated by the Working Group and approved by the Heads of Agencies, and served as a basis for discussions with OLAF.

The Anti-Fraud Strategy was reviewed in 2017 and approved by the Management Board at its December 2017 meeting. The Anti-Fraud Office and the other services and offices involved promoted such review, taking into account the lessons learned in the course of the implementation of the previous AFS over the last 3 years, the latest fraud trends as reported by OLAF, and the Agency's new needs with regard to fraud-related matters as they emerged from the annual fraud risk assessment.

Concerning the actions mandated by the Anti-Fraud Strategy (AFS) Action Plan for 2017, all have been successfully implemented within the assigned deadlines, including the delivery of tailored presentations to each division to continue to foster an anti-fraud culture, and the review of the Agency's sensitive positions from a more targeted anti-fraud perspective.

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 carrying out all of its responsibilities and to adhering 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.

Against this background, EMA's Management Board adopted in March 2017 'Policy 0072 on handling of information from external sources disclosing alleged improprieties concerning EMA activities on the authorisation, supervision and maintenance of medical products for human and veterinary use'. The 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 key principles underlying the handling of the information received from external sources. They relate to the confidentiality of the information received (including management and processing of personal data in accordance with Regulation (EC) No 45/2001); the acknowledgement of receipt; the treatment of the information; the interaction with EMA Anti-Fraud Strategy; the analysis of the competence; the 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).

EMA adopted SOP/EMA/0129 which is effective as of 1 August 2017 and which 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 2017, EMA received 25 reports from external sources. The majority of the cases regarded allegations of improprieties on GMP non-compliance or misconduct during manufacture of medicinal products (11), and GCP non-compliance or misconduct during clinical trials (11). In 7 cases, the external source remained anonymous. EMA followed up on each of these cases in accordance with the Policy and SOP. In 11 cases, EMA coordinated the investigation with the involvement of the relevant National Competent Authority (NCA). For 5 cases, the EMA was not competent on the matter and handed the case over to the concerned NCA. For 2 cases, a regulatory action was taken on Member State level. None of the other cases entailed the need for EMA to take specific regulatory action. In total, 15 cases received in 2017 were closed and an additional 7 cases received in 2016 or 2015 were closed.

3.7. Assessment of audit results during the reporting year

Internal Audit Service (IAS)

In 2017, the IAS conducted an audit of the 'Implementation of the New Pharmacovigilance Fees Regulation in the European Medicines Agency'.

The objective of the audit was to assess the adequacy of the design and the effective functioning of the management and internal control systems put in place by the Agency for implementing its tasks and responsibilities related to fee collection under the European pharmacovigilance legislation.

The final report confirms that 'the implementation of the Pharmacovigilance Fees Regulation has been a challenging task, which has required EMA to invest heavily in the development of processes, procedures and IT systems'. EMA has responded to this challenge by setting up the structure and systems in a relatively short period of time. The audit team noted effective processing of the fees, professionalism of staff, compliance with the reporting requirements of the Fees Regulation, as well as systematic planning and monitoring of the underlying activities. However, the IAS concludes that although the design of the management and the internal control system put in place by EMA for the Implementation of the Fees Regulation is adequate, there is a significant weakness, recorded as very important recommendation, regarding EMA's management of the continuous deficit between the pharmacovigilance fees income and the related costs. To rectify the issue above, the Agency promptly devised an action plan, which also includes the ongoing evaluation of the European Commission of the current fee and remuneration system.

The audit did not identify any critical issues.

Internal audit capability (IAC)

In 2017, the Agency's audit function carried out audits and other tasks, as foreseen in the Annual audit plan approved by the EMA Management Board.

The audit engagements covered 'Cyber Security and Cloud Readiness', 'Employee welfare system', 'EudraVigilance Functionalities' (as required by Article 24.2, paragraph 3 of Regulation (EC) No. 726/2004), 'IMI – Get-real project' (as required by the Grant Agreement), the 'External assessment of the quality of audit activities' (required on the basis of the IIA Standards), 'Fire Risk Assessment' (as required by the Regulatory Reform – Fire Safety – Order 2005).

Some audits planned for 2017 were cancelled or postponed due to the business continuity plans endorsed by the management in June 2017. The cancelled and postponed audits were related to the 'Effectiveness of the EMA support to the work of the committees', 'Request for access to documents', 'EU Clinical Trials portal and database', 'IMI Web-RADR project', and the 'Environmental Audit' (in accordance with Regulation (EC) No 1221/2009).

Based on the results of the audits, the Internal audit capability 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 relevant findings of the above mentioned audits for which management has prepared the improvement action plan and monitors the implementation continuously.

European Court of Auditors (ECA)

The European Court of Auditors adopted its 'Report on the annual accounts of the European Medicines Agency for the financial year 2016' on 19 September 2017.

The report provides a positive opinion with regards to the reliability of the accounts and legality and regularity of the transaction underlying the accounts.

The report includes no critical findings, only comments[3] that do not call the Court's opinion into question.

The comments relates to:

- IT accounting system;
- Corporate Rate Agreements for the provision of accommodation for experts with 25 hotels in London;
- European Commission's framework contract with one contractor for the acquisition of software, licences and the provision of related IT maintenance and consultancy;
- Agency's re-organisations;
- Implementation and control of two projects:
  - Implementation of the Regulations on Pharmacovigilance (1027/2012)
  - Clinical Trials (536/2014);
- European Commission evaluation of the Agency and its operations every ten years.

To address the comments above, the Agency has devised an action plan; all planned deliverables have been either completed or are ongoing.

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

Internal Audit Service

No critical recommendations were open as of 31 December 2017.

Only one very important recommendation was open as of 31 December 2017, for which management has set an improvement action plan with a 31 December 2018 deadline.

[3] For further details please refer to the European Court of Auditors Report on the annual accounts of the European Medicines Agency for the financial year 2016 [CH4089422EN05-17PP-CH033-17APCFIN-RAS-EMA_2016-OR.docx]

Internal audit capability

At the end of 2017, 22 very important recommendations (7 recommendations from 2017 audits), stemming from audits carried out up to 31 December 2017, were under implementation; all of them were within the timeline agreed with IAC. No critical recommendations remain opened.

3.9. Follow-up on observations from the discharge authority

EMA reported on the follow-up of the observations made by the discharge authority for 2016 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[4].

On 18 April 2018, the European Parliament voted positively on the discharge of EMA's 2016 accounts. This is the final approval of the budget implementation for 2016, and the decision is based on a review of the annual accounts, and the ECA annual report.

[4] http://www.europarl.europa.eu/cmsdata/130082/EMA%20-%20Follow-up%20report.pdf

3.10. Assessment of the effectiveness of internal control systems

Compliance and effectiveness of internal control standards

As in the previous years, the Agency reviewed the implementation of the internal control standards (ICS) in 2017. This was done via an internal questionnaire addressed to the Agency's management. In 2017, the review assessed the effectiveness and efficiency of all internal control standards.

The assessment concluded that the system in place is generally compliant with the standards, thus providing the Agency with reasonable assurance on the reliability of the internal control environment, even though two areas for improvement were highlighted, namely: objectives and performance indicators (ICS5), particularly in regards the introduction of more qualitative indicators and establishing clearer link between performance indicators and objectives that could improve the ability to monitor progress and achievement of the set objectives; and operational structure (ICS7) for the implementation of IT Risk Management process and continuous improvement of other operational processes. An action plan to rectify the above areas has been drafted and will be implemented in 2018.

The reliability of the information contained in this report is also supported by a number of building blocks of assurance described below:

Outcome of the risk management exercise

The European Medicines Agency operates in an environment of growing uncertainty. To assist the Agency in visualising, assessing, and mitigating the risks that threaten the delivery of its mission, the Agency has developed a sustainable process to identify, assess, and manage risks across the organisation, to ensure attainment of key organisational objectives and avoid surprises. This process is aligned with the principles of the Information Resource Manager (IRM) standard and the Agency-wide risk management manual, and consists of identifying, assessing, and mitigating enterprise risks. Significant risks are then reviewed by the EMA Executive Board which acknowledges the risks, and validates the action plans to further mitigate them.

Significant risks identified during the assessment carried out in 2017 and their respective mitigating actions and controls are outlined in the tables in Annex 9. None of the risks included were considered critical, and none had materialised during the reporting year.

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 standardised transactions requiring either an operational expertise or specific controls, such as fee revenue and expenditure. The aim of the financial ex-ante verification is to assure the authorising officer that the budget implementation does respect the budgetary principles, of which sound financial management and transparency are the two main principles on which attention is focused on.

The Verifying Office, as a general policy, performs checks focusing on medium/high-value commitments, sensitive contracts, or complex procurement procedures where higher risks have been identified. The SAP accounting system is an effective tool for mitigating financial risks associated with the payment processing.

In 2017, the Verifying Office performed its duties and achieved all objectives. No delays had to be reported. All transactions without exception were checked by applying appropriate checklists in line

with the EMA's internal control standards, the Financial Regulation, and the Charter of the Verifying Officer.

During the 2017 budget year, 455 (500 in 2016) rejections were recorded, of which 159 (35%) (260 and 52% in 2016) related to manual adjustments, technical rejections, or interface issues following the decentralised verification. The balance of 296 (65%) reflects the effective rejection rate for less than 0.1% (when taking into account 'sales' figures as well) of the total transactions being checked.

Out of the 296 rejected payments, 10% did not present a materiality, and 90% did not show a noticeable individual financial risk.

Four commitments were rejected following initiating agents' requests. The balance 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 have showed a breach of contract provisions. Most of the rejections were later corrected, amended and validated with due respect to budgetary principles and procedures in force.

One payment and one commitment deemed to be recorded into the register of exceptions. For the commitment, inconsistencies between resources and budget were detected whereas for the payment, a technical issue was raised when implementing a new service contract. However, their low materiality did not expose EMA to real financial risks. None of these records revealed any breach of rules or of contract provisions.

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 applicable provisions.

In 2017, with the launch of phase 1 of EMA Brexit preparedness business continuity plan, the Executive Board discussed and endorsed the reduction of ex-post control activities.
In 2017, the Agency completed 4 ex-post controls of which 2 were financial and 2 were non-financial.

The areas subjected to financial ex post controls were:

- Collection of fees and payments for the evaluation of
  - Scientific Advice procedures
  - Line Extensions procedures

The areas subjected to non-financial ex-post controls were:

- Correct handling of information from external sources, disclosing alleged improprieties concerning EMA activities;
- Accurate evaluation of the declarations of interests of experts involved in EMA activities.

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

Annual review of sensitive functions

In line with the EMA's 'Guidance on sensitive functions' (doc. ref. EMA/486191/2013) and in accordance with the Agency’s standards for internal control (ICS) No. 7 ('Operational structure'), a risk

assessment to identify the Agency's sensitive functions was carried out in 2017. The annual reassessment of sensitive functions 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, firstly, identify and, secondly, manage the risks associated with sensitive functions at EMA.

The review has been performed by the Quality and Risk Management Office in cooperation with the Anti-Fraud Office. The functions performed by staff occupying managerial positions were reviewed taking into account any recent Agency's reorganisation, any new post created, or functions transferred. The residual risk inherent to these positions after the controls already in place to mitigate the risks (preventive/detective controls) was assessed. Further to the assessment of the adequacy of the mitigating controls in place, a final inventory of the sensitive functions was established according to the methodology detailed below.

The functions deemed as sensitive were recorded in a register presented to the Executive Director on 20 December 2017.

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 2017, a new procedure to streamline the processing of legal and financial commitment was introduced and, as a consequence, the ACPC rules and membership were updated.

Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2017, reconciliations for 100% of the data between SIAMED (the product- and procedure-tracking system) and SAP (the budgetary system) were carried out on a regular basis. No findings that could impact the declaration of assurance were detected.

Data protection

EMA processes personal data in accordance with the rules laid down in Regulation (EC) 45/2001, and is subject to the supervision of the European Data Protection Supervisor (EDPS). In accordance with Regulation (EC) 45/2001, a Data Protection Officer (DPO) is appointed, with the main responsibilities of:

- advising data controllers on ensuring that all EMA activities are carried out in compliance with data-protection legislation;
- maintaining a register of processing operations;
- notifying and consulting the EDPS where necessary.

