EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Annual activity report 2016

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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 (EMA, or 'the Agency') and in particular Article 47 thereof;
- having regard to the 2016 work programme of the Agency adopted by the Management Board at its meeting on 16 December 2015;
- having regard to the annual report 2016 of the Agency adopted by the Management Board at its meeting of 16 March 2017;
- having regard to the annual activity report 2016 of the Agency presented to the Management Board at its meeting of 15 June 2017;

GENERAL

1. Welcomes the results presented in the Annual report 2016, as well as the considerable work programme delivered in 2016, and notes with satisfaction that the Agency achieved its targets for the majority of the monitored performance indicators set in its Annual activity report.
2. Recognises the significant uncertainties introduced into the Agency's work as a result of the UK decision to leave the European Union; and appreciates the Agency's efforts to prepare for the upcoming change and to ensure, to the best ability, a continuous and undisturbed running of its business, by setting up a dedicated taskforce.
3. Notes that the main risks threatening the achievement of key objectives were identified, and that mitigating measures were in place; and calls for the Agency to carry on with the work on the assessment of the risks related to 'Brexit'.

MISSION

4. Is pleased with the fact that the Agency's work is well-aligned with the European policy agenda and its mission to protect human and animal health in the EU, and to ensure access to medicines that are safe, effective and of good quality.
5. Appreciates that, in 2016, EMA recommended 92 (81 human, 11 veterinary) new medicines for marketing authorisation, including 33 (27 human, 6 veterinary) new active substances (93 new medicines and 39 new active substances in 2015).
6. Is pleased with the adoption of the EMA multiannual work programme in June 2016, which is built on the Heads of Medicines Agencies (HMA) and EMA high-level strategy to 2020, and which outlines main initiatives and activities that the Agency will undertake in the coming years. Appreciates the link between the EMA multiannual work programme and the HMA multiannual work plan, ensuring an aligned and coordinated approach to addressing the strategic issues facing the European medicines regulatory network and reaching the common goals of the network strategy.

ACTIVITIES

7. Welcomes the launch of PRIME to enhance support for the development of medicines that target unmet medical needs; and it is impressed that 84 requests for PRIME eligibility were received in the first 9 months of operation of the scheme.

8. Appreciates the Agency's efforts to be as transparent as possible about its work and decision-making processes. Is pleased with the launch of the clinical website for the proactive publication of clinical data which will help foster innovation and encourage development of new medicine, and awaits the results of its full implementation.

9. Acknowledges the conclusion of the pilot on parallel regulator-HTA scientific advice procedures, and calls on the Agency to report on the development of a final sustainable model.

10. Underlines the vital role, work, and contribution of the Agency to the global response to the threat of antimicrobial resistance; and recognises that the central pillar of the Agency's strategy to fight antimicrobial resistance is the creation of an environment that stimulates and facilitates development of new antibiotics.

11. Welcomes the CVMP strategy on antimicrobials for 2016-2020; the ESVAC strategy for 2016-2020; the publication of the EMA/EFSA joint scientific opinion on measures to reduce the overall need of use of antimicrobials in food producing animals; and the CVMP and CHMP opinion on colistin.

12. Supports the EU innovation network, which facilitates the development of innovative medicines by making seamless early regulatory support available at national and EU level, and acknowledges that this initiative is a supplementary evidence of the successful interactions and cooperation of the Agency with the national competent authorities.

13. Notes the importance of encouraging research and innovation in veterinary medicines, promoting availability of veterinary vaccines, and engaging with the veterinary community.

14. Notes with satisfaction the progress achieved in 2016 on the mutual recognition agreement on GMP inspections with the FDA, to be formally signed in 2017.

TELEMATICS/IT ISSUES

15. Stresses the importance of a continuous implementation of the Telematics strategy, including the pharmacovigilance programme, clinical trials programme and data integration programme; and looks forward to the participation of the industry in the EU Telematics strategy.

16. Emphasises the significance of the data integration programme (SPOR), and the importance of cooperation within the network to jointly safeguard the timely implementation of SPOR. Looks forward to the reactivation of the 'Substances and products management services', to finalise the implementation of a new operating model to register and maintain data to support EU regulatory activities.

17. Notes that a number of projects have been deprioritised (such as Substances and products management services of SPOR, veterinary union database and extranet) or delayed (including EU portal and the clinical trials database), due to insufficient resources or changes of contractors during the project delivery.

18. Recognises the effort in delivering the pharmacovigilance programme and looks forward to its full implementation in 2017.

19. Reaffirms the importance of the timely implementation of the new EU Clinical Trial Regulation, which is expected to significantly improve the European environment for conduct of clinical trials. Notes that there still are major challenges ahead.

20. Welcomes the organisation of the first 'big data' workshop, and recognises the importance of working together to identify opportunities and challenges linked with the use of big data in medicines development and regulation.

FINANCES AND HUMAN RESOURCES

21. Is pleased that the European Parliament granted the discharge, in respect of the implementation of the budget of the Agency for the financial year 2015.

22. Notes that the Agency's initial budget for 2016 amounted to EUR 324,711,000; but was reduced, following the weakening of the pound and the reduced estimate of fee application, by EUR 16.3 million, to EUR 308,422,000; representing a 0.1% increase over the 2015 final budget. Regrets that the Agency was not allowed to retain these funds to create a 'Brexit' contingency reserve.

23. Notes that 89.4% of the Agency's 2016 revenue came from fees paid by the pharmaceutical industry for services provided; approximately 5.5% from the European Union budget; and 5% from external assigned revenue, as described in the work programme.

24. Recalls the need to collect data to support a future re-draft of the legislation governing the fees charged by the Agency; is pleased with the comprehensive support provided, and the significant effort from all parties involved; and looks forward to the European Commission's (EC) evaluation of the existing system, based on the data collected, to establish the strengths and weaknesses of the current system, and to define the scope of the upcoming revision.

25. Notes, that at the end of 2016, the Agency achieved occupancy rate of 98% for temporary agents; and that during 2016, the Agency recruited 170 members of staff and had 157 staff leaving the Agency.

26. Is concerned about the cut of temporary agents' posts of EMA, which are mostly fee-financed, and therefore urges the EU institutions to adapt the approach, whereby temporary agent posts develop in line with the workload and income.

ORGANISATIONAL

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

28. Acknowledges the Agency's continuous pursuit of operational excellence and more effective and efficient use of available resources through the reorganisation of the human medicines divisions, that started in 2013; and the similar exercise currently taking place in the veterinary medicines division.

29. Appreciates the extension of the concept of the multinational assessment teams to post-authorisation assessment, and encourages the use of this approach, also in the context of 'Brexit',

to allow a broader involvement of national competent authorities in the work of the EMA scientific committees.

30. Notes with satisfaction that the EU Network Training Centre has become a reference, ensuring that good scientific and regulatory practice is spread across the European medicines regulatory network.

INTERNAL POLICIES

31. Welcomes the revision of the policies on the handling of competing interests of the scientific committee's members, experts, and Management Board members; and of the rules concerning the handling of declared interests of staff members.

32. 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. Welcomes the continuous emphasis the engagement with stakeholders, including with civil society, and involving general practitioners in regulatory decisions.

33. Reiterates the importance of enhanced international cooperation and work- and information-sharing among medicines regulatory authorities, in order to increase the global regulatory efficiencies and synergies, and to avoid duplication of efforts.

AUDIT AND INTERNAL CONTROLS

34. Welcomes the Internal Audit Service's final report for the audit on Paediatric Medicines, which confirms that the Agency deploys and uses adequate systems in the management and control of Paediatric Regulation procedures.

35. Notes with satisfaction that neither critical, nor significant recommendations stemming from audits, performed by the Internal Audit Service of the European Commission, were open as at 31 December 2016.

36. Acknowledges the results of the audit of the European Court of Auditors, confirming the reliability of the 2015 accounts, and the legality and regularity of the transactions underlying the accounts of the Agency.

37. Is satisfied that no critical recommendations stemming from audits carried out by the Internal Audit Capability up to 31 December 2015 were open, and expects the closure of the very important recommendations within the agreed timelines.

38. 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 calls on the Agency to implement the identified planned actions to further improve efficiency.

39. 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, and that the 2016 ex-post controls programme showed no significant weaknesses in the Agency's internal controls.

40. Notes that a system to support the executive director's declaration of assurance was in place;

41. Takes note of the declaration of assurance of the executive director, and acknowledges that no reservations were made.

42. Thanks the members of scientific committees, experts and patient representatives, as well as all NCAs and EMA staff, for their exceptional commitment.

London, 15 June 2017

[signature on file]

Christa Wirthumer-Hoche
Management Board Chair

Introduction

This consolidated annual activity report provides an overview of the activities and achievements of the European Medicines Agency (EMA) in 2016 and is based on the guidelines of the EU Agencies Performance Development Network.

The EMA annual activity report 2016 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 2016 comprises four main parts and annexes, as follows:

Part I: Achievements of the financial year 2016. Mirroring the structure of the annual work programme of EMA for the year 2016, Part I provides information on achievements of objectives set in the annual work programme. This section also includes references to key performance indicators (KPIs) and targets.

Part II: Management. This section provides information on EMA governance. It also includes major internal and external developments which had an impact on EMA during the reporting year; information on budgetary and financial management and human resources management; assessment provided by the EMA management; assessment of audit results during 2016; as well as the follow-up on recommendations and action plans resulting from audits. It also includes components of the follow-up on observations from the Discharge Authority.

Part III: Assessment of the effectiveness of the internal control systems. In Part III, the report details the most important areas of risks associated with the EMA's operation, as well as compliance with, and effectiveness of the internal control standards (ICS).

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 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, with respect to the authorisation, maintenance and supervision, of medicines 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, such as the recent outbreak of the Ebola virus disease. 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 past two decades – 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. New legislation is being implemented or underway to further widen EMA's role, for instance in the field of clinical trials.

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 whole of 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 34 working parties and scientific advisory groups, and can draw from a network of some 3,700 scientific experts made available by the Member States to the Agency.

A robust scientific assessment process is pivotal in order to make 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.

European Medicines Agency is a fee-funded agency, with 89.4% of its 2016 revenue stemming from fees paid by the pharmaceutical industry for services provided. Approximately 5.5% of the Agency revenues came from the European Union budget, to fund various public health and harmonisation activities (such as the special contribution for orphan medicinal products); and 5% came from external assigned revenue, as described in the work programme. The total revenue entered in the accounts as at 31 December 2016 amounted to EUR 305,098,697.55.