In accordance with article 25 of Regulation (EC) No 45/2001, EMA as a Data Controller must give a notice of processing operations to the DPO. The details of the notified processing operations shall be filed in a Register maintained by the DPO. There are currently 82 processing operations in the data protection register.

Further to the EDPS bi-annual monitoring exercise performed in 2017, EMA results have achieved 100% of the target notifications to be filed in the DP Register.[5] In terms of activities related to data protection, the DPO followed very closely the issues related to the adoption and implementation of the new General Data Protection regulation (GDPR) that will enter into force in May 2018. The DPO gave two presentations to the EXB on the new Regulation and its impact on EMA's activities, and a set of recommended actions to align EMA's data governance with the new EU data protection law was discussed internally. The DPO also coordinated the follow-up on the EDPS consultation opinion with regard to the use of cloud-based services by EMA for ADR. A set of comments to the draft Guidelines on cloud computing was subsequently provided to the EDPS in July 2017. Throughout the year, the DPO offered data protection training sessions on the GDPR to members of EMA staff, and participated as a member of the Technical Anonymization Group (TAG). The DPO was also an invited speaker at the Global ENT summit in Paris (June) and at the International Seminar on data protection organized by the Brazilian Chamber of Deputies (May). In October 2017, EMA hosted a 2-day meeting of the EDPS-DPO Network with the full agenda dedicated to the GDPR and its consequences for EU bodies.

The DPO has been providing advice to data controllers on a regular basis, in particular with regard to the application of personal data legislation to human resources activities, access to documents procedures, the Agency's IT projects, and to the Anti-fraud office.

Regular bilateral meetings took place between the DPO and the executive director/deputy executive director in 2017.

3.11. Management of competing interests

As of 2015, EMA reviews all of its policies on independence and rules for handling competing interests and their implementation on annual basis, and publishes an annual report. The report includes results of breach-of-trust procedures, any *ex-ante* and *ex-post* controls carried out, initiatives planned for the following year, and recommendations for improvement. The 2016 and 2017 European Medicines Agency Annual Report on Independence will be published in 2018.

Management Board

The Policy on the handling of competing interests of the Management Board remains unchanged following a revision in October 2016. This revision addressed an observed inconsistency between Policies 0044 for Scientific Committees members and experts and this policy, with regards to restrictions for grants/other funding to an organisation/institution, as well as for close family members. The restrictions for grants/other funding were therefore aligned with those in Policy 0044, while maintaining the restrictions for close family members as stated in Policy 0058.

The involvement of members and alternates in Management Board activities takes into account several factors: 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), and the action requested from the Management Board.

Since 2016, the revised policy includes an ex-ante evaluation which is performed to compare the details contained in each new declaration with those of the previous declaration, and with the CV provided. Members are required to undergo training before their declaration of interest can be submitted. In addition, the names of members having declared competing interests, which could affect their impartiality with regard to specific items on the agenda, are identified and communicated to the

[5] https://edps.europa.eu/sites/edp/files/publication/17-11-27_survey_2017-0130_en.pdf

chair and the Board (together with applicable restrictions), and noted in the minutes. Members are informed, in writing and ahead of the meeting, of the perceived competing interest which has been identified and the applicable restriction to their involvement at the meeting. At the start of each meeting, members are further asked to declare any specific interests which could be prejudicial to their independence with respect to the items on the agenda.

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

No breach of trust procedures were initiated for Management Board members in 2017.

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 has been 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, 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 to determine if an expert's involvement should be restricted or excluded in the Agency's specific activities. 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 which 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, like rapporteurs, are stricter than those for 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 which are incompatible with involvement in Agency's activities in accordance with the policy, the Agency would not allow this expert to participate and would 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 corporate website.

Completed e-DoIs, their interest levels, and the e-CVs of scientific committee members and experts are published on the Agency's corporate website for transparency purposes. The European experts' list on the Agency's corporate 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. The Agency last updated the procedure in April 2015. No breach of trust procedure was formally initiated in 2017.

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 2017, 7 experts informed the Agency of such intention and the restriction was immediately applied.

In 2017, 795 e-DoIs were checked before new experts were uploaded in the EMA Experts database as an *ex-ante* control. The 2017 *ex-post* control focused on SAG and Ad Hoc Expert Groups participants as a follow-up to findings from the 2015 and 2016 *ex-post* control. Overall, the control showed that the system for handling declarations of interests for meeting participation works well. No major problems with the e-DoI completion by the experts or the e-DoI evaluation by EMA staff were identified.

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 EMA and candidates before recruitment was revised as a result of the review of the policy on the handling of declarations of interests of scientific committee members and experts, as well as the review of the policy on competing interests of the MB members. The revised Decision rules were adopted by the EMA Management Board in October 2016 and became effective as of 1 January 2017.

As a result of these changes, the DoI form for staff was updated and all staff completed the new DoI form in early 2017. The submission and evaluation of the DoI is now performed in SAP HR.

Training was provided to all EMA staff and dedicated training sessions for managers were organised to facilitate implementation of the revised rules.

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).

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.

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 competing 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 competing interests.

For the period from 1 January 2017 to 31 December 2017, a total of 24 applications were made, resulting in 19 authorisations without restrictions and 5 applications with restrictions. Examples of restrictions 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; all decisions include a reminder of the binding obligation of confidentiality after leaving and a requirement that opinions given in public presentations must be stated to be the former staff member's own, and not linked to their former employment at the Agency.

Information on restrictions applied to applications in 2017 is given in Annex 7.

External consultants and contractors

Competing interests for external consultants and contractors are covered by the standard framework contract provisions[6] 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

[6] Article II.3

shall ensure that the contractor's staff are not placed in a situation that could give rise to conflicts of interest. Without prejudice to Article II.1, 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 Central sourcing office.

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 was developed by the Portfolio office that provides information on how project-related CCI should be handled, as well as practical measures that should be taken to avoid disclosure.

3.12. Telematics strategy implementation

The Network is responsible for implementing the European Union (EU) Telematics strategy. The Telematics system provides pan-European IT services to support the implementation of European pharmaceutical policy and legislation. During 2017, EMA and its partners made significant progress in implementation of the strategy. A new version of the EudraVigilance system for Human medicines was released: a major milestone for pharmacovigilance and a significant step forward in improving support for public health through monitoring of medicines safety. Solid progress was made in the design and delivery of substance, product, organisation and referential (SPOR) data management services. The referential management service (RMS) replaced EU Telematics Controlled Terms (EU TCT) as the central repository and provider of referentials data. Version 2.3 of RMS and organisation data (OMS) management services was deployed successfully in December 2017, allowing the registration of SPOR industry users for the first time. New versions of electronic Application Forms (eAF v. 1.22) used by pharmaceutical industry — MAA (Human and Vet), Renewal (Human and Vet) and Variation (Human and Vet) — were released and the common repository was extended to contain referral and all veterinary submissions. In April 2017, a meeting between industry associations and the EU Telematics Management Board took place where industry associations shared their consolidated views on the implementation of the eCTDv4.0 standard, in view of the updated eSubmission roadmap and on their ideas on the development of the Telematics strategy 2025. The first meeting of the Telematics Change Management Board (CMB) took place in 2017, to give Member States greater transparency around the

prioritisation and approval of business change requests for shared IT services. A think tank workshop was held in November 2017 in Berlin and attended by the EU Telematics Management Board members and chair of the EMA Management Board to confirm business needs and the input necessary from the Network in order to begin development of the new Telematics strategy (2020-2025).

3.13. Information security strategy

An Information Security strategy 2017-2018 was approved in early 2017 with the aim to enhance the Agency's activities in such domains like security governance, information security, technology security, and risk management.

In 2017, the Agency continued to implement the strategy through the following activities:

- Establishment of Cloud Security Consultative Group, followed by a continuous cooperation in this area;
- Implementation of Advanced Security systems to detect and prevent unauthorised access to the infrastructure;
- Implementation of Cloud foundations services to support the adoption of the Agency's Cloud strategy;
- The Agency's technology security controls were enhanced with additional systems to detect and prevent security attacks and incidents, such as: Advanced Threat Analytics (ATA), Privilege Access Workstation (PAW) and Red Test Exercise with CERT-EU;
- Finalisation of a mandatory training on IT security for all staff and planning for its roll-out;
- Revision of IT Risk Management process and development of security Key Risk metrics.

4. Management assurance

4.1. Review of the elements supporting assurance

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 were asked to draft a report and sign a declaration of assurance for their areas of responsibility.

The purpose of these declarations is to confirm, on the basis of the facts in their possession, that the information contained in the report gives a true and fair view, except as otherwise specified in any reservations related to defined areas of revenue and expenditure, and that the resources assigned have been used for their intended purpose and in accordance with the principle of sound financial management.

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

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.

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.

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.

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 2017 assurance, the Agency draws attention to the imposed reduction of 10% of the Agency’s establishment plan between 2014 and 2018, during the same period that fee-related workload (as reflected by increased fee income from like-to-like tasks) has grown by 55%. As noted by the European Court of Auditors, significant new tasks (e.g. in the area of Clinical Trials, development of pan European IT systems) were assigned to the Agency without any increase in staff, leading to a critical dependence on external expertise in affected areas.

The Agency therefore emphasises that the growth in volume and complexity of fee-related activities combined with new tasks require specific expertise in scientific and non-scientific areas. Establishment plan cuts are leading to an unsustainable reliance on staff employed under more precarious short-term, low-paid contracts or highly paid consultants. This has significant limitations due to expertise that cannot be obtained and knowledge loss particularly, bearing in mind that the Agency deals with large amounts of sensitive data and confidential information.

In addition, the relocation of the Agency requires significant resources to be redistributed for relocation tasks at the expense of discontinuing or reducing work programme activities, during a period when the Agency is facing a high rate of staff attrition and risk of loss of critical expertise.

Going forward, such shortage of establishment plan posts will result in risks to delivering on the future public health and legislative responsibilities of the Agency. This underlying risk is significantly increased as a consequence of the relocation, as drawing upon short-term or low-paid contracts to compensate for long-term stable establishment plan posts will no longer be sustainable due to different labour market conditions.

Therefore a change in the establishment plan is necessary, and such strategic direction will facilitate decrease in overall headcount over time.

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.

London, 7 June 2018

[Signature on file]

Guido Rasi

(Executive Director)

Annexes

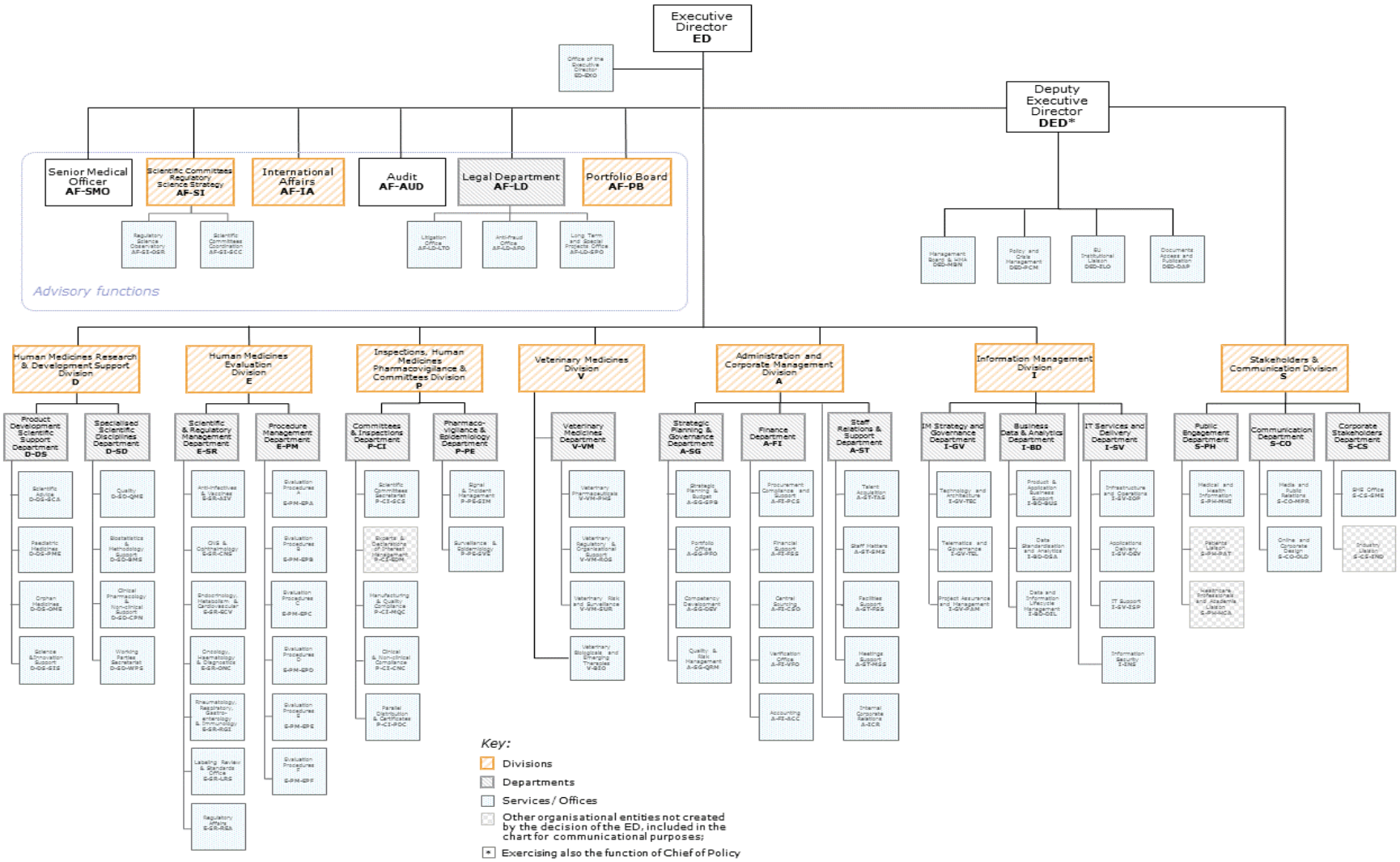
Annex 1. Core business statistics

Business statistics can be found in Part 1.

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 2017



Annex 4. Establishment plan

Category and grade	Authorised for 2016		Occupied as of 31/12/2016			Authorised for 2017		Occupied as of 31/12/2017			Authorised for 2018	
	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	-	4	-	2	1	-	4	-	3	1	-	3
AD 14	-	6	-	6	1	-	6	-	6	2	-	7
AD 13	-	9	-	9	10	-	11	-	11	10	-	11
AD 12	-	42	-	39	27	-	40	-	35	24	-	43
AD 11	-	38	-	37	25	-	40	-	40	29	-	43
AD 10	-	44	-	44	31	-	43	-	43	25	-	41
AD 9	-	37	-	37	35	-	42	-	42	38	-	45
AD 8	-	54	-	54	52	-	53	-	53	59	-	59
AD 7	-	54	-	54	56	-	61	-	61	54	-	65
AD 6	-	37	-	37	74	-	37	-	37	70	-	23
AD 5	-	18	-	18	18	-	3	-	3	18	-	0
Total AD	***0***	***343***	***0***	***337***	***330***	***0***	***340***	***0***	***334***	***330***	***0***	***340***
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	5	-	5	3	-	6	-	6	3	-	7
AST 9	-	7	-	7	3	-	7	-	7	4	-	6
AST 8	-	16	-	16	4	-	16	-	16	4	-	16
AST 7	-	19	-	17	12	-	19	-	18	13	-	22
AST 6	-	39	-	39	21	-	43	-	43	19	-	42
AST 5	-	43	-	42	30	-	43	-	39	36	-	46
AST 4	-	49	-	49	35	-	52	-	52	45	-	57
AST 3	-	47	-	46	78	-	45	-	44	65	-	46
AST 2	-	32	-	27	34	-	23	-	22	33	-	7
AST 1	-	0	-	0	37	-	0	-	0	31	-	0
Total AST	***0***	***259***	***0***	***250***	***257***	***0***	***256***	***0***	***249***	***253***	***0***	***251***
AST/SC1	-	0	-	-	0	-	0	-			-	
AST/SC2	-	0	-	-	0	-	0	-			-	
AST/SC3	-	0	-	-	0	-	0	-			-	
AST/SC4	-	0	-	-	0	-	0	-			-	
AST/SC5	-	0	-	-	0	-	0	-			-	
AST/SC6	-	0	-	-	0	-	0	-			-	
Total AST/SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Grand subtotal	***0***	***602***	***0***	***587***	***587***	***0***	***596***	***0***	***583***	***583***	***0***	***591***
Grand total	**602**		**0**	**587**	**587**	**596**		**0**	**583**	**583**	**591**	

Information on the entry level for each type of post

Interims: from 1 January 2017 to 31 December 2017, there have been 112 interims, and their interim assignment was for 7.03 months on average during 2017.

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 or 8 (Service Head), AD 9/10 (Head of Department) and AD 12 (Head of Division) in line with the functions of the post advertised.

Annex 5. Results of the screening exercise as of December 2017

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 contractor/consultant, external service provider) 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).

Job type (sub)category	2016 (%)	2017 (%)
Administrative support and coordination	**16%**	**18%**
Administrative support	16%	17%
Coordination	1%	1%
Operational	**79%**	**78%**
Top-level operational coordination	1%	1%
Programme management and implementation	20%	23%
Evaluation and impact assessment	43%	40%
General operational	15%	14%
Neutral	**5%**	**4%**
Finance/control	5%	4%
Linguistics	0.00%	0%
Total	**100%**	**100%**

Annex 6. Human and financial resources by activity

Activities	FTEs	Staff expenditure	Infrastructure, IT and project exp.	Meetings cost (incl. overhead)	Evaluation cost (NCAs)	Other operational expenditure	TOTAL
		€'000	€'000	€'000	€'000	€'000	€'000
1 Evaluation activities for human medicines	**389**	**52,948**	**34,634**	**12,317**	**103,077**	**7,771**	**210,747**
1.1 Pre-authorisation activities	82	11,459	3,685	5,471	18,084	7	38,706
1.2 Initial evaluation activities	81	11,709	3,154	2,114	10,801	873	28,652
1.3 Post-authorisation activities	83	10,506	8,435	1,210	61,217	1,542	82,910
1.4 Referrals	6	745	217	178	180	386	1,705
1.5 Pharmacovigilance activities	106	13,565	11,673	2,252	12,795	3,781	44,067
1.6 Other specialized areas and activities	31	4,964	7,470	1,091	0	1,181	14,707
2 Evaluation activities for veterinary medicines	**42**	**5,387**	**3,097**	**2,375**	**3,662**	**573**	**15,093**
2.1 Pre-authorisation activities	3	407	141	876	198	0	1,622
2.2 Initial evaluation activities	14	2,000	592	535	1,142	196	4,465
2.3 Post-authorisation activities	13	1,274	1,835	506	2,322	148	6,085
2.4 Arbitrations and referrals	2	242	64	205	0	229	739
2.5 Pharmacovigilance activities	5	614	204	0	0	0	818
2.6 Other specialized areas and activities	6	849	261	252	0	0	1,363
3 Horizontal activities and other areas	**158**	**21,433**	**7,948**	**5,103**	**7,986**	**1,529**	**43,999**
3.1 Committee coordination	25	2,916	1,026	1,381	0	0	5,323
3.2 Inspection and Compliance	36	3,585	2,245	1,214	7,986	2	15,032
3.3 Partners and Stakeholders	39	6,567	1,757	2,477	0	803	11,605
3.3a Transparency and access to documents	21	2,831	1,195	31	0	0	4,057
3.3b Information	22	2,799	1,009	0	0	722	4,530
3.4 International activities	14	2,734	716	0	0	2	3,452
4 Corporate Governance and Support activities	**189**	**26,759**	**9,647**	**452**	**0**	**1,127**	**37,985**
4.1 Governance, Quality Management and Internal Audit	28	4,776	1,256	452	0	662	7,147
4.2 Finance	36	4,479	1,888	0	0	73	6,440
4.3 Information technology	50	8,765	2,414	0	0	0	11,179
4.4 Human resources	40	4,481	2,211	0	0	0	6,692
4.5 Infrastructure services	13	1,407	623	0	0	0	2,031
4.6 Communication (corporate)	22	2,850	1,254	0	0	393	4,497
Total	**778**	**106,527**	**55,327**	**20,247**	**114,725**	**11,000**	**307,825**

Annex 7. Report for 2017 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 2017:

Case No	Job title / Function at EMA	Length of service	Date of application	Date of JC opinion	Decision of Executive Director (ED)	Date of ED decision
1	SNE	2 years	15-Feb-17	07-Mar-17	The staff member should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he/she may have dealt with in the performance of his/her responsibilities at the Agency during his/her 2 years here, for a period of six months, to be counted as of the date he/she left the Agency (15.10.2016). This does not apply to attendance of public meetings.	21-Mar-17
2	TA	3 years and 2 months	20-Apr-17	04-May-17	1. The staff member should not, for one year, engage in work related to EMA's Information Technology service and delivery (e.g. software development and maintenance, infrastructure and service operations) and Data Management activities. 2. The staff member should, for one year, refrain from individually liaising with any member of staff of the European Medicines Agency with regards to any professional activity he/she may have dealt with in the performance of his/her responsibilities at the Agency.	19-May-17
3	TA	15 years	25-Aug-17	06-Oct-17	During a period of twelve months, to be counted as of the date he/she leaves service, the staff member should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he/she may have dealt with in the performance of his/her responsibilities during his/her 15 years at the Agency.	06-Oct-17
4	TA	15 years	27-Sep-17	11-Oct-17	During a period of twelve months, to be counted as of the date he/she leaves service, the staff member should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he/she may have dealt with in the performance of his/her responsibilities during his/her 15 years at the Agency.	14-Nov-17

Case No	Job title / Function at EMA	Length of service	Date of application	Date of JC opinion	Decision of Executive Director (ED)	Date of ED decision
5	TR/CA	Trainee for 9 months CA for 5 years and 3.5 months	19-Sep-17	11-Oct-17	Reminds staff member that during a period of twelve months, to be counted as of the date he/she leaves service, he/she should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he/she may have dealt with in the performance of his/her responsibilities at the Agency during his/her 6 years 1 month at the Agency.	27-Oct-17

Annex 8. Risks

Operational activities

Risk	Mitigating actions and controls
Product assessment – procedure management	
Lack of experts having the required competences and expertise	In place: • Legal requirements, e.g. regarding composition for CxMPs • Appointment process for CxMP, working party and SAG members • Management Board review of CHMP, CVMP and PRAC competencies • Criteria for competence and expertise of committee members and alternates for CHMP, CVMP, PRAC, HMPC PDCO, COMP and CAT • Defined roles and responsibilities of experts and committees • Establishment of specialised forums for experts (including SAGs) • Proactive search for expertise from academia/learned societies • Possibility for expert witnesses having a limited controlled role • Joint EMA-HMA training strategy
Product assessment – Applicant fraud	
Incorrect scientific opinion due to infringement of compliance involving data fraud by applicant or third party supplying data	In place: • Cross-Agency infringement action group • Procedures for implementing Penalties Regulation • Standards for documentation of investigations and ensuing procedures to ensure integrity of any future infringement procedures • Processes for taking regulatory action • EMA policy on handling of information from external sources, disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision or maintenance of human or veterinary medicinal products • Established contact point for anybody with suspicious evidence of misconduct to bring information to the attention of EMA, if necessary, in confidence (reporting@ema.europa.eu) In progress: • Active publication of clinical trials data post authorisation • Process for triage of cases and decision-making (with Head of Department, CxMP, supervisory authorities, EC, third country regulators etc.) on further action • Increased transparency to third parties through access to documents encouraging reporting of infringements
Inspections	
Risk of substandard data and information which can impact on scientific opinions on medicinal products due to the framework for compliance with GMP/GCP/GLP/PhV from non-EU countries not meeting EU standards	**For GMP** In place: • The ICH process • Third countries policies/work programmes (Mutual Recognition Agreements, Agreement on Conformity Assessment and Acceptance of Industrial Products • EC/EMA bilateral relations with other third countries, and exchange of inspections information and reports, in particular non-compliance cases • GMP pilot programme on active pharmaceuticals ingredients and joint GMP inspections for finished products (pilot) • GMP inspections project with ICMRA (in progress) • Listing of third countries APIs and written statement • EMA-FDA GMP initiative in the area of GMP inspections (ongoing) • Reduction of duplication of inspections with consequent resource saving, leading to wider range of sites being inspected at global level • Better use of information from other authorities and the use of such information for the triggering of inspections (Inspection agreements with international partners)