[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. Achievements of the financial year 2016

The year 2016 was a challenging year for EMA, affected by the outcome of the UK referendum of 23 June, whereby the UK has decided to leave the European Union, introducing significant level of uncertainty around the seat and operations of the Agency.

In this climate, EMA is undertaking general preparedness planning to assess the steps needed to ensure continuity of its business operations. As part of these efforts, the Agency is looking at possible measures, in the event of relocation, to compensate for the potential loss of UK experts in the assessment of medicines, to attract and retain highly qualified staff, and to ensure that scientific recommendations and supervision of medicines can continue being delivered on time, and to the same high standard the Agency's stakeholders have come to expect.

Despite the uncertainties, the Agency continued – and will continue – to carry out its mission to protect public health, and successfully delivered its work plan for 2016.

1.1. Key achievements in 2016

Assessment activities highlights

In 2016, EMA recommended for marketing authorisation **81 medicines for human use**, including 27 new active substances, i.e. substances that have previously never been authorised in a medicine in the European Union, and that are not related to the chemical structure of any other authorised substance.

Average clock-stop for the assessment of new active substances and biosimilars in 2016 was 136 days. The average clock-stop for variations, that include extension of indication, was 73 days.

More than one in two applicants, who received a positive opinion for their medicine, had received scientific advice from EMA during the development phase of their product. Scientific advice is EMA's key tool to promote the collection of high-quality data, and to ensure that patients take part in clinical trials that are robust enough to support a marketing authorisation application.

In 2016, more than one in three medicines containing a new active substance was recommended for approval, using one of EMA's tools to facilitate early access to medicines that address unmet medical needs. Seven new medicines received a recommendation for marketing authorisation, following a review under accelerated assessment, and eight medicines received a recommendation for a conditional marketing authorisation. This tool allows for the early approval of a medicine, on the basis of less complete clinical data than normally required, if the medicine addresses an urgent unmet medical need. These medicines are subject to specific post-authorisation obligations that aim to obtain complete data on the medicine.

Following the analysis of the use and experience with conditional marketing authorisation and accelerated approval, a revised process for accelerated assessment was implemented in the first half of 2016, and revised guidelines on conditional marketing authorisation and accelerated assessment were published in March.

Umbipro (antiseptic gel preventing umbilical cord infections [omphalitis] in newborn babies) was recommended for use in countries outside the EU in April; and Pyramax (antimalarial) was the first Article 58 product included in the WHO-EMA collaborative registration pilot with low- and middle-income countries (LMICs) in Africa.

Following the positive feedback on the 'Early background' summary pilot, whereby background information from previous relevant evaluations is provided to rapporteurs and peer reviewers at day 10

of the procedure, an initiative to extend the provision of early background summaries to more marketing authorisation applications will start in Q2 of 2017.

In 2016, EMA recommended **11 new veterinary medicines** for marketing authorisation; six of these medicines contain a new active substance. Four medicines recommended for approval prevent viral or bacterial infections in food-producing animals. Two novel vaccines based on biotechnology were recommended for approval and four of the products with positive opinions were indicated for minor use in a major species or for minor species (MUMS), demonstrating the continued interest of the animal health industry in addressing availability issues in animals.

Advancing human health

In March 2016, EMA launched **PRIME** (PRIority MEdicines), a new scheme providing early and enhanced support to medicines that have the potential to address the patients' unmet needs. The scheme helps developers of promising medicines optimise their development plans, collect robust data, and submit high-quality marketing authorisation applications, so that these promising treatments can be authorised in a timely manner for the benefit of patients. 84 requests for PRIME eligibility were received during 2016.

In August 2016, EMA completed a two-year pilot project that explored how the **adaptive pathways** concept can be applied in practice. The experience from the pilot was discussed with stakeholders during a workshop held in December 2016 and organised together with the European Commission. The workshop tackled important questions arising from the adaptive pathways pilot, including how to best address patients' needs and expectations; how to generate appropriate data to aid medicines evaluation; and how to ensure that high standards for approval in the EU continue to be met.

In 2016, EMA started to offer parallel scientific advice with **Health Technology Assessment (HTA) bodies** on a routine basis, as part of the Agency's scientific advice activities. The joint scientific advice is based on the experience gained from a five-year pilot project allowing developers of new medicines to receive simultaneous feedback on their development plans from both EMA and HTA bodies. 63 parallel scientific advice procedures were included in the pilot and a report showed that the parallel scientific advice procedure achieved a high level of alignment between the data requirements of regulators and HTA bodies. EMA published a consolidated best practice guide, which sets out the different phases of the process for regulatory-HTA parallel scientific advice, and highlights ideal timelines and actions for all parties involved. This guide, together with a document that gives an overview of the HTA bodies that have participated in this EMA initiative so far, provides comprehensive information on the procedure. Parallel scientific advice is one of the Agency's key initiatives to improve patient access to important new medicines. It ensures that medicines development programmes generate appropriate data for regulators and HTA bodies, and allow the assessment of both benefit-risk balance and added value. This can reduce delays between a medicine's marketing authorisation for the European market, and decisions on reimbursement that are taken at the national level.

During 2016, the conceptual framework on EMA interactions with EUnetHTA with regard to providing the CHMP assessment report at the time of opinion, and particularly the establishment of a robust confidentiality framework under which such exchange can occur, was agreed with the EC, and presented to the industry at the EFPIA/EUnetHTA meeting in June. A high-level process was agreed with EUnetHTA and presented at the meeting in December 2016. It was also agreed to facilitate a direct interaction between regulatory assessors and HTA authors, in order to allow debriefing from the finalised regulatory assessment.

In May 2016, EMA organised a multi-stakeholder expert meeting to explore possible ways to **foster the development of advanced therapies medicinal products** (ATMPs) in Europe, and to expand

patients' access to these new treatments. ATMPs comprise gene therapies, tissue engineered products, and somatic cell therapies. These medicines have the potential to reshape the treatment of a wide range of conditions, particularly in disease areas where conventional approaches have proven to be inadequate. However, since the EU legislation on ATMPs entered into force in 2008, only eight ATMPs have been authorised.

Based on the ideas and solutions proposed, EMA and its scientific committees, together with the European Commission and the NCAs, are developing an action plan that will be published in 2017.

Pharmacovigilance

In January 2016, the Pharmacovigilance Risk Assessment Committee adopted the 'Strategy on measuring the impact of pharmacovigilance activities'. This strategy details how to gather data and knowledge on the concrete effect of the risk management measures and processes that are meant to ensure the safe use of medicines for patients in the EU. This was further discussed at a workshop, held in December 2016, which resulted in a number of recommendations and proposals to modify the strategy for a more systematic public health approach. This could help to determine how regulatory actions are affecting patient outcomes and enable regulators to change decision making in the future.

Encouraging research and innovation in veterinary medicines

In 2016, the Agency initiated a public consultation for stakeholders on possible issues encountered when new veterinary medicines are developed based on stem cells or monoclonal antibodies. The consultation phase was concluded for the five statements issued, and the outcome of the consultation is the starting point for the development of future guidance for these types of innovative veterinary medicines, building also on the experience gained so far with these technologies in human medicines.

Engaging with the veterinary community

One of the focus areas in veterinary pharmacovigilance is **reporting of adverse events** (AER). A number of measures have been implemented to promote AER reporting, and the success of these is reflected through the continuously increasing number of adverse event reports for veterinary medicines.

In November 2016, EMA held a stakeholder focus group meeting on promotion of pharmacovigilance for food producing animals. The meeting was attended by representatives from various stakeholder groups and mainly targeted practising veterinarians specialised in cattle, pigs, poultry, fish and horses. The meeting participants discussed reasons for underreporting of adverse events in food producing animals, and approaches to encouraging reporting and providing feedback to reporters.

Veterinary vaccines are effective tools for improving animal health without the need for antimicrobials, and essential in controlling outbreaks of epizootic disease (such as Bluetongue and avian influenza). EMA followed up on a joint EMA/HMA workshop, held in 2016, by creating a web page on the EMA website, dedicated to the availability of veterinary vaccines; and by consulting extensively with the veterinary pharmaceutical industry, to understand what they consider the main factors that limit access to the EU market for veterinary vaccines. Impact analysis of measures proposed by the industry for promoting the availability of vaccines was also conducted, and the results were presented to the industry in December 2016.

The EU network action plan to promote the availability of veterinary vaccines was developed in the first half of 2016.

As part of preparations to upload data on national products into the **common European database of veterinary medicinal products** and to support for the compilation of data, bilateral meetings with eighteen NCAs took place throughout 2016.

Tackling antimicrobial resistance

The emergence of antimicrobial resistance is a major public health concern. A central pillar in EMA's strategy to fight antimicrobial resistance is the creation of an environment that stimulates and facilitates development of new antibiotics. In September 2016, EMA, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and the United States' Food and Drug Administration (FDA) met at the EMA premises to discuss regulatory approaches for the evaluation of new antibacterial agents.

Additionally, the establishment of an EMA/FDA working group, to discuss in more detail the clinical development and data requirement aspects in the context of concrete applications for new antibiotics, was under discussion at the end of 2016.

In October 2016, the Agency's Committee for Medicinal Products for Veterinary Use adopted a strategy on antimicrobials for 2016-2020. The aim of this strategy is to secure the availability of effective antibiotics for the treatment of serious infectious diseases in animals, while minimising the risks to animals or humans emerging from their use.

Following a request from the European Commission, EMA and the European Food Safety Authority (EFSA) were tasked to deliver a joint scientific opinion on measures to reduce the overall need of use of antimicrobials in food producing animals (RONAFA). The joint EMA/EFSA opinion on RONAFA was finalised and adopted by EMA's and EFSA's scientific committees in December 2016 and sent to the EC. In this context, EMA reviewed and assessed in 2016 the measures that have been or are being taken by Member States, and recommended options to decrease antimicrobial use in animals. In response to a specific request from the European Commission, EMA also updated its advice on the use of colistin in human and veterinary medicine, following the discovery of transferable resistance to this 'last resort' antibiotic. The CVMP and CHMP recommended that use of colistin in animals should be reduced to the minimal feasible level, and proposed practical measures to achieve this.

In 2016, EMA also published the sixth European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report. This report includes sales figures of antimicrobials in animals from 2014, collected through the ESVAC initiative in a total of 29 countries (28 countries in the EU and EEA, and Switzerland). The report is published every year, and the continuous efforts from the Agency and national competent authorities to collect and analyse this information are reflected in the improved overall quality of sales data observed year on year. The trends highlight a more responsible attitude towards the use of antibiotics in animals.