Risk	Mitigating actions and controls
	• Planning module for GMP inspections available in EudraGMP **For GCP** In place: • The ICH process • GCP Inspection Policy (expansion of routine inspections for third countries) • Third countries policies/work programmes • EC/EMA bilateral relations with other third countries and exchange of inspections information and reports, in particular non-compliance cases • EMA GCP Working Group on acceptability of third country clinical trials established – Ethics Advisory Group • Guidance on the acceptability of third country clinical trials • International cooperation through training and capacity building activities for inspectors (ongoing activity) • EMA-FDA GCP initiative in the area of GCP inspections (ongoing) • Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline • Inspection validation of the MAA • Reduction of duplication of inspections with consequent resource saving, leading to wider range of sites being inspected at global level In progress: • Capacity building activities **For GLP** In place: • The OECD programme • Validation process of MAAs feeds into the decision on inspections (site selection) • Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline • Promoting the verification of the GLP status of sites at the time of the Clinical trial application, rather than MAA. **For PhV** In place: • The ICH programme • Inspection programmes • PhV inspectors working group • Planned international cooperation • International cooperation through training activities • Cooperation between EMA and Member States on inspections in third countries • Informal network of PhV inspectors to enable capacity building • Better use of information to focus the scope of the inspections on the issues of most concern
Need for an inspection not identified or inspection not carried out on time	In place: • Relevant SOPs/WINs are in place to identify the need for an inspection, to ensure that the inspection is carried out on time, and to cover the handling of quality defects • Relevant external guidance document available • Contracts in place with NCAs, specifying the expertise of the staff involved and the timeframes for the procedures
Pharmacovigilance	
Lack of additional post-marketing authorisation data on	In place: • Launch of post-authorisation studies, using ENCePP network • Independence, transparency and methodological standards of ENCePP

Risk	Mitigating actions and controls
human medicines to proactively identify, qualify and quantify risks related to the use of authorised medicines	studies ensured • Implementation of pharmacovigilance legislation (PASS and PAES) • 'Best evidence' procedure to support PRAC discussions In progress: • EMA studies conducted using longitudinal patient record databases (in-house and commissioned studies) • Registries initiative • Real world evidence
Inability of the Agency to effectively conduct veterinary pharmacovigilance, if suitable IT system is not developed to replace EVVet2	In place: • Review of the Agency's requirements for IT, related to pharmacovigilance of veterinary products *Creation and maintenance of single EU product database now included in SPOR scope.*
Lack of an agreed and consistent approach for the evaluation of benefit-risk balance for mature (old) products	In place: • Peer review of reports • Strengthened input from specialists during evaluation Planned: • Discussion with Committees at strategic review and learning meetings • Reflection with Committees on the approach
Procedure management – resources	
Lack of Agency resources for the introduction of the new PSUSA procedure	In place: • Documented procedure for management of PSUSA procedures • Redistribution of workload across the different procedural teams • PSUR repository for management of PSURs • Existence of quality-controlled reliable source of data about products on the EU market and MAHs (e.g. Art 57 of Regulation (EU) No 1235/2010) (Human) In progress: • Operational validation of the Article 57 database Planned: • Initiation of ICT tools, i.e. inclusion of NAPs into SIAMED
Lack of Agency resources to support the management of procedures (reliance on interims)	In place: • Documented procedures for managing different types of procedures • Optimised organisational design to maximise resource utilisation • Reduced resource allocation to other non-core fee generating tasks, projects (e.g. e-submission, workflow tool) and initiatives • Training to interim staff • Use of SIAMED templates In progress: • Change request for SIAMED to automate procedure tracking and improve management of procedures

Support activities

Risk	Mitigating actions and controls
Data management – data protection and security	
Existing security controls may not be adequate to mitigate an accidental leak of confidential information to external parties by internal employees, interims, trainees, or contractors with access to EMA information	In place: • EMA Security Policy adopted (including 3 annexes related to IT Security) and continuously reviewed • Security officer and dedicated Information security service • IT tools including adequate security measures to protect confidential data • IT security measures to manage access to data (e.g. access rights management)

Risk	Mitigating actions and controls
systems	• Declaration of confidentiality and conflicts of interests for staff and for IT contractors • Complementing the internal log reviews with independent log reviews • Annual checks to validate the control of access to database by system/data owner • Security tools against data leak • USB restriction on laptops • Information Security strategy 2017-2018 in place • Implementation of Advanced Security systems to detect and prevent unauthorised access to infrastructure • The Agency's technology security controls enhanced with additional systems (to detect and prevent security attacks and incidents) • IT Risk Management process and security Key Risk metrics in place • 2018 audit on incidents concerning disclosure of confidential information to unintended recipients (implementation action plan in progress)
Intentional leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • Data-access management • Firewall system in place to protect the information systems • Antivirus system in place • Data centre access limited to relevant resource • Access control lists to restrict contractors' data access • Checklist to manage contractors' access to IT systems that have not been added to the SAP HR system • Data encryption tools to allow data transfer between parties outside the EMA network (e.g. via an encrypted USB stick) • Passwords are required to be updated every 6 months • USB restriction on laptops Planned: • Data logs activated on all systems (where possible) and red flags set up and actively monitored • Proactive markings on sensitive documents • Each new system account given appropriate level of access and necessary access restrictions applied • Access rights reviewed on regular basis to ensure that permissions are appropriate
Sensitive and/or confidential data intentionally accessed or removed from EMA premises by external suppliers	In place: • Security awareness training • Code of conduct • CCTV • Access control • Printing control • Confidential waste stored in locked confidential bins
Financial, legal and reputational damages for the Agency in case of data protection failure	In place: • Identification of systems to be notified and regular management review • Data protection Regulation (EC) 45/2001 • Data protection implementing rules • Data protection function within the Agency • Appointment of data protection officer (DPO) • Notification procedures from data controllers to DPO • Notification procedures from DPO to European Data Protection Supervisor (EDPS) • Register of data processing • Training programme for existing members of staff and newcomers • Data protection microsite on intranet

Risk	Mitigating actions and controls
Data management – data quality	
Data required for scientific and regulatory procedures and decision making is of poor quality, incomplete, inaccurate and/or lacks integrity	In place: • Validation of data entry in SIAMED and EudraVigilance • Data manager/stewards functions with defined roles and responsibilities • Data analytics tool (SAS) and processes for monitoring data quality • Ensure that the data management activities have enough human skilled resources (e.g. to SIAMED OBIEE support) • Governance structure for data management • Centralised activity in single department responsible for data governance and information assets • Design and maintain core data (SIAMED) reports and templates In progress: • Cleaning of existing data to ensure reference quality level • Agency quality standard and reference for data based on ISO standards • Single trusted, identifiable master copies of substances, referentials, organisations and products data available as service Planned: • Data quality control level based on risk assessment of individual data assets • Data quality monitoring and data quality processes
Data management – document management	
Loss of information due to inadequate document management system and processes	In place: • EMA records management policy and business classification scheme • Rolling programme to develop RM processes and procedures and education • Basic back-up procedures undertaken on shared drives, Outlook and document management system • Awareness and training session on document/records management best practices • Procedure on Core Master File Product (SOP 1004 on Core master files of medicinal products for human and veterinary use following the centralised and referrals procedures) In progress: • KPIs to monitor compliance with EMA records management policy • Identification of data-set owners and definition of clear roles and responsibilities Planned: • Records management embedded in redesigned human medicines evaluation processes • Ex-post controls on compliance with SOP 1004 for product related EMA core documents • Compliance assessment of Agency's document/records management IT systems • Automatic assignment of retention policy and classification • Reporting tools in the document management system to automate monitoring and control measures
IT development and management	
Loss of knowledge due to contractors leaving the Agency	In place: • Reducing reliance on contractors for critical skills and knowledge (e.g. solution architecture, data architecture, system administrators) • Review of IT operating model to insource further critical skills and knowledge • Outsourcing less critical skills and services, managed by strict contracts and SLAs (in progress) • Documenting most critical applications (in progress)

Risk	Mitigating actions and controls
Recruitment	
Staff planning and recruitment do not cover the needs of the Agency in order to achieve its objectives	In place: • The Agency's management meets at least four times a year (quarterly EXB meetings) to identify future competencies needed and adequate staff levels to meet the Agency's objectives. The EXB sets up the resource plan, which is then monitored throughout the year. In addition, other ad hoc meetings are set throughout the year to discuss particular resource needs. • Two separate reports are downloaded from the SAP HR system with all the staff information, and a comparison is made of the reports in order to mitigate any discrepancy on numbers, and to assure that the Agency does not go above the establishment plan. A separate database with all the staff levels is updated daily. This creates a three-layer system which improves the quality of the data. Afterwards, a monthly report is produced, comparing the staff levels expected, the actual staff levels, and any deviation from the plan, which is then sent out to the Head of Administration Division, Head of HR, Head of Strategic planning and budget, and HR business partners. • Monthly meetings between the Resource planning coordinator and HR business partners to monitor actual staff levels compared to the plan. These meetings also set the basis for planning of potential resignations, retirements and resource planning for part-time, maternity and unpaid leave covers. • Fortnightly recruitment planning meetings between Head of Talent Acquisition, Head of HR, Head of Staff Matters and HR business partners to go through the recruitment planning • Bi-monthly salary budget meetings between Resource Planning Coordinator and Salary officers • Quarterly budget meetings between Resource Planning Coordinator and Budget team • Fortnightly meetings between Resource Planning Coordinator and Head of Strategic planning and Budget • Fortnightly meetings between Resource Planning Coordinator and Head of Administration In progress: • Coordinated planning entity to include resource planning in cooperation with recruitment and management, competence identification and ABB
Inadequate recruitment procedures due to substandard IT tools	In place: • Manual control • Ex-post control In progress: • Talent recruitment tool implementation
Procurement	
Failure to deliver timely procurement and obtain value for money	In place: • Adequate/realistic planning, based on a solid methodology in order to justify and optimize procurement procedures, launched and aligned with budget planning • Clear assignment of responsibilities is defined at the outset of a procurement procedure when defining the business case for capital expenditure. All procurement procedures are performed in close cooperation with procurement control office. • Clear definition of needs, including justification (e.g. ex-ante evaluation of needs for new projects or expenditure, a cost/benefit analysis, justification for outsourcing, etc.) • Systematic conduct of a lessons learned exercise at the time when a procurement decision is made. A debriefing is also conducted by procurement control office on any procurement over €60,000, to identify

Risk	Mitigating actions and controls
	improvements • Regular monitoring of planned deadlines and reporting (e.g. monitoring tools in place, deadline management, quality assurance, etc.) • Procurement procedures included in the scope of the enhanced ex-post controls under Article 46 of the Financial regulation
Lack of contract management competencies, processes and tools may impact continuity of services	In place: • Sourcing request system tracking requests • Templates • Weekly, monthly and three months in advance reporting to requestors In progress: • Awareness/training sessions to contract managers requestors/programme/project managers
Tenders are late and/or specifications are poor due to delays in the allocation of relevant staff and/or insufficient capacity of allocated staff to dedicate sufficient time to complete tender documentation and progress evaluation activities	In place: • Tenders are managed through a harmonised approach, based on project management practices and using Microsoft Projects tool; plans (including timelines) and resource plans are created • Staff is formally allocated to run tender procedures • Staff allocated to tender procedures to be released from other conflicting priorities in order to dedicate sufficient capacity to ensure the tender is run smoothly In progress: • Increase business involvement and understanding, skills and capacity to perform this task
Finance - Revenue collection and Treasury management	
Loss on currency exchange rate fluctuations	In place: • Decision of the Accounting officer on the management of the Agency's cash and currency exposure • Regular budget monitoring, EUR revaluation of GBP denominated commitments, inclusion of salaries realised exchange rate difference in the budget result, and inclusion of unrealised exchange rate difference in the year end account balance with EC • Disclosure of liquidity, solvency and market risks in Section 11 of the Agency's annual accounts
Clinical data publication	
Non-compliance of MAHs/pharmaceutical industry with the policy	In place: • Consultation with stakeholders in context of particular procedures In progress: • Identification of non-compliance scenarios and remedial actions to be taken Planned: • Annual report on implementation experience, including details of non-compliance
Delay in establishing a dedicated, proactive publication team	In place: • Recruitment of staff members to create the team • Training of new team on process and specifically redaction consultation phase • Establishment of business process In progress: • Automated workflow tool
Not meeting expectations with stakeholders	In place: • Tagging (with text) Protection of Personal Data (PPD) and Commercially Confidential Information (CCI) differently in the text • Communication strategy including targeted interactions with stakeholders • Introducing a colour scheme to identify PPD from CCI

Risk	Mitigating actions and controls
	In progress: • Establishing technical anonymisation group Planned: • Review of experience six months after implementation of the policy, resulting in lessons learned, remedial actions and continuous interactions with stakeholders
Stakeholder relationships	
Insufficient resources to implement legally required activities to meet expectation of stakeholders	In place: • Long-term strategy (Network strategy 2016-2020) • Programming process (Programming document, MAWP) • Portfolio management process • ABB/ABC/ABM (activity based budget) • Priorities setting and resources allocation (EXB meetings)
Failure to meet stakeholder expectations	In place: • Framework for interaction with patients and consumers • Framework for interaction with healthcare professionals • Framework for interaction with academia • Framework for interaction with industry stakeholders • SME surveys and other initiatives • Communication perception surveys • Targeted stakeholder meetings • Rudimentary tools including website/media monitoring/google alerts • Involvement of patients and health care professionals
Issues not identified and subsequently escalated into a crisis	In place: • Media monitoring • Escalation process to DED-PCM level • MLT rules of procedure (escalation of issues) • Incidence Review Network process • Involvement of stakeholders and partners (in particular HCP and patients) in all EMA's activities

Fraud

Risk	Mitigating actions and controls
Intentional leak of confidential information to external parties by internal employees, interims, trainees or contractors who have access to EMA's information systems with the purpose of personal gain	• Data access management in place • Firewall system in place to protect the information systems • Antivirus system in place • Datacentre access limited to relevant resource • Checklist in place to manage Contractors access to IT systems that has not been added to the SAP HR system. • Tools to encrypt Data are in place to allow the transfer between the parties outside of the EMA network, for example via an encrypted USB stick • Contractor rates data access is restricted using access control lists • Passwords are required to be updated regularly • USB restriction on EMA laptops. • EMA Security Policy adopted (Policy 0076) • (11) Internal guidance on access control to Agency premises approved on 27/09/2017 (doc ref EMA/276354/2017)
Sensitive and/or confidential data is intentionally accessed or removed from EMA network for personal gain through a cyber-attack	• Monitoring of traffic across EMA firewalls is undertaken by IT • Penetration test and vulnerability assessment performed regularly • Intrusion Prevention and Detection system systems in place • Security policy in place detailing how employees can protect data

Risk	Mitigating actions and controls
The NCA experts participating in EMA assessment work at national level (not included in the EMA Experts database) are not independent	• Legal requirements for independence (Article 63(2) of Regulation (EC) No 726/2004.). • Contractual arrangements and memorandum of understanding with NCAs
Incorrect scientific opinion because of infringement of compliance involving data fraud by applicant or third party supplying data =>> public, animal health, legal and reputational risk	• Cross-Agency infringement action group established • Increased transparency to third parties through access to documents encouraging reporting of infringements • EMA Policy 0072 on handling of information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products was adopted on 17/03/2017 • EMA Policy 0070 on publication of clinical data for medicinal products for human use was adopted on 02/10/2014

Brexit

In light of the UK's decision to withdraw from the EU, the Agency is conducting impact and risk assessment. Along other aspects, the main risks identified are as follows:

Risk	Impact
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, requiring remedial actions to address workload and capacity aspects; • potential loss of specific expertise, requiring remedial actions to ensure that the quality of scientific output is not affected.
Loss of existing staff and inability to recruit new staff, resulting in loss of professional competencies and knowledge	Due to high uncertainty: • current EMA staff may choose to leave the Agency for other organisations to re-acquire longer-term stability and perspective; • the Agency is not able to provide longer-term stability when recruiting new employees, and as such may fail to attract competent experts to fulfil the roles and tasks.
Currency volatility	• High fluctuations of GBP to EUR exchange rate introduce instability in the Agency's cash flow and budget

Annex 9. Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2017

(Those contracts signed during reference period 01/01/2017 – 31/12/2017)

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/2015/48/IS	Framework contract	BNP Paribas Real Estate Advisory & Property Management UK Ltd	Non-residential property consultancy, property related client representation and assistance and ancillary services.	GBP 1,000,000	Open procedure in OJEU	Administration Division
EMA/2016/51/COM	Shortform contract	Wolters Kluwer Health (Medical Research) Ltd	Evidence-base database	EUR 101,120	Negotiated (mid-value)	Communications Department
EMA/2016/22/DF	Framework shortform contract	Gratte Brothers Catering Equipment Limited	Catering equipment and appliances	GBP 100,000	Negotiated (mid-value)	Administration Division
EMA/2016/28/SG	Framework contract	Sungard Availability Services (UK) Limited	Provision of work area recovery site	GBP 270,000	Open procedure in OJEU	Administration Division
EMA/2016/33/PH	Service contract	IMS World Publications Ltd	Access to a European primary and/or secondary care medical database	EUR 1,380,000	Competitive procedure with negotiation (Art 135(1)(a) RAP)	Deputy Executive Director

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/2016/03/HR	Framework contract	Berkshire Consultancy Ltd	Provision of learning and development activities for personal development and management skills learning - 1st priority	GBP 1,511,000	Open procedure in OJEU	Administration Division
EMA/2017/03/COM	Framework contract (shortform)	RB Creative Group Ltd trading as Red Blizzard	Modular Exhibition Solutions	EUR 16,541	Negotiated (mid-value)	Communications Department
EMA/2017/18/HR	Framework contract	Corporate Learning Solutions PLC	Provision of learning and development activities for personal development and management skills learning - 2nd priority	N/A	Open procedure in OJEU	Administration Division
EMA/2017/19/HR	Framework contract	GBS Corporate Training Limited	Provision of learning and development activities for personal development and management skills learning - 3rd priority	N/A	Open procedure in OJEU	Administration Division
EMA/2016/64/ST	Service contract	Corporate Travel Management (UK) Ltd.	Travel management services for Agency's staff and visitors	EUR 12,000,000	Open procedure in OJEU	Administration Division
CON/17/ETF/0001	Framework contract	Pricewaterhouse Coopers EU Services EESV	Staff engagement survey	EUR 96,000	Open procedure in OJEU	Administration Division

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
PMO3/PR/2016/027	Framework contract	AWP Health & Life S.A.	Insurance covering risk of accidents, work-related illness and natural death of civil servants, temporary staff and contract staff at the European Union institutions, bodies and agencies.	N/A	Open procedure in OJEU	Administration Division
PMO/PO/2016/034	Framework contract	Axa Belgium NV	Accident and death insurance for non-statutory staff 2017-2021.	N/A	Open procedure in OJEU	Administration Division
EMA/2017/12/COM	N/A	Dun & Bradstreet	Financial information on companies and legal entities	GBP 31,000	Negotiated (low-value)	Communications Department
EMA/2015/26/PH SC01	Specific Contract (re-opening of competition)	The University of Dundee	Scientific study	EUR 198,854.00	Re-opening of competition	Deputy Executive Director Office
EMA/2017/34/LD	Framework contract	Wilberforce Chambers	Pre-litigation and conciliation services in relation to the lease agreement for the EMA building.	GBP 75,000	Negotiated Article 134(1)(h) RAP	Legal Department

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/2015/26/PH SC02	Specific Contract (re-opening of competition)	The University of Dundee	Scientific study	EUR 199,384	Re-opening of competition	Deputy Executive Director
EMA/2017/22/ST	Framework Contract	CNLR Horizons Ltd	Employee assistance programme	GBP 33,660	Negotiated (low-value)	Administration Division
EMA/2017/32/ST	Framework Contract	Move Plan	Consultancy for removal services	EUR 13,800	Negotiated (low-value)	Facilities Support Service
DI/07590	Framework Contract	Oracle	Oracle software licences, maintenance, training, consult	EUR 6,750,000	EU - DIGIT	Central sourcing Office
DI/07611	Framework Contract (re-opening of competition)	Bechtle Brussels NV/SA	Acquisition of compute solutions for data centres – special purpose compute solutions, optimised for special workloads. (DCCS) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 700,000	EU - DIGIT	Central Sourcing Office
DI/07612	Framework Contract (re-opening of competition)	CANCOM JV Consortium (CANCOM on line BVBA/SPRL, CANCOM on line GmbH, CANCOM GmbH)	Acquisition of compute solutions for data centres – special purpose compute solutions, optimised for special workloads (DCCS) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 700,000	EU - DIGIT	Central Sourcing Office

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
DI/07613	Framework Contract (re-opening of competition)	COMLIN Consortium (Telindus SA, Proximus NV/SA, Dimension Data belgium NV/SA)	Acquisition of compute solutions for data centres – special purpose compute solutions, optimised for special workloads (DCCS) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 700,000	EU - DIGIT	Central Sourcing Office
DI/07614	Framework Contract (re-opening of competition)	Econocom Products & Solutions Belux NV/SA	Acquisition of compute solutions for data centres – special purpose compute solutions, optimised for special workloads (DCCS) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 700,000	EU - DIGIT	Central Sourcing Office
DI/07610	Framework Contract (re-opening of competition)	CANCOM JV Consortium (CANCOM BVBA/GmBh)	Acquisition of computer solutions for data centres – encompassing general purpose compute solutions (x86 servers) (DCCS) – Lot 1	EUR 2,247,447.95	EU - DIGIT	Central Sourcing Office
DI/07630	Framework Contract (re-opening of competition)	Bechtle Brussels NV/SA	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 1	Overall value of all contracts under the re-opening of competition EUR 1,650,000.00	EU - DIGIT	Central Sourcing Office

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
DI/07631	Framework Contract (re-opening of competition)	CANCOM JV Consortium (CANCOM BVBA/GmBh)	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 1	Overall value of all contracts under the re-opening of competition EUR 1,650,000.00	EU - DIGIT	Central Sourcing Office
DI/07632	Framework Contract (re-opening of competition)	HECO4EU (Econocom Products & Solutions Belux NV/SA, HP Belgium BVBA/SPRL)	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 1	Overall value of all contracts under the re-opening of competition EUR 1,650,000.00	EU - DIGIT	Central Sourcing Office
NP-EFSA-HUCAP-2016-15	Framework Contract	LinkedIn	LinkedIn Services	EUR 58,000	EU - EFSA	Administration Division
DI/07650	Framework Contract (re-opening of competition)	Bechtle	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 500,000.00	EU - DIGIT	Central Sourcing Office
DI/07651	Framework Contract (re-opening of competition)	Cancom JV	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 500,000.00	EU - DIGIT	Central Sourcing Office
DI/07652	Framework Contract (re-opening of competition)	Econocom Products & Solutions Belux NV/SA	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 500,000.00	EU - DIGIT	Central Sourcing Office

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
DI/07653	Framework Contract (re-opening of competition)	Proximus	MEQ IV - mobile equipment (laptops, tablets, iPhones) - Lot 2	Overall value of all contracts under the re-opening of competition EUR 500,000.00	EU - DIGIT	Central Sourcing Office
30-CE-0756464	Specific Contract (re-opening of competition)	Baker Tilly Belgium	Technical assistance in the field of audits and controls	EUR 11,000	EU - DG Budget	Audit
30-CE-0756492	Specific Contract (re-opening of competition)	Moore Stephens LLP	Technical assistance in the field of audits and controls	EUR 16,680	EU - DG Budget	Audit

Annex 12. Annual report 2017

Please see the Agency's 'Annual report 2017', publicly available on the EMA corporate website.