EMA also held a public consultation on a new ESVAC strategy for 2016-2020. The strategy details the Agency's approach, over the next four years, to collect and publish overall sales data from as many EU and EEA countries as possible. This will help policy makers to better analyse European-level trends in antimicrobial consumption per animal species.

Measures to help protect patients from falsified medicines

In February 2016, EMA and the EC have taken further steps to help protect European citizens against the threat of falsified medicines, by preparing an implementation plan for centrally authorised medicines to guide applicants and marketing-authorisation holders to meet the requirements of a new regulation of the Falsified Medicines Directive. The Directive, introduced back in 2011, strengthened

the protection of patients by preventing falsified medicines entering the legal supply chain, and allowed citizens to buy high-quality medicines online through verified sources.

Falsified medicines are fake medicines that present themselves as real, authorised medicines. The new regulation introduces two safety features — a unique identifier, and an anti-tampering device, to be placed on the packaging of most medicines for human use. Marketing authorisation holders are required to place the safety features on the packaging of most prescription medicines and certain non-prescription medicines no later than 9 February 2019.

Strengthening capacity and expertise

In December 2016, the extension of the concept of **multinational assessment teams** (MNAT) to post-authorisation assessments was endorsed by EMA's Management Board. This means that assessment teams, made up of experts from several Member States, will be able to evaluate applications for extensions of marketing authorisations of existing medicines as of April 2017.

Seven Member States took part in the multinational assessment team pilot in 2014. In 2016, 20 Member States participated in the assessment of new medicines for human use as part of a multinational assessment teams, and 5 Member States participated in MNAT for new veterinary medicines.

In 2016, a total of 25 Member States participated in the assessment of new medicines for human use, either as rapporteurs or co-rapporteurs, compared to 21 in 2013. For veterinary medicines, a total of 17 Member States participated in the assessment of new medicine applications in 2016, compared to 12 in 2013.

To strengthen the expert capacity of the network, and to ensure good scientific and regulatory practice across the assessment teams, the **EU Network Training Centre** (EU NTC) was established in 2014 by EMA and national competent authorities, and reached its full development in 2016.

The central online platform provides access to high-quality and relevant regulatory and scientific training materials that are made available either by EMA or by national competent authorities. The network-wide training catalogue included 110 courses and 55 training webinars. A new learning management system was also launched to make it easier for users to find, register for, give feedback on, and recommend courses from the EU NTC catalogue.

As part of the initiative to enhance **involvement of non-EU regulators** in EMA scientific reviews and to facilitate work-sharing, the assessment report for a centralised product was shared with regulators in Israel, who, for the first time, participated as observers in the May CHMP meeting during the discussion on the list of questions. Colleagues from Israel were also invited to join the Day 120 discussion for the product in question at the November CHMP meeting.

Data gathering

In 2016, following the 2015 pilot on scientific advice, the Steering Group of the Management Board data gathering initiative extended the exercise to all major fee-generating and non-fee generating activities of the Agency. Throughout the year, approximately 900 work streams were initiated across the various domains, both on the EMA and NCA side.

Response from the Member States has been positive and consistent, with overall compliance fluctuating between 70 and 85% for most fee-generating activities. Response level for non-fee generating activities varied between 55 and 70%.

Considering the EC deadline for the final report at end of Q1 2017, the launch of new work streams has been gradually closed from October onwards. Collection of previously included work streams will carry on until reporting deadline is reached, as long as within the time limits set by the Commission. Interim analysis of the human medicines data set was presented to the Management Board in December. Report on veterinary scientific advice was also completed.

At the end of the year, first interactions with the external consultant hired by the Commission started, in order to provide them with all the relevant background information necessary for them to carry out the analysis of the data collected.

Telematics strategy implementation

As part of delivering information systems in accordance with the EU Telematics roadmap, the PSUR repository was delivered in the first half of 2016. Delivery of clinical trial systems has been handed over to a new contractor. New timeline for EudraVigilance (EV) was agreed by the Management Board in June 2016, to further strengthen performance of the new EV system prior to its go-live. Organisation and referentials management services are delayed, and a new go-live date has been agreed for Q2 2017.

Industry's participation in the EU Telematics at a strategic level was agreed in February 2016, with two meetings per year to take place with the pharmaceutical industry associations. In 2016, industry associations took part in the February and November meetings.

Supporting innovation throughout the EU

In 2016, an EU innovation network was formally created, consisting of the EMA's innovation task force (ITF) and national agencies' innovation offices that wish to collaborate. In 2016, 17 countries participated.

The objective of the network is to facilitate the development of innovative medicines by making seamless, early regulatory support available at national and the EU levels.

It also provides a platform for regulators to share experience with upcoming innovative therapies, and discuss regulatory science challenges emerging at an early stage in medicines development.

The platform allows EU regulators to identify and address gaps in regulatory science, and anticipate the expertise needed for the assessment of innovative medicines. The initiative is closely linked with the EU Network Training Centre, which identifies areas where training may be required, to ensure the appropriate capability in the network.

EMA's ITF provided a means for companies to enter into dialogue with regulators at an early stage of development of veterinary medicines as well.

Open access to clinical data

In October 2016, EMA took a major step towards higher transparency, by giving open access to clinical reports for new medicines for human use authorised in the EU, on a dedicated website. Citizens, including researchers and academics, can now directly access thousands of pages from clinical reports, submitted by pharmaceutical companies to EMA in the context of marketing authorisation applications for every new medicine. EMA is the first regulatory authority worldwide to provide such broad access to clinical data.

The new website was launched with the publication of data submitted for two medicines, representing approximately 260,000 pages of information in over 100 clinical reports. Data will be progressively added online for all applications concerned since the policy entered into force. By the end of 2016, data for 6 medicines was available. According to current forecasts, EMA expects to offer access to approximately 4,500 clinical reports per year, once the website is fully operational.

By the end of 2016, 1,455 general users and 365 academic users had registered on the new website. Documents had been viewed 6,474 times and downloaded 23,443 times; giving an average of around 90 views and 330 downloads per calendar day.

While the policy gives unprecedented access to clinical data, it also demands the highest standard of protection of patients' personal data. During the development process, the Agency extensively consulted with all stakeholders, making sure to integrate their sometimes divergent views.

Public hearings

In 2016, the Pharmacovigilance Risk Assessment Committee (PRAC) adopted the rules of procedure for public hearings, after they had been endorsed by EMA's Management Board. The rules explain the process and practical arrangements for public hearings, including how the PRAC will decide when to hold a public hearing, and how members of the public can participate — either as speakers or observers. EMA carried out an internal practice exercise, or a dry run, to test the process and procedures for the hearings in July. Using a fictional safety review, the PRAC experienced how such hearing would unfold. This enabled the Agency to ensure that all practical arrangements are in place, and allowed PRAC members to test this new form of interaction. Following the successful simulation, the PRAC is now ready to incorporate public hearings into its core activities.

Strengthening engagement with stakeholders, including civil society

In 2016, the Management Board adopted an overarching framework for stakeholder relations management which defines the guiding principles for the management of interactions with key stakeholders. The framework builds on the Agency's experience of interacting with stakeholder associations, representing patients and consumers, healthcare professionals, animal health professionals, the pharmaceutical industry and, more recently, academia. It aims to streamline activities across the various stakeholder groups and align working methodologies where possible.

Involving general practitioners in regulatory decisions

In April 2016, EMA hosted a workshop with representatives of general practitioners and family doctors, to explore new ways of engaging with these providers of primary care, and to further involve them in EMA's activities. The workshop led to the creation of an expert group of general practitioners, who will act as facilitators and communicate to their broader communities. This group will be involved in a wide range of EMA's activities whenever their specific feedback is needed. They can, for example, contribute to EMA's scientific advice to medicine developers; give input on the feasibility and impact of risk minimisation measures on patients; and review product information and disseminate information to their networks and patients. EMA's existing framework of interaction with healthcare professionals was updated to reflect this new focus on the involvement of general practitioners and family physicians.

Improve the safety of 'first-in-human' clinical trials

In 2016, the Agency worked on an overhaul of the EU guideline on first-in-human clinical trials, to further improve the safety of trial participants. EMA's current guideline, released in 2007, provides

advice, in particular on the data needed to enable the appropriate design of these trials and to allow the initiation of treatment in trial participants.

Between July and the end of September 2016, EMA released a concept paper for public consultation, which outlined the major areas that needed to be revised in the guideline. This consultation served as a basis for the revision of the guideline, which was carried out by experts from EMA and national competent authorities who authorise clinical trials in the EU. The draft revised guideline was released for public consultation in November 2016. The final guideline will be published in the first half of 2017.

Mutual recognition agreement with the FDA

Work on the establishment of a Mutual Recognition Agreement (MRA) on good manufacturing practice (GMP) inspections concluded in 2016, ready for formal signature on both sides. In 2016, it became clear that collaborative work on GMP within the mutual reliance initiative would progress towards a formal agreement. In order to strengthen the possibility of an agreement as early as possible, it was decided to progress this separately from the Transatlantic Trade and Investment Protocol (TTIP), through a revision of the relevant sectoral annex of 1998 MRA, which had never become fully operational. EMA led technical discussions with support from a small team of Member States experts, and provided support to the European Commission as the work moved into an intensive phase of negotiation, led by trade deputations on both sides. The agreement, expected to be signed in early 2017, defines the path towards implementation of mutual recognition of GMP documents issued by FDA or inspectorates of Member States, and becomes operational from November 2017. This reduces or eliminates the need for GMP inspections of manufacturers located in the EU and the US by both FDA and EU authorities, thereby allowing resources to be better deployed, according to risks posed to manufacturing quality.

Bilateral interactions reinforced and extended

The Agency continued to collaborate closely with the Therapeutic Goods Administration (TGA) in Australia, Health Canada, 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, based on confidentiality arrangements. Interactions with these authorities take place almost daily, partly structured around clusters of activities, and partly ad hoc.

Addressing global challenges through multilateral interactions

In December 2016, the ongoing collaboration on good manufacturing practice inspections of active-pharmaceutical-ingredient (API) manufacturers between EMA and its international partners was expanded to include Japan's PMDA. This international collaboration allows participants to share information on inspections — including planning, policy and reports — of manufacturers of APIs that are located outside the participating countries. The overall objective is to increase cooperation and mutual reliance between regulators participating in the initiative, as well as to ensure the best use of inspection resources worldwide.

In 2016, the coverage of pivotal clinical trials submitted in marketing authorisation applications was improved by 34% through information exchange on inspections carried out by international partners. Additional 19% of routine GMP re-inspections of manufacturing sites were also addressed through information exchange with international partners.