Annex 13. Administrative appropriations – Building policy

Financial Regulation, Article 87(3.a) Current building(s)

	Name, location and type of building	Other comments
	30 Churchill Place, London, E14 5EU	The building is a multi-tenanted office premises and EMA occupies parts of the basement, ground and promenade levels, and levels 1 through 10
Surface area (in square meters) of which office space of which non-office space	26,450	
	18,448	
	8,002	
Annual rent	GBP 14.0 million : - Rent - GBP 11,759,937 Estimated Building Service Charge: 2,200,000	Rent for level 10 is payable from 2018
Type and duration of rental contract	Rental lease of 25 years duration; term commencement is 1 July 2014	
Host country grant or support	None	
Present value of the building	Not applicable	

Financial Regulation, Article 87 (3.b) Building projects in planning phase

Due to the UK's announced departure from the EU in 2019, planning for new premises for the Agency took place during 2017. Following the decision on 20 November 2017 for the new location to be Amsterdam, the preparations entered into an operational phase with in-depth planning for this relocation.

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

On 26 February, the EMA Management Board supported a notification of the European Medicines Agency's intention to move to a new building for further submitting to the EP and the Council.

The notification includes a move to temporary premises by 30 March 2019, while the new permanent premises are under construction. The permanent building, located in the Amsterdam Zuidas area, includes a total lettable floor area of 31,496 m^2 whereof 21,828 m^2 are office space, and also includes

200 bicycle parking spaces and 35 scooter parking spaces. The Dutch Real Estate Agency, CGREA, that will be the owner and lessor of the building, will provide the premises fully fitted and furnished with expected delivery date of 15 November 2019. Total rent of the permanent premises payable from 2020 is €10,193,600, including building maintenance.

Annex 14. Environmental performance

Environmental management at the Agency

In 2017 the Agency adopted and endorsed its Environmental framework and included it into an exhaustive European Commission's Eco-Management and Audit Scheme (EMAS) manual describing the structure in place. Due to the business continuity situation that the Agency found itself in on 29 March, the planned next step of 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 registration to EMAS once located in the final premises, planned for the end of 2019.

EMAS is site-based and an updated version will be prepared with the environmental statement for the new EMA offices in Amsterdam. The programme requirements include an aim for BREEAM excellent.

The environmental footprint continues to be monitored, with the main impact coming from running the Agency offices with resource consumption, waste, carbon emissions, and staff engagement and behaviour. The Agency aims to pursue setting objectives and targets for the new final premises to be monitored and achieved over the course of 2020 and onwards.

Overview of EMA performance in 2017

The following table shows an overview of consumption, expressed also per workstation. The office space accounts for approximately 80% of the total space occupied, with capacity of 1,359 workstations; the remainder being delegate and visitor, common and storage areas.

Indicator	Units	2014		2015		2016		2017	
		Overall	Per workstation	Overall	Per workstation	Overall	Per workstation	Overall	Per workstation
Energy consumption	kWh	3,321,927	2,844	3,635,921	2,990	3,266,036	2,686	3,087,933	2,272
Water consumption	m^3	2,429	2.08	2,607	2.14	1,345	1,11	1,525	1.12
Paper consumption	kg	41,287	35.35	26,554	21.84	22,953	18.88	19,951	14.68
Waste (incl. non-recyclable, recyclable and confidential)	kg	240,130	205.6	176,530	145.2	176,676	145.3	182,277	134.1
Work related travel (incl. delegates, missions, training and candidates)	miles	9,229,023	7,902	9,785,507	8,048	8,848,604	7,277	9,035,488	6,645
Overall net CO2e	kg CO_2e	2,724,461	2,333	2,842,558	2,338	2,854,120	2,347	2,902,786	2,136

Annex 15. Project implementation

Project progress and delivery as of 31 December 2017 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 2017 **in comparison to what was planned and approved at the end of 2016** (i.e. as noted **in the work programme 2017**). Notes explaining the changes are added.

In certain cases where the project start or end dates foreseen in the work programme 2017 were revised during 2017, the current dates are added in the relevant cells, with the original date from the work programme 2017 shown as crossed out.

Projects in human medicines evaluation activities

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2017
Pharmacovigilance programme						
EudraVigilance auditable requirements	Q4 2013	Q2 2018				• Based on the positive final audit report, PRAC issued their recommendation that EudraVigilance database meets the functional specifications and that it has achieved its full functionality • System went live in production in November 2017 • EVDAS art.57 reports have been delivered successfully to NCAs • Data submission to WHO • Switch of eRMR (electronic reaction monitoring reports) functionalities

Clinical trials programme						
Clinical Trials Information Systems (CTIS)	Q3 2014	2020				This new project has been approved as a result of merger between EU Portal and clinical trials database and Safety reporting in November 2017. Therefore its start date backs to the original approval of EU Portal and clinical trials database and Safety reporting, presented below.
EU Portal and clinical trials database **(merged into CTIS)**	Q3 2014	*Q3 2019*				• Postponed the delivery of fully functional system (i.e. EU portal and database) for audit towards 2018 • User Acceptance Test (UAT) was performed for initial releases. Results led to the setup of a joint planning task force between the EMA and the vendor in charge of delivery (IT4U). • In December 2017, this project was merged with Safety reporting into a new project named Clinical Trials Information Systems (CTIS. Software development and configurations by external supplier presented quality issues causing delays in project delivery and increased cost.
Safety reporting **(merged into CTIS)**	Q4 2014	2018				• In December 2017, this project was merged with Safety reporting into a new project named Clinical Trials Information Systems (CTIS) • In 2017, the majority of safety reporting analysis and design phase deliverables were completed, including business requirements for the integration with the upgraded EudraVigilance Clinical Trial Module. Finalisation of analysis and design is expected in the first half of 2018.
eCollaboration programme						
Standalone projects						
Add Value: raising the standard of scientific output **(Completed)**	Q3 2017	Q4 2017				• Knowledge basis drawn on the experience gained with the patient preference study in Myeloma and subsequent analysis of its applicability to other therapeutic areas • Revised assessment report (AR) template in light of understanding the operational feasibility and value of systematically integrating patient involvement in the assessment process • AR template revised to include benefit/risk section that better corresponds with the need for more explicit scientific rationale in key documentation • New process flow for documenting assessments in an iteractive way; more economic sequence of steps has been discussed and agreed with the CHMP core group and is now an established principle that is due to be tested through a pilot after the closure of the project. The results of the pilot will determine the shape in which the new process flow will be formalised and documented.

						• Specific guidance for assessors on the Quality part of the Overview for Day 80/120/150/180 ARs and LOQs/LOIs • Knowledge on the practical feasibility of making adaptive changes to the EMA ARs to better suit the data needs of HTAs

Projects in veterinary medicines evaluation activities

Programme / project	Project start	Project delivery target	Project delivery against Time Budget Scope	Results 2017
Veterinary change programme				
Eudravigilance veterinary v3.0	Q3 2017	2019		• Preliminary business case and gate 2 approval • Analysis and Design artefacts in progress Cost estimates by external supplier presented divergence to baselined value, causing an increase in project cost.
Veterinary business processes **(Completed)**	Q1 2016	Q3 2017		• As-is mapping of all major veterinary regulatory procedures • To-be process maps for all major veterinary regulatory procedures; and harmonised sub-processes, where applicable to several procedures • Comprehensive toolkits (checklists) for revised business procedures • A revised proposal of organisational structure for the Division

Projects in horizontal activity areas

Programme / project	Project start	Project delivery target	Project delivery against Time Budget Scope	Results 2017
Data-integration programme				
Substance & Product Management Services	Q2 2017	2020		• Preliminary business case and approval at gate 2
Referentials management service	Q1 2017	~~2017~~ ~~Q2 2017~~ Q1 2018		• A referential management service (people, processes, data, and change management) providing high quality controlled vocabularies for use by the complete European Medicines Regulatory Network and Pharmaceutical Industry • A system to support ISO IDMP standards 11239 & 11240 • Replacement of the current EUTCT system with RMS for the management of

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2017
						controlled vocabularies • The technical and procedural foundation for the organisations management service and for the substance and product management service Software development and configurations by external supplier presented quality issues causing delays in project delivery and increased cost.
Organisations management services	Q1 2017	~~2017~~ ~~Q2 2017~~ Q2 2018				• A new Organisation Management Service based on streamlined processes to support the efficient management of Organisation master data within EMA and the EU regulatory network Software development and configurations by external supplier presented quality issues causing delays in project delivery and increased cost.
Identity and access management 2	Q1 2017	~~Q4 2017~~ Q3 2018				• Approval of final business case and gate 3 • Analysis and design documentation for the on-boarding of selected applications • Progress the configuration of the identity governance solution to integrate with the selected applications
ISO IDMP	Q4 2013	~~Q4 2017~~ 2018				• Contribution to the ISO process towards finalisation of IDMP standards and technical specifications • Progressed updating of documentation based on ISO ballot comments • Decision in ISO for publishing 4 new international standards for products: ISO 11615, ISO11616, ISO/TS 20443, ISO/TS 20451 • EU IG for products (framework) updated accordingly • ISO standards ISO11615, ISO11616, ISO/TS 22443, ISO/TS20451 (MPID/PhPID) sent to ISO for publication • HL7 messaging standards for products (SPLv8 & CPM4) completed • Revised Products EU IG (Document Framework) completed • ISO 11238 substance mappings to HL7 V3 CPM4/SPL8 completed • HL7 V3 messaging for substances (SPLv8 & CPM4) completed • Substances EU IG (Document Framework) delivered • ISO 11238 & ISO/TS 19844 standards voted for publication • HL7 FHIR design prototypes for IDMP products and chemical substances

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2017
						submitted to HL7 Due to the ISO balloting processes it was necessary to extend the ISO IDMP project timelines during 2016, so as to completely finalise the deliverables without interruptions in the activities. The budgetary/resource increase was due to the extension of the project.
Online programme						
Corporate website	Q1 2014	2019				• Technology and development approach defined with the delivery partner (DG DIGIT) • Project entered construction and migration phase in October 2017 • Content type development was completed (pending minor outstanding points) and content migration work has started • Improvements on usability were agreed (i.e. navigation structure) • The front-end display for two (out of 9) types of content was implemented
Standalone projects						
Publication and access to clinical data **(Completed)**	Q2 2014	~~Q4 2017~~ ~~Q1 2017~~ Q3 2017				• The clinical data publication website and tools • New internal processes • Training and change management
Rationalising working parties **(Completed)**	Q1 2017	2017				The project was prematurely closed but nevertheless delivered several outcomes, including: • A report that summarises the findings of the project team and provides recommendations • A new office (WPS) providing centralised administrative support to 17 CHMP Working Parties and other working groups • A forum to facilitate collaboration, exchange of information and coordination between the groups
IT application maintenance transition and transformation	Q4 2017	Q4 2018				• Business case and gate 2 approval
Data centre relocation preparedness	Q4 2017	Q1 2019				• Preliminary business case and gate 2 approval
Data centre strategy phase 1	Q1 2017	Q2 2018				• Business case and gates 2 and 3 approval
S-REPS (formerly	Q3 2017	Q2 2018				• Business case and gates 2 and 3 approval

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2017
SIAMED systems integration phase 1)						
Project 2014 (Level 10) **(Completed)**	Q2 2014	Q2 2017				• Project closure approved in June 2017 • The project was planned to deliver one office floor with 80% generic layout and 20% redesigned for the purpose. All business requirements have been delivered.