In addition, EMA hosted a meeting with PMDA and the FDA to discuss regulatory approaches for the evaluation of antibacterial agents. A joint training activity with the FDA on data integrity was also organised in 2016, and took place in October and November in China.

A study, looking at stakeholder awareness, experience and views on the Article 58 procedure, was published on the EMA website in April 2016. Article 58 guidance and questions and answers (Q&A) for sponsors were reviewed and submitted to CHMP for comments in December 2016. In 2017, consultation with the Commission and WHO will take place, prior to the finalisation of the revised documents.

Mapping of international regulatory initiatives

In 2016, EMA published an overview of existing international regulatory initiatives for human medicines. The mapping was carried out by the Agency on behalf of the International Coalition of Medicines Regulatory Authorities (ICMRA). The report lists all international projects and provides regulatory agencies with comprehensive details on the number and scope of global initiatives that can support decision-making regarding future engagement, prioritisation and coordination. The aim of the mapping exercise was to raise awareness of ongoing activities; to establish a basis for a more strategic coordination to avoid duplication of efforts; and to identify possible gaps. The report was presented at the annual ICMRA meeting in Interlaken, Switzerland in October 2016.

Big data

In November 2016, the Agency organised a workshop to identify opportunities and challenges linked to the use of big data in medicines development and regulation. The workshop brought together over 160 individuals and attracted many hundreds more online, and informed on the latest developments being made in the field. It was clear that globally, the health and research community needs to agree best practices; develop open sources analytical tools; and establish quality standards and robust privacy and security mechanisms to build trust in the evidence it generates, and to encourage patients to contribute and share data. EMA is committed to continuing to engage with stakeholders to develop skills and regulatory processes to ensure big data is harnessed to support robust medicines assessment and to complement clinical trial data.

EMA multiannual work programme

In December 2015, the EMA Management Board adopted the first common strategy that EMA and NCAs had developed to guide the work of their network over 2016-2020. With the strategy being a high-level, overarching document, separate multiannual work plans were foreseen, to provide the detail of how the strategy will be taken forward within the remit of each of the components of the European network.

In June 2016, the EMA Management Board adopted EMA Multiannual work programme (MAWP). It builds on the Network strategy 2016-2020, and outlines main initiatives and activities that the Agency will undertake in the coming years, to support achievement of common goals. EMA MAWP reflects the structure of the Network strategy and is linked with the HMA multiannual work plan, to ensure an aligned and coordinated approach to addressing the strategic issues facing the Network, and reaching the common goals of the Network strategy.

EMA MAWP is structured into 4 themes, each outlining four strategic objectives. Main areas of work are identified for each strategic objective and, for each of these areas, key medium-term objectives and

initiatives, supporting the achievement of these objectives, are identified. Performance indicators are included for each initiative to allow monitoring its progress and success.

In accordance with the Article 32 of Financial Regulation and the Commission guidelines on the Programming document, the EMA MAWP has now been incorporated in the Programming document, and constitutes the multiannual programming part of the document.

The multiannual work programme is envisaged to be a rolling document, and as such will be reviewed annually during the preparation of the Programming document. It will reflect on the key actions and initiatives, removing the completed ones, and including new ones that may arise as time passes.

1.2. 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 2016 forecast/target
	Results within +/- 10% of the 2016 forecast/target
	Results 10%~25% below the 2016 forecast/target
	Results more than 25% below 2016 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.

Evaluation activities for human medicines

Pre-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Scientific advice/protocol assistance pre-submission meetings	116	137	89	115	117
Scientific advice and protocol assistance requests, of which:	473	551	510	510	582
Parallel scientific advice with international regulators	8	2	3	4	6
Joint scientific advice with HTA bodies	7	11	30	16	23
Post-authorisation scientific advice	108	122	89	90	148
Scientific advice for PRIME products[1]	n/a	n/a	n/a	2	4
Protocol assistance requests	108	113	137	124	126
Novel technologies qualification advice/opinions	15	22	20	15	14
PRIME eligibility requests	n/a	n/a	n/a	120[1]	84
Scientific advice finalised	363	432	386	385	439
Protocol assistance finalised	111	101	139	122	122
Orphan medicines applications, of which:	201	329	258	330	329
Parallel orphan applications with international regulators	82	109	86	100	96
Submitted applications on the amendment of an existing orphan designation	-[2]	0[2]	1	5	4
Oral explanations for orphan designation	-[3]	-[3]	-[3]	90	87
Paediatric procedure applications (PIPs, waivers, PIP modifications, compliance checks)	471	485	515	500	549
Finalised procedures for compliance check on PIPs	58	85	67	80	73
Annual reports on paediatric deferred measures processed	121	155	172	170	189
EMA paediatric decisions processed	325	345	319	350	369
Requests for classification of ATMPs	20	28	61	60	60
Innovation Task Force briefing/meeting requests	28	27	35	42	41
Innovation Task Force Art 57 CHMP opinion requests	10	5	0	4	2

[1] PRIME initiative was launched in March 2016. The forecast provided is for 12 months of operation (i.e. March 2016-March 2017), thus the expectation for 2016 was approx. 90 applications.
[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	2013 result	2014 result	2015 result	2016 target	2016 result
Scientific advice/protocol assistance procedures completed within regulatory timeframes	99.5%	99%	100%	100%	99.5%
Orphan designation opinions delivered within the legal timeframe	99%	100%	100%	100%	100%
PDCO opinions sent to applicants within legal timelines	100%	99.7%[1]	99.7%[1]	100%	99.5%[1]
Increase in scientific advice requests	12.6%	17%	-8%	10%	14%
SME requests for scientific advice (percentage of total SA requests)	29%	24%	32%	30%	30%

[1] 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
Provide high-quality, efficient and consistent support to medicines development.	Develop and implement best practices for significant benefit in protocol assistance letters.	100%	COMP working group for protocol assistance was established in Q1 and regular monthly meetings have been held since March. A peer review system was implemented, whereby all protocol assistance reviewed by COMP does not only have a coordinator, but also a dedicated peer reviewer. A template for protocol assistance answer letters was developed and is in use since Q4 2016.
	Organise workshop for the Network and EMA on the definition of orphan condition.	100%	The workshop successfully took place on December 9. The follow-up report has also been prepared.
	Revise collaboration between SAWP and SWP to focus on the most relevant issues for expert input.	10%	The activity is put on hold and will be reconsidered once the revision of EMA working parties is completed, and the new operational model for the working parties is established.
Improve cooperation with partners (e.g. HTA bodies, European networks, international	Draft recommendation documents/white papers, and provide regulatory input to the methodology and outcomes of the selected four IMI GetReal Consortium case studies.	95%	As part of IMI GetReal project, EMA provided input into the development of a glossary of real-world evidence and real-world navigator framework for decision making during 2016. Publication is expected at the end of the project.

Objective	Activity	% complete	Achievements/results
partners) throughout the product lifecycle.			In order to complete the work, the project was extended at the request of the consortium and is now expected to finish in early 2017.
	Implement a collaboration framework with HTAs, with regard to the maintenance of orphan status at the time of marketing authorisation application.	0%	This activity has currently been cancelled due to lack of interest/resources on the partner's side. However, it might be re-activated at a later point in time, e.g. as part of Joint Action 3 (JA3), or otherwise.
Facilitate research and development of new medicinal products.	Identify areas in need of further research and communicate them to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects.	30%	Processes regarding EMA involvement with externally funded regulatory science projects were agreed in the first half of 2016. More structured processes were also implemented for a more effective communication with IMI, especially regarding earlier input into the research agenda. Dialogue with DG Sante and the IMI office in Brussels was initiated, with the aim of establishing a framework for interaction that helps better plan EMA resource allocation to Horizon 2020 funded projects, including IMI. During 2016, the Agency and Horizon 2020 also discussed how best to incorporate quality assurance and protocol assistance requirements, and provided suggestions regarding research needs in the area of medicine safety in pregnancy.
	Develop a triage process to increase the effectiveness of selection and coordination of EMA involvement in various research activities, including IMI.	95%	In the first half of 2016, the EMA Management Board agreed on the Agency's role and the criteria to feed into the triage process.
	Develop business forecasting and analysis tools to enhance availability of information on prospective development of medicines.	70%	A system that enables more intelligent interrogation of information received through business pipeline activities — in order to identify opportunities for better signposting to guidance, develop or refine Q&A, highlight gaps in regulation where guidance may be useful, and other potential action items — was implemented in the first half of the year. As a result, quarterly updates are being prepared, with identification of action items and follow-up to close the loop. Further work will take place in 2017, to enhance efficiency and to improve the use of the system

Objective	Activity	% complete	Achievements/results
			to proactively identify the trends in medicines development.
	Identify recurring questions in areas of highest potential benefit from science and innovation, and develop the relevant Q&A or regulatory guidance documents.	95%	During the first half of 2016, recurring questions were identified and development of the relevant Q&A documents and guidance documents started in the areas of regulatory affairs, labelling and international affairs. Systems to systematically evaluate the questions received from pharma companies, to identify recurring questions or themes, and to ensure follow-up as appropriate, were developed and implemented over the course of 2016. The use of the systems needs to be monitored, to identify any potential further improvements.
	Develop and implement a scheme to provide reinforced regulatory and scientific advice to priority medicines from the early stages of development.	100%	A reflection paper was finalised in the first half of the year, and supportive guidance and templates were launched in March 2016.
	Organise workshop on the development of orphan medicinal products for academic researchers.	100%	The workshop was successfully held in March.
	Support scientific committee discussions on PrEP (pre-exposure prophylaxis) to combat HIV infection.	100%	The Agency provided scientific support to the evaluation of Truvada for PrEP indication in the first half of 2016, including peer reviews, labelling reviews and consultations with patient groups on the actual labelling and educational material. The final CHMP opinion was given in July. Reflection on the opportunity to further adjust the current draft reflection paper on PrEP took place in the context of the IDWP activities in 2016.
	Strengthen collaboration and integration across the Network and with academia, to facilitate the translation of innovation into medicinal products, including through the work undertaken by the Innovation Network.	100%	A mandate and work plan were prepared by the European Innovation Network during the first half of this year, and adopted by EMA and HMA in September.
	Organise workshops with key opinion leaders and innovators, and involving NCAs, to address	50%	One of two planned workshops was successfully organised with the oncology community in the first part of 2016. The second workshop was