Projects in corporate support and governance activities

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2017
Recruitment tool **(Completed)**	Q2 2017	Q1 2018				• A new e-recruitment system • A tool to manage competence and skill of roles and families per recruitment selection • Training

Deprioritised projects

The list below presents projects that were de-prioritised from the 2017 portfolio.

Due to the Agency's relocation and consequent business continuity planning, projects prioritisation for 2018 was brought to a minimal scope. As a consequence, a number of projects are classified as 'on hold' until further notice.

A number of projects were also cancelled as their remit was overtaken by events or absorbed by other projects' scope or by business activities.

Programme / project	Status on 31 December 2017
Pharmacovigilance programme	
EudraVigilance signal management critical requirements	Project on hold
EudraVigilance Fixes	Project cancelled
Clinical trials programme	
EudraCT and EU Portal Legacy	Project on hold
eCollaboration programme	
New delivery dates for the delivery of the single submission portal and implementation of eCTD4 have been adopted by the Telematics Board (EU TMB) and endorsed by the HMA on the 28 February 2018. New timelines are	

Programme / project	Status on 31 December 2017
reflected in the final updated version of the eSubmission Roadmap (version 2.1)	
eCTD 4 pre-project activities	Project on hold (the timeline has been further postponed, now proposing optional use of eCTD v.4.0 from Q3 of 2020 for CP submissions)
Single submission portal (internal and external project activities)	Project on hold (the stepwise deliveries towards the mandatory, fully integrated, single submission portal have been updated. The date for preparation of mandatory use of an EU single submission portal is set to Q1 2021 which will also include a stepwise implementation of a common telematics service desk)
Veterinary IT programme	
Implementation of veterinary legislation	Project cancelled (undertaken as part of the programmes' remit; not a project)
Union database	Project cancelled (covered by the scope of SPMS)
Governance / potential centralisation of functions	Project on hold
Online programme	
European Medicines Web Portal	Project on hold
Intranet Interface Design	Project on hold
Extranet Interface Design	Project on hold
Standalone projects	
IT Delivery Lifecycle	Project cancelled (progressing as business as usual)
Building EU network capacity to gather and analyse information on clinical use	Project cancelled (absorbed by business activities)
Single Submission Portal and integration	Project cancelled
Single Submission Portal and integration (external project activities)	Project cancelled

Annex 16. Pharmacovigilance Fee Regulation

Key Performance Indicators and performance information for the calendar year 2017

1. 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 to medicinal products, taking as a basis a high level of protection of health'* and inseparable from this is the aim *'to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products'.*

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

Section 2 of this report presents these key performance indicators for the calendar year 2016, and section 3 presents the more detailed performance information required by the regulation.

2. Key Performance Indicators

Key Performance indicator 1:

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

Pharmacovigilance activities financed by PhV fees	2017 actual
Number of PSURs and PSUSAs procedures started	923
Number of imposed PASS protocol procedures started	6
Number of imposed PASS report procedures started	6
Number of pharmacovigilance referral procedures started	7
Number of pharmacovigilance annual fee chargeable units invoiced	158,630

Key Performance indicator 2:

The 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	2017 estimated %	2017 actual procedures	2017 actual %
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **CAPs only**:		565	
· Micro sized enterprises	2.25%	3	0.53%
· Small and medium sized enterprises	7.50%	34	6.02%
MAHs invoiced for **PSURs and PSUSAs** procedures started involving **NAPs or CAPs/NAPs**:		7,861	
· Micro sized enterprises	2.50%	74	0.94%
· Small and medium sized enterprises	7.50%	289	3.68%
MAHs invoiced for **Imposed PASS protocol** procedures started for **CAPs only**:		8	
· Micro sized enterprises	2.25%	0	0.00%
· Small and medium sized enterprises	0.75%	1	12.50%
MAHs invoiced for **Imposed PASS protocol** procedures started for **NAPs or CAPs/NAPs**:		34	
· 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**:		2	
· Micro sized enterprises	2.25%	0	
· Small and medium sized enterprises	0.75%	0	
MAHs invoiced for **Imposed PASS report** procedures started for **NAPs or CAPs/NAPs**:		128	
· Micro sized enterprises	2.5	0	0.00%
· Small and medium sized enterprises	7.50%	3	2.34%
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:**		525	
· Micro sized enterprises	2.50%	7	1.33%
· Small and medium sized enterprises	7.50%	43	8.19%

Key Performance indicator 3:

The 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	2017 estimated %	2017 actual	2017 percentage
Pharmacovigilance **annual fee** chargeable units invoiced		158,630	
· Micro sized enterprises	2.50%	1,353	0.85%
· Small and medium sized enterprises	7.50%	8,704	5.49%
· Generics (non-SME)	36%	67,524	42.57%
· Authorised homeopathic, authorised herbal, and well-established use products	0%	26,285	16.57%

Key Performance indicator 4:

The 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	[7] Invoiced in 2017	Cash collected in 2017	[8] Percentage	Remuneration to NCAs for assessment performed
	€ '000	€ '000		€ '000
Income recovered for PSURs and PSUSAs procedures started	17,620	15,430	88% (87% in 2016)	9,887
Income recovered for imposed PASS protocol procedures started	162	144	89% (94% in 2016)	109
Income recovered for imposed PASS report procedures started	128	94	74% (100% in 2016)	54
Income recovered for pharmacovigilance referral procedures started	1,240	882	71% (99% in 2016)	957
Income recovered for pharmacovigilance annual fee chargeable units invoiced	9,098	9,063	100% (99% in 2016)	n/a

[7] The figures in this table differ slightly from the ones in tables 4,5,6 and 9 because they also include adjustments and corrections related to 2017 and processed in 2018, whereas the amounts shown in the tables below show only the value of the invoices related to the applications started between January and December 2017.
[8] Invoices are issued with 30 days credit which means that the payment of invoices issued in November and December 2017 was done in 2018. The final 2017 cash recovery rate as of April 2018 is 100% for PSURs and PSUSAs, PASS and Referrals.

3. 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 2017

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

Note: The Agency has made every effort to complete the detailed reporting requirements of the following tables, but in a small number of cases some data has not been available for the full calendar year 2017, pending the development of additional IT reporting functionality, in which cases the relevant fields are left blank.

1) Number of FTEs involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees.	Full Time Equivalence (FTEs)
Periodic safety update reports	18
Post-authorisation safety studies	2
Referrals initiated as a result of the evaluation of pharmacovigilance data	7
TOTAL	**27**

	2017	
2) Number of hours outsourced to third parties with specification of the activities concerned and costs incurred.	**Units**	**Cost €'000**
Identifying and managing duplicates	Number of duplicate couples assessed:275,020 (72,665 in 2016)	1,900
	Number of 'master' reports generated based on duplicated data: 133,635 (48,111 in 2016)	
Coding of reported medicines and active substances	Number of reported medicinal products/active substance terms recoded: 35,727 (91,650 in 2016)	
	Number of adverse reaction reports recoded: 41,124 (64,686 in 2016)	
Providing feedback on data quality	Total number of organisations subject to ICSR data quality review: 125 (120 in 2016)	
	Number of medicinal products in the xEVMPD quality reviewed and, where necessary, corrected: 369,073 (235,058 in 2016)	
The European Medicines Agency (EMA) is responsible for the monitoring of 400 substance groups (300 chemical and 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. In 2017, 233,556 (275,954 in 2016) literature references were screened and reviewed and 14,198 (5,595 in 2016) individual case safety reports (ICSR) were entered into Eudravigilance database and made available to National Competent Authorities and Marketing Authorisation Holders.		901

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	1,729	12,473
Cost for assessment of post-authorisation safety studies	196	194
Cost for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	772	1,111
Annual cost for information technology systems and literature monitoring		18,963
Overall pharmacovigilance costs	**35,438**	

4) Performance information relating to the assessment of periodic safety update reports (PSURs)

Number of procedures started	Number of reports received	Number of MAHs expected to submit	Number of MAHs who submitted	Number of CUs[2]	Number of joint submissions[3]	Number of MAHs who submitted joint report[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
923	n/a	8,426	n/a	48,502.00	356	7,859.00	326.00	3	83	6	17,518,080

5) Performance information relating to the assessment of draft protocols and of final reports of post-authorisation safety studies (PASS)

Number of procedures started	Number of protocols and reports submitted[1]	Number of (parent) MAHs[2]	Total number of MAHs[2]	Number of joint submissions[3]	Number of (parent) MAHs in case of joint submission[4]	Total number of MAHs in case of joint submission[4]	Number of SMEs Claimed	Number of SMEs Denied	Number of Micro Claimed	Number of Micro Denied	Total Amount Invoiced (€)
6	n/a	10	42	2	6	21	1	0	0	0	96,320
6	n/a	65	130	3	62	127	3	0	0	0	153,862

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 (€)
7	528	2,161	44	1	9	2	1,298,568

7 (a) Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	169	3
Fee for assessment of post-authorisation safety studies	4	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	44	1
Annual fee for information technology systems and literature monitoring	460	4

7 (b) Number of marketing authorisation holders that have claimed micro enterprise status involved in each procedure, number whose claim has been denied	Claimed	Denied
Fee for assessment of periodic safety update reports	54	3
Fee for assessment of post-authorisation safety studies	0	0
Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data	9	2
Annual fee for information technology systems and literature monitoring	206	3

8) Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees	2017
Generic application (Article 10(1) of Directive No 2001/83/EC)	1,999
Well-established use application (Article 10a of Directive No 2001/83/EC)	1,766
Authorised homeopathic medicinal product	84
Authorised herbal medicinal product	255

9) Performance information on annual fees

Number of marketing authorisation holders invoiced for annual fees	Number of CUs	SME status claimed?	SME status denied?	Micro status claimed?	Micro status denied?	Number of CUs: Generic Application	Number of CUs: Well-established Use Application	Number of CUs: Authorised Homeopathic	Number of CUs: Authorised herbal	Total Amount Invoiced (€)	Average Amount Invoiced (€)
3,806	158,630	460	4	206	3	72,862	25,441	2,831	1,829	9,094,232	57.33

10) Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure started.			
Member State	**PSUR**	*** PASS**	***Referral**
Austria	22	0	0
Belgium	20	0	1
Bulgaria	1	0	0
Czech Republic	15	0	1
Germany	40	1	3
Germany	59	1	0
Denmark	63	0	0
Estonia	5	0	0
Spain	54	0	1
Finland	17	0	0
France	58	3	0
Greece	1	0	0
Croatia	15	0	0
Hungary	9	0	0
Ireland	31	1	0
Italy	43	1	0
Lithuania	10	0	0
Latvia	7	0	0
Malta	2	0	0
Netherlands	80	0	2
Norway	8	0	0
Poland	19	1	0
Portugal	38	1	2
Romania	3	0	0
Sweden	91	2	2
Slovenia	2	0	0
Slovakia	2	0	0
United Kingdom	208	1	2
Total	**923**	**12**	**14**

11) Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.							
	PSUR and PSUSA			PASS		Referrals	
NCAs	No. of procs.	Total hours	Average per proc.	No. of procs.	Total hours	No. of procs.	Total hours
Austria	18	1,161	64			1	305
Belgium	18	1,780	99			1	852
Croatia	13	1,430	110				
Czech Republic	4	320	80				
Denmark	60	5,818	97				
Estonia	4	251	63				
Finland	14	965	69				
France	29	2,491	86				
Germany (BfArM)	42	4,377	104	1	115	1	1,173
Germany (PEI)	56	3,830	68	1	48		
Hungary	2	220	110				
Ireland	31	2,613	84	1	86		
Italy	39	3,184	82	1	50		
Latvia	7	698	100				
Lithuania	3	336	112				
Norway	5	329	66				
Poland	4	418	105				
Portugal	34	1,373	40	1	125	2	606
Romania	2	186	93				
Slovakia	1	82	82				
Slovenia	2	124	62				
Spain	39	2,820	72			1	801
Sweden	87	5,132	59	1	96		
Grand Total	**514**	**39,937**	**78**	**6**	**520**	**6**	**3,736**

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

Not all NCAs were in a position to provide data for 2017.