Objective	Activity	% complete	Achievements/results
	specific areas for innovation.		postponed to 2017. The follow-up work to ensure achievement of the desired impact, including guidance development on the basis of the findings and workshop discussions, is being carried out.
Support development and availability of medicines for specific target groups.	Implement EMA geriatric medicines strategy.	90%	The Quality Working Group continued drafting the quality guideline during 2016. The EMA geriatrics group contributed to the drafting of clinical needs aspects of the document. The guideline is almost completed, and the adoption is expected in Q1 2017.
	Finalise the 10-year report to the Commission on the implementation of the Paediatric Regulation. Identify (2016) and implement (2017) activities to increase compliance and results.	100%	The 2007-2015 report was drafted and sent to the EC in May 2016. As per the agreement with the Commission, an update with the data for 2016 was provided to the EC in November.
	Provide recommendations to the Commission on priority areas for research in paediatrics, in line with the objectives outlined in the Horizon 2020 strategy.	100%	The priority areas for research in paediatrics were discussed by the PDCO-COMP working group and some criteria were identified during the first half of the year. In the second half of the year, PDCO agreed on some areas of paediatric research that may be suggested for a future call of Horizon 2020, and a dedicated letter for the EC containing these suggestions was adopted by the committee in December. The Agency aims to publish the research areas in 2017.
	Develop, with the FDA, regulatory science approaches for paediatric diseases (including rare diseases). Finalise the joint guidance document for Gaucher disease, and formally implement TIGRE.	100%	Gaucher disease guidance document: FDA's comments were received in the first half of the year. Changes in the agreement with the FDA, to address the comments received in the public consultation phase, were supported by the FDA. The draft document is being finalised and will be used as a model for innovative approaches in the development of medicines for rare diseases. The document is expected to be published in early Q2 2017. TIGRE project: the scope of the project was redefined during the first half of 2016, focusing on creation of a 'Rare disease cluster', the kick-off meeting of which took place in September 2016. Paediatric development in rare diseases will be addressed under the umbrella of the current paediatric cluster.

Objective	Activity	% complete	Achievements/results
	Establish early interaction on paediatric development.	100%	The process for early interaction on paediatric development was implemented in the first half of 2016 and a pilot took place throughout 2016. Discussions with the FDA on potential expansion into bilateral early interaction are taking place.
	Conduct open regulatory sessions on Alzheimer's disease in academic settings, including a follow-up session at the ECNP congress.	100%	An open session was delivered as part of ECNP conference in September 2016.
	Promote data-sharing from applicants with failed Alzheimer trials, in order to explore pitfalls and opportunities.	100%	A series of meetings with the applicants was conducted in the first half of 2016 and an internal report was prepared during the year.
	Develop a regulatory framework for extrapolation across age groups, supporting informed and efficient drug development.	100%	A reflection paper on extrapolation across age groups was published, and a workshop with the relevant stakeholders was held.
Optimise use of existing regulatory framework for early access to medicinal products.	Coordinate the review of the guideline on conditional marketing authorisation, and update the existing guidance documents (Q&A) on conditional marketing authorisation.	100%	The guideline on conditional marketing authorisation was adopted by the CHMP and published on the EMA website in March, along with PRIME, the accelerated assessment guideline, and the new website for early access tools. Report on 10 years of experience with the Conditional Marketing Authorisation Regulation was finalised in Q4 2016, and will be published on the EMA website in January 2017.
	Review the experience with the compassionate use procedure at the EU level, and identify aspects to optimise use of this procedure through review of existing guidance.	50%	In March, a presentation was given at STAMP on the experience with the compassionate use procedure at the EU level. It was agreed at the STAMP meeting to organise follow-up discussions with Member States to understand the reasons for the underuse of the possibility for a compassionate use opinion at the EU level. The EC did not progress this topic further at level of STAMP, and discussions are expected to continue at the upcoming meetings in 2017.
	Provide technical support to the EC in relation to optimisation of the existing regulatory framework, including the development and/or implementation of new or amended laws and regulations.		The Agency provided close technical support to the revision of the Commission communication on orphan medicinal products, including comments through public consultation in February. In April, the Agency sent to the EC a proposal for revision of the definition of similar medicinal products, which was subsequently published for a public consultation by the

Objective	Activity	% complete	Achievements/results
			Commission.
	Develop an implementation strategy on companion diagnostics legislation and related guidance documents for industry.		Regulation on medical devices and on in vitro diagnostic medical devices expected to be adopted in April 2017. The Agency has conducted an impact assessment on these new pieces of legislation and will be setting up a cross-Agency group to work on the implementation of legislation.
	Conduct joint reviews and participate in other support activities with WHO and regulators from LMICs, on regulatory aspects related to vaccines and treatments for neglected diseases.	100%	In June 2016, EMA took part in the WHO meeting in relation to Zika virus research and development (R&D) efforts, and target product profile for vaccines for Zika virus. Additionally, the Agency contributed to the global forum on immunisation in Africa in March, and also participated in the SAGE meeting in April and ad hoc meetings on a malaria vaccine.
Reduce 'time-to-patient' of medicines through the use of existing and new assessment approaches within existing legal frameworks, including through the collaboration with international partners.	Hold early, flexible brainstorming discussions with applicants and other stakeholders, to explore adaptive ways to optimise development pathways and accelerated patients' access to medicines.	100%	The platform for providing scientific advice for PRIME products was implemented in Q1-Q2 and discussions on SA for PRIME started in Q2 2016.The final report on adaptive pathways pilot was completed in June, and published in August 2016.
	Reinforce early dialogue with HTAs through existing procedures, and finalise guidance for parallel SA with HTAs.	80%	The best-practice guidance for parallel EMA-HTA scientific advice was published in the first half of the year. Further discussions on interactions within Joint Action 3 (JA3) took place, and it was agreed that EMA will participate as an observer in the HTA-only advice, launched by EUnetHTA in January 2017. Major HTAs have committed to participate in the JA3 - work package 5 parallel EMA-HTA advice. Guidance for the latter is expected in Q2 2017.
	Implement regulatory advice for promising medicines, benefiting from the PRIME scheme, from the early stages of development.	100%	Draft guidance to applicants for the kick-off meeting was prepared, to ensure that relevant scientific and regulatory aspects are addressed as part of this meeting. Kick-off meetings started in July 2016, and the guidance will be finalised and adjusted based on the experience gained with these meetings.
	Lead and coordinate EMA's input into and engagement with HTA Joint Action 3.	40%	During the first half of the year, EMA provided input into the setting of objectives and milestones of JA3, specifically with regard to the

Objective	Activity	% complete	Achievements/results
			activities that are relevant for regulators and might facilitate regulator-HTA interactions (e.g. data and information sharing, joint scientific advice). Interaction with HTA JA3 continued throughout the year, to concretise the collaboration between regulators and HTA bodies in the domains of parallel early dialogues, sharing of information at time of licensing, and generation of post-marketing evidence.
	Provide scientific leadership to the ADAPT-SMART project.	50%	Successful workshops were held, resulting in timely completion of the planned deliverables, including glossary, engagement criteria document, managed entry agreement paper, and seamless pathway document.

In addition to the above activities, the Agency revised the 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. The draft guideline was released for a 3-month public consultation in November.

Initial evaluation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Number of MAA pre-submission meetings	59	57	102	50	85
Initial evaluation applications, of which:	80	100	111	114	114
New non-orphan medicinal products	48	38	36	44	41
New orphan medicinal products	18	21	25	26	27
Similar biological products	1	3	12	13	12
Generic products, hybrid and abridged applications	12	37	37	30	31
Scientific opinions for non-EU markets (Art 58)	1	1	1	0	0
Paediatric-use marketing authorisations	1	0	1	1	1
Number of granted requests for accelerated assessment	8	12	17	15	12
Number of consultations of SAGs/Ad-hoc expert groups in the context of MAAs	20	14	7	10	8
Reviews on the maintenance of the orphan designation criteria at MAA stage	-[1]	-[1]	-[1]	28	20

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

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Percentage of applications evaluated within legal timeframes[1]	99%	100%	100%	100%	99%
	Average assessment time for new active substances and biosimilars (days)	207	197	200.7	205	197.2
	Average clock-stop for new active substances and biosimilars (days)	218	166	138.4	180	136.1
	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]	-[2]	90%	97%
	Percentage of requests granted for accelerated assessment	67%	80%	73%	70%	48%
	Percentage of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	-[2]	-[2]	-[2]	70%	43%[3]
	Percentage of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	-[4]	-[4]	82%	75%	63%

[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 since 2015.

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound, and consistent scientific assessments of marketing authorisation applications.	Consolidate the use of patients' preferences in benefit-risk assessment for initial marketing authorisation applications.	100%	A study on understanding and using patient preferences in benefit-risk assessment in patients with myeloma was completed in Q3 2016.
	Discuss with HTA bodies the use of, and experience with the effects tables, identifying improvement opportunities.	-	-
	Organise workshops to identify areas for improvement in the assessment reports, and develop a toolkit for improvement of quality, consistency and robustness of benefit-risk assessments.	90%	A workshop and follow-up subgroups were organised in the first half of the year. The updated benefit-risk assessment report template and guidance were published and implemented. Training was also delivered in 2016.
	Develop and implement a	100%	Draft guidance for writing a benefit-risk

Objective	Activity	% complete	Achievements/results
	specific benefit-risk guidance document to support evaluation of biosimilar medicines.		assessment, specific to biosimilar medicinal products, was adjusted on the new version of the template.
	Implement and monitor the provision of early background summaries.	100%	Regular calls for candidates for producing early background summaries have been implemented since the end of 2014. A survey on experience with the early background summaries and opportunities for improvement from the perspective of rapporteurs/assessors was conducted in the first half of the year. Revision for further improvements in collaboration with CHMP sponsors started in the second half of the year. Reporting to the committees started in July.
	Improve the tools (guidance, templates, databases) available to assessors and EMA staff who are supporting scientific evaluation activities of the committees.	100%	The tools for assessors and EMA staff who are supporting scientific evaluation activities of the committees are regularly updated, in line with the plan. Among others, the updates in 2016 included guidance on the RMP assessment process in the framework of initial marketing authorisations, modifications to the SOP/WINs, and the regular publication of knowledge-sharing bulletins.
	Review and optimise the conduct of pre-submission meetings to improve support for the later evaluation process.	75%	Analysis of the experience with pre-submission meetings was conducted and presented at the industry stakeholder platform meeting in April. The feedback was presented to CHMP in May, and the follow-up activities are being prepared. Work will continue in 2017.
	Develop guidance to ensure early availability of a core (overview) document to deliver high-quality assessment reports in the area of quality of medicines.	100%	In the first part of the year, internal assessment report templates were implemented and are now being used as overview guidance. Quality office peer review and quality control processes were enhanced to improve topic lead input and tracking.
	Streamline and strengthen the process of input by the Quality Working Party and other quality of medicines working groups to the relevant parts of assessment reports.	75%	Internal templates for preparation of CHMP assessment reports for chemical and biological human medicines were prepared and implemented in the first half of 2016. The need for guidance on the quality part of the overview was agreed by the Quality Working Party and Biologics Working Party. Draft guidance was prepared and circulated to the working parties for comments. Following the consolidation of comments, a trial phase, assessors training, and full

Objective	Activity	% complete	Achievements/results
			implementation of the guidance is planned.
	Strengthen the support for clinical pharmacology aspects of centrally authorised products along their lifecycle, with a special focus on innovative medicines, including GMOs.	100%	All clinical pharmacology peer reviews for centrally authorised products, requested in the course of the year, have been performed. In addition, proactive and ad hoc clinical pharmacology support was provided for other products during their lifecycle.
	Coordinate and develop the capability of the Network in the area of new methodological approaches to clinical trials	70%	The Agency coordinated and participated in the discussions between statisticians of the Network, on the methodology approaches for clinical trial design and analysis (e.g. in paediatric development and single-arm trials, and treatment cross-over in oncology).
Ensure and run highly effective and efficient processes to deliver initial evaluation activities.	Implement (2016) and optimise (2017) a process performance management system, with strong customer focus on quality, simplification and regulatory procedural excellence.	100%	A process performance tool for tracking agreed KPIs for marketing authorisation applications was developed in Q1 through business intelligence, using SIAMED data. Results of the KPI monitoring will be used to assess the appropriateness of the KPIs in 2017. A matrix system was established in the Agency with process owners and process champions, who ensure procedural consistency in operations across teams handling initials and sharing of learnings. Process owners and champions also review the established KPIs through automated dashboards, and identify and implement improvement opportunities. The process performance management system is fully in place. The tools for monitoring process performance are reviewed annually.
	Develop and improve guidance, and provide internal training to ensure regulatory procedural consistency.	100%	Internal procedural training for marketing authorisation applications was delivered in Q1-Q2 2016. A knowledge-sharing system, based on interesting cases identified during process review meetings, was developed to ensure continuous training. Implications from such cases for external guidance are systematically being considered. An IT knowledge-sharing tool in JIRA is being developed to support the management of the cases.
	Establish an internal system of knowledge-sharing with the aim of providing consistent regulatory advice to NCAs and MAHs.	100%	An internal pre-submission query service was established in Q1-Q2 and launched in Q3, to ensure accuracy and consistency of support provided to the procedure managers. A knowledge-sharing system, based on interesting cases/precedent and identified

Objective	Activity	% complete	Achievements/results
			during meetings with process owners and champions, was developed to ensure continuous training. The cascade to relevant staff is implemented through monthly case studies, inclusion in biannual knowledge sharing bulletin, and updates of internal and external guidance with subsequent dedicated training. The IT support through JIRA is in development as part of the knowledge-sharing tool.
	Identify improvement opportunities and optimise regulatory procedures supporting initial evaluation.	80%	During the first half of 2016, a revised process for accelerated assessment was developed and implemented. A revised process for EPAR preparation for initial MAAs was also finalised. The early background summary pilot, whereby background information from previous relevant evaluations is provided to rapporteurs and peer reviewers at Day 10 of the procedure, continued in the first half of the year, receiving very positive feedback. An initiative to extend the provision of early background summaries to more MAAs will start in Q2 2017. A tri-partite survey with industry rapporteurs and EMA was prepared to define the level of satisfaction with the current process for initial MAAs, and to identify further improvement opportunities. The survey started in September 2016 and will last for six months.
	Develop and implement a complexity-based approach to handling generic product applications.	50%	As part of redesigning the generic product marketing authorisation application process, roles and responsibilities within the product team were agreed in the first half of the year. It was also agreed, that the risk-management plan process for generics would not require PRAC plenary discussion in the first phase. Workflow simplification was agreed in Q1-Q2. Due to reorganisation of the Division, the activity was put on hold in the second half of 2016, and will recommence in Q3 2017.
	Develop regular interactions with industry, focusing on the centralised procedure; and engage with industry in optimising the operation of evaluation activities	100%	The third meeting of the industry stakeholder platform on the centralised procedure for medicines took place in April. A survey on the performance and satisfaction of the initial marketing authorisation process from both the industry and EMA/rapporteur side was developed in the first half of the year, and presented at the platform meeting. The survey

Objective	Activity	% complete	Achievements/results
			was launched in September 2016 and will run for six months. Discussions with the industry associations regarding the next platform on initial marketing authorisations in 2017 took place in the second half of the year. The interactions are now well established.
Provide high-quality, robust, scientifically sound, and consistent product information.	Develop and maintain guidance and other tools (training material, checklist, metrics or labelling review guide) supporting SmPC review.	100%	In June, the Agency, together with MHRA, organised training session for EMA staff on the aspects related to the handling of labelling/package leaflets. The aim was to give an insight into the aspects of labelling review, to support safe and effective use of medicines from an NCA's point of view. In November, a training session on the 'Principles and best practices in creating the EU Summary of product characteristics (SmPC)' from the industry perspective was held. The session provided colleagues with an insight of the challenges that industry is facing in creating an EU SmPC and the relevant methodology followed. In addition, 6 SmPC advisory group Q&A were produced, covering aspects of interpretation of the SmPC guideline, and 5 webinars were organised, enhancing the guidance in the area of labelling review, both for EMA staff and for assessors from NCAs.
	Develop tools for improved oversight of labelling development during the lifecycle, supporting consistent and evidence-based reviews.	0%	The activity has been postponed.
	Monitor the implementation of new labelling review process, to ensure scientific committees' labelling review is based on evidence from the scientific review.	100%	A report on implementation of new labelling review, for new MAAs and renewals during June 2015 to June 2016, was prepared and shows high uptake of EMA labelling comments by both the assessors and applicants.
	Update the internal reflection paper describing elements to consider when assessing the 'therapeutic indication'.	100%	The reflection paper was finalised and endorsed by the CHMP in February 2016. A pilot to verify suitability and appropriateness of the reflection paper to guide finalisation of indication wording started in May and will continue until May 2017.
	Analyse external requests regarding the contents of	n/a	No external requests were received in 2016.

Objective	Activity	% complete	Achievements/results
	approved SmPCs, and provide consistent responses.		
	Review the use of patient-reported outcomes in approved SmPCs, and develop guidance based on the outcomes of the review.	100%	The first phase of the review was completed in Q1-Q2 2016, and an inventory of patient-reported outcomes was set up. All centrally approved oncology products that were authorised between 2005 and 2015 (except RGI) were analysed, and patient-reported outcome statements were extracted.
	Provide technical and scientific support to the review of safety concerns of excipients and their appropriate labelling.	85%	All excipients have been reviewed and adopted according to the work plan for 2016. Work will continue in 2017, according to the work plan.
Reduce time-to-patient of medicines through the use of existing and new assessment approaches within the existing legal frameworks, including through the collaboration with international partners.	Analyse the application of accelerated assessment, including acceptance outcomes and reasons for changing from accelerated to standard review.	100%	Regular monitoring of accelerated assessment is conducted and an annual report, including analysis of the application, acceptance outcomes and reasons for changing, will be prepared. Thirteen requests for accelerated assessment were rejected in 2016, compared to 6 in 2015. The main reasons for rejection were that the unmet medical need was not adequately justified, or that data was not sufficient to substantiate the claim of major public health interest.
	Develop and implement a framework to provide CHMP assessment reports to HTA bodies.	80%	Agreement on the conceptual framework was achieved in the first half of 2016. A high-level process has been agreed with EUnetHTA and was presented at the meeting in December 2016. A model agreement for the provision of assessment reports under a confidentiality framework was developed. The finalisation of the process and the implementation will follow in 2017.
	Support activities stemming from Joint Action 3, to facilitate the provision of relevant information from regulatory assessments to HTA bodies for relative effectiveness assessments.	60%	A conceptual framework for the Agency's interactions with EUnetHTA, with regard to providing the CHMP assessment report at the time of opinion, and particularly the establishment of a robust confidentiality framework under which such exchange can occur, was agreed with the EC in the first half of 2016 and presented to industry at the EFPIA/EUnetHTA meeting in June. A high-level process has been agreed with EUnetHTA, and was presented at the meeting in December 2016. A model agreement for the

Objective	Activity	% complete	Achievements/results
			provision of assessment reports under a confidentiality framework was developed. The finalisation of the process and the implementation will follow in 2017. Further to the agreement of a high-level process for provision of elements of the CHMP assessment report, it was agreed to facilitate a direct interaction between regulatory assessors and HTA authors in order to allow debriefing from the finalised regulatory assessment. The concrete modalities will be developed in 2017, along with the first live assets under Joint Action 3 work package 4.
Improve knowledge on the risks of the use of medicinal products for the environment.	Revise the Safety Working Party guideline on environmental risk assessment for human medicinal products.	30%	The revision of the guideline started in 2016 and the concept paper was published as planned. The review of the guideline will continue over the next few years, with the draft guideline expected to be published for public consultation by the end of 2017.

Post-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Variation applications, of which:	5,841	6,006	5,999	6,011	6,204
Type IA variations	2,922	2,969	2,864	2,757	3,019
Type IB variations	1,958	1,886	1,980	2,051	2,000
Type II variations	961	1,151	1,155	1,203	1,185
Line extensions of marketing authorisations	16	16	14	20	25
PASS scientific advice through SAWP	n/a[1]	n/a[1]	1	5	2
Number of consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	-[2]	-[2]	-[2]	12	6
Renewal applications	-[2]	-[2]	-[2]	66	107
Annual reassessment applications	-[2]	-[2]	-[2]	25	25
Transfer of marketing authorisation applications	-[2]	-[2]	-[2]	41	35
Article 61(3) applications	-[2]	-[2]	-[2]	190	216
Post-authorisation measure data	-[2]	-[2]	-[2]	900	1,016

Procedure		2013 result	2014 result	2015 result	2016 forecast	2016 result
	submissions					
	Plasma master file annual update and variation applications	-[2]	-[2]	-[2]	17	19

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

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Percentage of post-authorisation applications evaluated within legal timeframes	99%	100%	99%	100%	99%
	Average assessment time for variations that include extension of indication	-[1]	175	160	180	165
	Average clock-stop for variations that include extension of indication	-[1]	90	65.5	90	73
	Percentage of submitted risk-management plans, peer-reviewed by the Agency as part of the extension of indication and line extensions	100%	100%	100%	100%	100%

[1] New indicator, introduced since 2014.