Annex 1

Performance information required as per Part V of the regulation

The following information shall relate to each calendar year:

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

Terms and abbreviations

Term/abbreviation	Definition
3Rs	'3R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AA	Accelerated assessment
AAR	Annual Activity Report
ABB	Activity Based Budget
ABC	Activity Based Costing
ABM	Activity Based Management
ACCELERATE	A multi-stakeholder Paediatric Oncology platform to improve drug development for children and adolescents with cancer
ACPC	Advisory Committee on Procurement and Contracts
AD	Administrators function group
ADAPT-SMART	Accelerated development of appropriate patient therapies – a sustainable, multi-stakeholder approach from research to treatment outcomes; IMI-funded project
ADI	Acceptable daily intake
ADR	Adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	Ad hoc Expert Group on Veterinary Novel Therapies
AEMPS	Spanish Agency for Medicines and Medical Devices
AERS	Adverse event reports
AFS	Anti-Fraud Strategy
Agency	European Medicines Agency
AMR	Antimicrobial Resistance
API	Active pharmaceutical ingredient
AR	Annual Report
Art.	Article
AST	Assistants function group
ASTERIX	Advances in Small Trials dEsign for Regulatory Innovation and eXcellence project
ATA	Advanced Threat Analytics
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AWP	Antimicrobials Working Party
BCP	Business Continuity Plan
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
BI	Business Intelligence
BIO	Biotechnology Innovation Organization
BNP Paribas	Banque Nationale de Paris and Paribas
BREEAM	Building Research Establishment Environmental Assessment Method
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
BWP	Biologics Working Party
CA	Contract Agent
CADVVA	CVMP Ad hoc Group on Veterinary Vaccine Availability

Term/abbreviation	Definition
CAP	Centrally Authorised Product
CAT	Committee for Advanced Therapies
CCI	Commercially confidential information
CCTV	Closed-circuit television, video surveillance system
CDP	Clinical Data Publication website
CDSCO	Central Drugs Standard Control Organization
CERT-EU	The Computer Emergency Response Team for the EU Institutions, bodies and agencies
CHMP	Committee for Medicinal Products for Human Use
CMA	Conditional Marketing Authorisation
CMB	Telematics Change Management Board
CMC	Focus on chemistry, manufacturing and controls
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDh WP	Coordination Group for Mutual Recognition and Decentralised Procedures Working Party
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CNSWP	Central Nervous System Working Party
CO2e	Carbon dioxide equivalent
COBIT	Control Objectives for Information and Related Technologies, a good-practice framework for information technology management and IT governance
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
CPAPE	China Pharmaceutical Association of Plant Engineering
CRISPR	Gene editing technique
CTIS	Clinical Trials Information Systems
CV	Curriculum vitae
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Generic abbreviation for EMA scientific committees
DED-PCM	Policy and Crisis Management Office at the EMA
DG	Directorate-General of the European Commission
DG Growth	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG Research	European Commission Directorate-General for Research and Innovation
DG Sante	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
Division	Organisational entity of EMA
DNA	Deoxyribonucleic acid
DoI	Declaration of interests
DPO	Data Protection Officer at the Agency
e.g.	Exempli gratia, for example
EAB	Enterprise Architecture Board
EAC	East African Community
EC	European Commission
ECA	European Court of Auditors

Term/abbreviation	Definition
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
eCTD	Electronic common technical document
ED	Executive Director
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
EFPIA	European Federation of Pharmaceutical Industries and Associations
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
EP	European Parliament
EPAR	European public assessment report
EPITT	European pharmacovigilance issues tracking tool
EPL	EMA product lead
eRMR	Electronic reaction-monitoring report
e-SME	Electronic SME application
ESS	The European Surveillance Strategy
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
etc.	Et cetera, and so forth
EU	European Union
EU contribution	EU special contribution for orphan medicines
EU IG	European union Implementation Guide
EU NTC	EU network training centre
EU TCT	EU Telematics Controlled Terms
EU TMB	EU Telematics Management Board
EU-DIGIT	European Commission Directorate General for Informatics
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice database
EudraLex	EU legislation; collection of rules and regulations governing medicinal products in the European Union
EudraLink	European Union Drug Regulating Authorities secure file sharing
EudraSmPC	European Union Drug Regulatory Authorities & Summary of Product Characteristics Database
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EU-IN	EU innovation office network
EUnetHTA	European network for health technology assessment
EUPAS Register	The European Union electronic Register of Post-Authorisation Studies
EUR	Euro
EURD list	EU reference dates and frequency of submission of periodic safety update reports (PSUR)

Term/abbreviation	Definition
Euro DIA	Drug Information Association meeting taking place in Europe
EUTCT	EU Telematics Controlled Terms
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
EVVet	EudraVigilance veterinary
EWG	Expert Working Groups
EWP	Efficacy Working Party
EXB	EMA Executive Board
Executive Board	EMA Executive Board
FAQs	Frequently Asked Questions
FDA	United States Food and Drug Administration
FP7	Seventh Framework Programme
GBP	Pound sterling
GCP	Good Clinical Practice
GCP IWG	Good Clinical Practice Inspectors Working Group
GDP	Good Distribution Practices
GDPR	General Data Protection Regulation
GL	Guideline
GLP	Good laboratory practice
GMDP	Good manufacturing and distribution practice
GMDP IWG	Good Manufacturing and Distribution Practice Inspectors Working Group
GMP	Good Manufacturing Practice
GP	General practitioner
GRP	Good regulatory practice
GVP	Good pharmacovigilance practice
GxP	Good practice (e.g. laboratory, clinical, manufacturing)
HC	Health Canada
HCP	Health Care Professionals
HCPWP	Healthcare Professionals Working Party
HIV	Human immunodeficiency virus
HL7	Health Level seven international
HL7 FHIR	Health Level 7 Fast Healthcare Interoperability Resources
HL7 V3	Health Level seven international version 3
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
Horizon 2020	EU Research and Innovation programme
HR	Human Resources
HTA	Health technology assessment
i.e.	Id est, that is
IAC	Internal audit capability of EMA
IALN	Inter-Agency Legal Network
IAS	Internal Audit Service of the EC
ICDRA	International Conference of Drug Regulatory Authorities, a forum of WHO Member State drug regulatory authorities

Term/abbreviation	Definition
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
ICMRA GMP	International Coalition of Medicines Regulatory Authorities on good manufacturing practice
ICS	Internal control standards
ICSR	Individual case-safety report
ICT	Information and communication technology
ID	Identification
IDeAL	Integrated Design and Analysis of small population group trials project
IDMP	Identification of medicinal products
IDWP	Infectious Diseases Working Party
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGDRP	International Generic Drug Regulators Programme
IIA standards	Internationally accepted audit standards
IMI	Innovative Medicines Initiative
IMP	Incident Management Plan
Implementing Rules	Implementing rules of the EMA Financial regulation
IMS database	Databases of electronic health care claims data
INC	International Neonatal Consortium
InSPIRe	Innovative methodology for Small Populations Research project
INT	Interim
IPA	Informal network of EU agencies working with pre-accession
IPRF	International Pharmaceutical Regulators Forum
IQM	Integrated Management
IRM	Institute of Risk Management
ISO	International Organisation for Standardisation
ISO IDMP	International standards for the identification of medicinal products
ISOP	The International Society of Pharmacovigilance
IT	Information technology
ITF	EMA Innovation Task Force
IWG	Inspectors Working Group
JA3	Joint Action 3
JC	Joint Committee
JECFA	Joint Expert Group on Food Additives
JIACRA	Joint Interagency Antimicrobial Consumption and Resistance Analysis report
JIRA	Software application that provides tracking and management functionalities (e.g. bug-tracking, issue-tracking, project-management)
kg	Kilogram
KPI	Key performance indicator
kWh	Kilowatt-hour
LMICs	Low- and middle-income countries
LMS	EU NTC Learning Management System
LSD	Lumpy skin disease
m3	Cubic metre

Term/abbreviation	Definition
MA	Marketing authorisation
MAA	Marketing-authorisation application
MAH	Marketing-authorisation holder
Management Board	EMA Management Board
MAWP	Multiannual work programme
MB	EMA Management Board
MedDRA	Medical Dictionary for Regulatory Activities
Member State	Member state of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MHRA	Medicines and Healthcare products Regulatory Agency, UK
MLM	Medical literature monitoring
MLT	Medicines Leadership Team
MNAT	Multinational assessment team
MRA	Mutual-recognition agreement
MRL	Maximum residue limit
MRP	Mutual-recognition procedure
MS	Member state of the European Union
MUMS	Minor use, Minor species
NAP	Nationally authorised product
NCA	National competent authority
Network	European medicines regulatory network
NIPH	National Institute of Public Health
NL	Netherlands
OBIEE	Oracle Business Intelligence Enterprise Edition – a comprehensive business intelligence and analytics platform
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health
OJEU	Official Journal of the European Union
OLAF	European Anti-Fraud Office
OMS	Organisations management service
ORP Task Force	Operations and Relocation Preparedness Task Force of the Agency, set up to ensure EMA preparedness for various development scenarios following Brexit
P3i	EMA's methodology for portfolio, programme, project management and IT delivery lifecycle
PAES	Post-authorisation efficacy study
PAM	Post-Authorisation Measure
PASIB	Public assessment summary information biosimilars
PASS	Post-authorisation safety study
PAW	Privilege Access Workstation
PB	EMA Portfolio Board
PBT	Persistent bioaccumulative and toxic substance
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PDF	Portable document format, a file format used to present and exchange documents reliably, independent of software, hardware or operating system

Term/abbreviation	Definition
PEI	The Paul-Ehrlich-Institute
PGWP	Pharmacogenomics Working Party
PhV	Pharmacovigilance
PIC/s	The Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/pharmacodynamic
PLC	Public Limited Company
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PMF	Plasma Master file
PPD	Protection of Personal Data
PPHOVA	The expert group working on the pilot project on harmonisation of old veterinary antimicrobials
PRAC	Pharmacovigilance Risk Assessment Committee
PREDICT-TB	Model-based preclinical development of anti-tuberculosis drug combinations, IMI project
PRIME	PRIority Medicines – a scheme to foster the 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
QWP	Quality Working Party
R&D	Research and development
Rev. (1,2,…)	Revision
RFI	Request for information
RMP	Risk-management plan
RMS	Referentials management service
RONAFA	EMA and EFSA joint scientific opinion on measures to reduce the overall need for use of antimicrobials in food-producing animals
RSO	Regulatory Science Observatory
SA	Scientific advice
SAG	Scientific advisory group
SAP	Systems, Applications & Products (budgetary system)
SAP HR	Human resources module of SAP
SAWP	Scientific Advice Working Party
SciCoBo	The Scientific Coordination Board
SE	Sweden
SG	Steering Group
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	Service-level agreement
SME	Small or medium-sized enterprise
SmPC	Summary of product characteristics
SmPC AG	Summary of product characteristics Advisory Group
SNE	Seconded national expert
SOP	Standard operating procedure

Term/abbreviation	Definition
SPOR	Substances, Products, Organisations, Referentials – and EMA programme
SWAP	Scientific Advice Working Party
TA	Temporary Agent
TAG	Technical Anonymization Group
TATFAR	The Transatlantic Taskforce on Antimicrobial Resistance
Term/abbreviation	Definition
TGA	Therapeutic Goods Administration, Australia
THIN	A medical research database of anonymised patient records from information entered by general practices
TOPRA	The Organisation for Professionals in Regulatory Affairs
TR	Trainee
TTIP	Transatlantic Trade and Investment Protocol
TWGs	Thematic Working Groups
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 lA 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
UAT	User Acceptance Test
UEMO	European Union of General Practitioners
UK	United Kingdom
Union	European Union
US	United States
USB	Universal Serial Bus
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
vPvB	Very persistent and very bioaccumulative substances
Web-RADR	Recognising Adverse Drug Reactions – IMI project exploring use of social media and new technologies for pharmacovigilance purposes
WHO	World Health Organization
WHO-UMC	World Health Organization's Uppsala Monitoring Centre – collaborating centre for international drug monitoring
WIN	Work instruction
WONCA	World Organization of Family Doctors