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, efficient and consistent scientific assessment of post-authorisation changes to marketing authorisations.	Explore opportunities for peer review in later phases of the MAA review process and in case of substantial changes to the marketing authorisation.	80%	In the first half of the year, agreement was reached to conduct this work, and CHMP participating members were identified. A workshop with CHMP members took place in July. The principles developed by the CHMP members were presented at the presidency meeting in October 2016. If followed by a later process description (planned for 2017), this will enable the later peer review activity to improve quality of output.
	Streamline and coordinate the clinical pharmacology support to centrally authorised products throughout their lifecycle.	100%	The process for review of assessment reports was streamlined in the first part of the year, with extraction of the relevant information in a dedicated template, leading to more efficient screening of the issues. This now enables identifying products where specialised input can provide added value. In addition, requests for support from the

Objective	Activity	% complete	Achievements/results
			product team members are now sent through a single access point, based on pre-defined criteria for involvement. Following previous staff training on clinical pharmacology, conducted in 2015, the proportion of EPL requests for peer review support versus proactive support in clinical pharmacology has increased, as compared to 2015.
	Develop and improve guidance and provide internal training, to ensure regulatory procedural consistency.	100%	Internal procedural training for post-authorisation procedures was delivered to all Agency staff in procedure management in Q1-Q2 2016. A knowledge-sharing system, based on interesting cases identified during process-review meetings, was established to ensure continuous training. Implications from such cases for external guidance are systematically being considered. An IT knowledge-sharing tool in JIRA is being developed to support the management of the cases.
	Develop a process for monitoring the fulfilment of specific obligations for conditional marketing authorisations, to ensure timely switch to full marketing authorisation.	100%	A 'track and chase' process was developed to establish an active monitoring system that allows the Agency to act in case of an outstanding obligation from the MAH. A SIAMED dashboard, based on the track and chase implementation, was also developed to monitor and improve compliance. In addition, analysis of specific obligations was conducted and published on the Agency website.
	Establish an internal system for knowledge-sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs.	100%	An internal pre-submission query service was established in Q1-Q2, and launched in Q3, to ensure accuracy and consistency of support provided to the procedure managers. A knowledge-sharing system, based on interesting cases/precedent identified during meetings with process owners and champions, was developed to ensure continuous training. The cascade to relevant staff is implemented through monthly case studies, inclusion in biannual knowledge sharing bulletin and updates of internal and external guidance with subsequent dedicated training. The IT support through JIRA is in development as part of the knowledge-sharing tool.
Further promote	Analyse the impact of scientific	0%	Activity not started due to resource limitations.

Objective	Activity	% complete	Achievements/results
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).	advice on the likelihood of obtaining a positive opinion for extensions of indications.		
	Implement a procedure for non-imposed PASS through the SAWP, and finalise the guideline on PAES.	100%	Public consultation on the scientific guidance on PAES ended in January 2016. Following the implementation of the comments, the guidance was adopted in the committees in Q4 2016 and will come into effect on 1 June, 2017. A Q&A document on procedural and regulatory guidance was also finalised and published in the first half of 2016. Non-imposed PASS through the SAWP have had very limited uptake since their establishment.
Ensure and run highly effective and efficient processes to deliver post-authorisation activities.	Implement a framework to monitor implementation of imposed PAES.	100%	The advisory group on classification of post-authorisation studies (CPAS) was established in February 2016, to provide guidance on post-authorisation studies imposed on marketing authorisation holders. This group supports product teams in the context of evaluation activities, by advising on classification and objectives of such studies, and allows for capacity-building and oversight. Development of metrics started in June 2016; the results were collected and analysed, and will be presented to PRAC and CHMP in Q1 2017.
	Implement (2016) and optimise (2017) a process-performance management system with strong customer focus on quality, simplification and regulatory procedural excellence.	100%	A process performance tool for tracking agreed KPIs for post-authorisation applications involving CAPs was developed in Q1 through business intelligence, using SIAMED data. Results of the KPI monitoring will be used to assess the appropriateness of the KPIs in 2017. A matrix system was established in the Agency with process owners and process champions who ensure procedural consistency in operations across teams handling post-authorisation applications, and sharing of learnings. Process owners and champions also review the established KPIs through automated dashboards, and identify and implement improvement opportunities. The process performance management system is fully in place. The tools for monitoring process performance are reviewed annually.
	Conduct surveys and meetings with NCAs to capture their satisfaction level and	0%	The activity was put on hold due to reorganisation of the Division in the second half of 2016.

Objective	Activity	% complete	Achievements/results
	improvement opportunities in handling procedures for CAPs and NAPs		

Referrals

Workload indicators

Procedure		2013 result	2014 result	2015 result	2016 forecast	2016 result
	Pharmacovigilance referrals started	18	7[1]	5	8	8
	Non-pharmacovigilance referrals started	25	11	16	12	10

[1] Lower numbers than before due to change in legislation and accounting/grouping of products in the procedures.

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Percentage of 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.	100%	In 2016, internal guidance (WINs, templates, lessons learned, etc.) were developed, and internal training was given to EMA staff involved in managing referral procedures, with the aim of increasing the effectiveness, quality and regulatory excellence of the referral process. Knowledge-sharing through a 'buddy' system was implemented and evolved to monthly review and knowledge sharing meetings, as with the rest of the procedures. Process optimisations were completed and new and improved guidance (Q&A) was published, to ensure regulatory procedural consistency for marketing authorisation holders.
Ensure and run highly effective and efficient processes to deliver assessment of	Implement (2016) and optimise (2017) a process performance management system with strong customer focus on quality, simplification, and	100%	A set of KPIs was defined in Q1-Q2 and is regularly reviewed. KPIs are currently being tracked via Excel. A dashboard is expected to be developed as part of a SIAMED upgrade.

Objective	Activity	% complete	Achievements/results
referrals.	regulatory procedural excellence.		
	Conduct surveys and meetings with NCAs to capture satisfaction levels and improvement opportunities in handling procedures for CAPs and NAPs	0%	The activity was put on hold due to reorganisation of the Division in the second half of 2016.

Pharmacovigilance activities

Workload indicators

Procedure		2013 result	2014 result	2015 result	2016 forecast	2016 result
	Number of signals peer-reviewed by EMA	2,449	2,030	2,372	1,800	2,372
	Number of signals validated by EMA	43	34	61	35	61
	PSURs (standalone CAPs only) started	518	520	512	475	518
	PSUSAs started	-[1]	-[1]	268	266	243
	Number of imposed PASS protocol procedures started	-[2]	32	31	20	12
	Number of imposed PASS result procedures started	-	-	2	8	3
	Number of emerging safety issues received	24	19	34	35	21
	Number of notifications of withdrawn products received	18[3]	132	160	175	118
	Cumulative number of products, on the list of products, to be subject to additional monitoring	152	203	261	300	301
	Number of incident-management plans triggered	-[4]	-[4]	-[4]	9	7
	Number of non-urgent information or rapid alert notifications submitted through EPITT	-[4]	-[4]	-[4]	55	49
	Number of external requests for EV analyses	-[4]	-[4]	-[4]	50	34
	Number of MLM ICSRs created	-[4]	-[4]	-[4]	7,000	8,495

[1] New procedures, established in 2015.
[2] New procedures, established in 2014.
[3] Notifications only received, starting November 2013.
[4] New indicator, introduced in the 2016 work programme.

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	99.2%	100%	100%	100%
	Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	-[1]	-[1]	98.5%	95%	100%
	Percentage of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	98.4%	100%	100%
	Percentage of reaction monitoring reports, supplied to the lead Member State monthly	100%	100%	100%	100%	97%
	PRAC recommendations on signals and translation of labelling changes in EU languages published	-[2]	-[2]	-[2]	100%	100%

[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 collection and analysis of data to measure the impact of pharmacovigilance.	100%	The PRAC strategy on measuring the impact of pharmacovigilance activities was adopted during the January PRAC meeting, and published on 15 January 2016. In July, PRAC adopted the prioritisation criteria for the selection of topics to be subject to additional monitoring activities. A workshop on the PRAC strategy, to measure the impact of pharmacovigilance, was organised on 5 and 6 December. Seventeen expressions of interest were received in 2016, 9 of which came from industry, and 8 from registry holders.
	Finalise the update of the GVP module V on risk-management systems, and the revision of the marketing authorisation holders' template for risk-management plans.	90%	Public consultation of the GVP module V on risk-management systems, and the revised MAH template for risk-management plans, was completed in the first half of the year. Both the GVP module and the template were finalised in Q4 2016, with the final adoption expected in Q1 2017.
	Draft and implement GVP on pregnancy, to enhance drug safety in pregnancy considerations throughout a product's lifecycle.	55%	Monthly teleconferences with the drafting group have been held during 2016, each time discussing a particular topic of the GVP. The topic of 'long-term or delayed pregnancy outcomes' was agreed for inclusion in the GVP.

Objective	Activity	% complete	Achievements/results
			Input on this topic is expected in Q2 2017, when a dedicated workshop will be organised. The GVP module is expected to be ready for public consultation in the second half of 2017
	Conduct public consultation on the GVP module on biological medicines and on updates for ADR reporting and signal management.	100%	Guideline on good pharmacovigilance practices Product- or Population-Specific Considerations II: Biological medicinal products, was published on 15 August 2016. GVP Modules V on Risk management systems (Rev 1); VI on Management and reporting of adverse reactions to medicinal products (Rev 1); and IX on Signal management (Rev 1), were published for public consultation in August 2016.
	Finalise draft proposals on governance and code of conduct for vaccine benefit-risk studies from the ADVANCE project.	100%	In the first half of 2016, draft documents on governance and code of conduct for vaccine benefit-risk studies were finalised for consultation, in collaboration with the ADVANCE consortium. The governance and code of conduct will be included in the good practice guide, and the publication of the code of conduct is expected in Q1 2017.
	Develop and integrate a sustainable process to collect information on clinical use, based on the experience gained, and on collaboration with NCAs and academics.	90%	Draft results of the codeine pilot study were discussed in June 2016. Analyses by two partners are awaited, enabling completion of the final report on the codeine study. The results are expected to be published in Q2 2017.
	Organise a follow-up workshop on medication errors (2016). Revise as necessary the guidance and Q&A on medication errors (2016-2017).	100%	EudraVigilance analysis on medication errors was completed in December 2016, and will be made public in 2017. Revision of the guidance and Q&A on medication errors is not considered at this stage. A DIA information day on medication errors was held on 20 October 2016.
	Conduct a dry run and implement public hearings in PRAC.	100%	The dry run of public hearings took place during the PRAC meeting on 5 July. The report on the dry run was presented to PRAC in September, and to the Management Board in October.
Maximise benefits to public health promotion and protection, by enhancing benefit-risk monitoring of authorised	Finalise and publish revised guidance for signal detection methods.	95%	The GVP module M IX Rev 1 on signal management, including its addendum, was drafted in the first half of the year. The public consultation was concluded in October and the final revised GVP module IX Signal management (Rev 1) will be published in 2017.
	Organise a second workshop	70%	Within the IMI Web-RADR project, preparation

Objective	Activity	% complete	Achievements/results
medicines and pharmacovigilance decision making, through the use of high-quality data, information and knowledge.	with stakeholders, to review interim Web-RADR project deliverables, and to obtain feedback on recommendations of the draft policy on the use of social media and other tools in ADR reporting.		of the final draft report on the use of social media and other tools, taking into account various analyses conducted in 2015, continued in the first half of 2016. On 19 October 2016, EMA hosted the second IMI Web-RADR project workshop, where the developments and outputs from the project were discussed, in order to inform the policy recommendations. Draft policy and a list of regulatory questions on the use of mobile applications have been started, and will be completed in 2017. The paper on the assessment of the current legal framework on data protection was finalised. The draft literature review on recommendations for ethical aspects was also completed.
	Finalise operational aspects for the registries strategy to support decision making.	50%	Discussions with industry and registries managers are being held during the pilot phase, enabling the preparation of the draft recommendations for supporting patient registries. The draft recommendations were discussed at the registries workshop on 28 October 2016. A report about the workshop was prepared in Q4 2016 and will be published on the EMA website in Q2 2017. A cross-committee task force was established, to evaluate the implementation of the recommendations.
	Finalise (2016) and implement (2017) a proposal for an integrated system for management of notifications and alerts.	35%	Conceptual discussions and analysis, of the options for an integrated webpage to signpost for management of notifications and alerts, took place in 2016. Work to develop an integrated webpage, to facilitate the management of notifications and alerts from the industry, will continue in 2017.
	Develop (2016), implement, and manage (2017) a new process for reception, prioritisation, assessment and action of signals detected by MAHs.	80%	Drafting the business process for receipt, prioritisation, assessment, and action of signals detected by marketing authorisation holders took place throughout 2016. The final process will take into account the comments received during the public consultation on revised GVP module IX on Signal management. Related tools, such as SOPs, templates, tracking tools, etc., are also being developed.
Provide consistent,	Publish annual reports on	100%	The 2015 EudraVigilance annual report was

Objective	Activity	% complete	Achievements/results
high-quality information on pharmacovigilance topics to stakeholders and partners.	EudraVigilance.		published in March 2016.
Provide high-quality, robust, scientifically sound, and consistent post-authorisation scientific assessments.	Implement improved scientific support to imposed and non-imposed PASS protocol review.	100%	The review of the process for PASS protocol review was begun, to identify improvement opportunities; drafting of a scientific guidance document began in the first half of 2016. Both of these were completed in Q3 2016.
	Develop guidance on PASS, and complete reflection on the use of registries for regulatory purposes.	75%	GVP module VIII on PASS (Rev 2) was published in August 2016, with a revised text of Annex 1 (Methods) on registries. The pilot phase of the patient registries continued in Q1-Q2 2016, enabling the preparation of the draft recommendations for supporting patient registries. The draft recommendations were discussed at the registries workshop on 28 October 2016. A report with the observations and recommendations arising from the workshop was prepared in Q4 2016, and will be published on the EMA website in early 2017. Further methodological guidance on registries will be included in Rev. 6 of the ENCePP Guide on Methods in pharmacoepidemiology, work on which is expected to start in early 2017.

In addition to the above activities, an HMA/EMA taskforce, co-chaired by HMA and EMA, was established in 2016, to ensure that the EU regulatory network has both the skills and regulatory processes to enable the exploitation of big data in the regulatory setting. Specific objectives include mapping and understanding the relevant sources of data; identifying areas of use now and in the future; and finally, generating recommendations to ensure the regulatory network is well positioned, to ensure that the opportunities of these emerging datasets are realised. The taskforce is composed of 11 members from national competent authorities, in addition to the chair, co-chair and secretariat.

Other specialised areas and activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Herbal monographs, new[1]	9	11	14	10	8
Herbal monographs, revised	7	5	3	10	9
List entries	0	1	0	2	2

[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	2013 result	2014 result	2015 result	2016 target	2016 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Implement the new Clinical Trials Regulation (EU) No 536/2014.	Review existing, and prepare new procedures and guidance documents supporting full implementation of the Clinical Trial Regulation.	100%	A document on risk-proportionate approaches in clinical trials was developed and launched for a 3-month public consultation by the Commission in June. The review of the comments received took place over the second half of the year, and the document is expected to be finalised in the first half of 2017. Draft guidelines on good clinical practice, specific to advanced therapy medicinal products, were prepared in collaboration with the Member States and the Commission. Draft guidance and recommendations on the content of the trial master file and archiving were reviewed, and will be released for public consultation in Q1 2017. Two guidance documents on serious breaches and inspection-related procedures were also finalised in 2016, and will be published for public consultation in Q1 2017. The GCP IWG reviewed and adopted the relevant procedures of EudraLex Volume 10 chapter IV, including guidance on preparation, coordination (for MRP and DCP) and conduct of GCP inspections, with related annexes; as well as preparation of inspection reports and communication of findings. The documents will be published in Q2 2017. For status update on the progress of the development of the EU Portal and Database, please refer to annex 16: Project implementation.
Support a high level of coordinated, cross-European preparedness	Interact with ECDC and VE to develop a new platform for influenza vaccines effectiveness.	100%	In the first half of the year, EMA gave a presentation at the I-MOVE meeting on the Agency's perspective on public-private partnership for vaccines effectiveness studies, and held meetings with the EC C3 and ECDC on

Objective	Activity	% complete	Achievements/results
activities, to act on public-health threats.			the Agency's position regarding such partnerships, and how studies could be conducted.
	Continue discussion with ECDC and EC on development of a sustainable framework for vaccines benefit-risk monitoring in the EU.	100%	Interactions with the EC have been limited due to their current difficulty in proceeding with this topic. However, the topic has been added to the list of potential activities in a draft EC document on vaccine policies.
	Deliver the pandemic plan revision, transforming the previous pandemic influenza preparedness plan into a wider-ranging preparedness for emerging health threats.	-	-
	Develop a revised policy for dealing with emerging health threats (2016), and issue specific working procedures, in accordance with the new structure and plan (2016-2017).	100%	The revision of the pandemic plan continued, and was reaching completion in the first half of 2016. A few additional aspects, relating to SOPs and refinement of roles and responsibilities, were addressed in the second half of the year.
Facilitate the development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation.	Organise workshops or discussions with interested parties (e.g. CPTR and IMI PREDICT-TB) to obtain the latest scientific input for revision of the guideline for developing medicines for tuberculosis.	100%	In April, a draft addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to mycobacterium tuberculosis was agreed by the Infectious Diseases Working Party. The Agency contributed to the WHO meeting for the definition of target regimens for tuberculosis. A workshop was organised in November.
	Provide scientific support to writing a new guideline on paediatric aspects of new antibiotics and to revision of SmPCs for already approved antibiotics.	100%	A concept paper was adopted in the first half of the year and was released for consultation.
Facilitate availability of herbal medicines in the European Union.	Compile an overview of herbal substances/preparations from non-European traditions, related to pharmacopoeia, as tools to identify candidates for future EU herbal monographs.	80%	A list for ayurvedic herbal substances was prepared and finalised, in coordination with EDQM. In November 2016, a letter on behalf of HMPC and the consolidated list were sent to AYUSH, Government of India, as a basis for cooperation.
Contribute to minimising the	Improve the guidance on regulatory acceptance of 3Rs	90%	The reflection paper, providing an overview of the current regulatory testing requirements for

Objective	Activity	% complete	Achievements/results
need for animal testing of human medicinal products.	(replacement, reduction, refinement) testing approaches.		medicinal products for human use, and of the opportunities for implementation of the 3Rs; as well as a report on actions taken on the 'Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products', were prepared during 2016, and published in Q4 2016 for consultation.
	Engage with scientific advances in experimental models to refine or replace in vivo animal studies.	100%	Nominated working party and EMA experts took part in an EC-organised conference on 'Non-animal approaches – the way forward'.
Effectively manage risks to the environment, arising from the use of human and veterinary medicines.	Provide technical support to the European Commission as part of the development of a Commission strategy for managing risks to the environment, related to the use of medicines (both human and veterinary).	100%	All requests received from the EC in the first half of the year were addressed. No additional requests were received in the second half of the year. Engagement in the development of the EC strategy has been minimal, as this is not yet mature.
Promote the application of harmonised international standards.	Provide technical and scientific contribution to the development of an addendum to the ICH statistical principles guideline E9, and of an addendum to the ICH Paediatrics guideline E11, relating to the design and analysis of clinical trials.	60%	In February 2016, the Agency organised and contributed to an EMA/Biostatistics Working Party workshop on estimands, to discuss the concept of estimands and their impact on regulatory assessment. In May, the Agency organised an EMA workshop and participated in an FDA workshop on the framework of extrapolation of efficacy from adult to paediatric populations. In addition, the Agency participated in the ICH expert working group meetings through the year, including two in-person meetings in June and November, and contributed to the development and drafting of the ICH E9 addendum on estimands.
	Provide technical and scientific contribution to the development of ICH safety guidelines (carcinogenicity assessment document evaluation for ICH S9).	50%	Over the course of the year, the Agency organised monthly teleconferences and contributed to the work related to the revision of ICH S1 guideline.

Evaluation activities for veterinary medicines

Pre-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Innovation Task Force briefing requests	-[1]	2	2	4	4
Scientific advice requests received	40	31	27	20	18
Requests for classification as MUMS/limited market	23	29	27	25	25

[1] ITF procedure made available to veterinary products in 2013.

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of scientific advice procedures completed within set timeframes	97%	97%	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 markets activities.	100%	The 6th annual report on veterinary MUMs/limited markets was adopted by the EMA Management Board at its March meeting, and was subsequently published on the Agency's website.
	Finalise the review of the MUMS/limited markets guidelines.	85%	Revised guidelines on data requirements for veterinary medicinal products intended for MUMS/limited market (quality, safety and efficacy) were adopted in December 2016 by CVMP, and published on the Agency website. The immunologicals guideline is expected to be finalised in the first half of 2017.
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%	The Innovation Task Force (ITF) was presented at several events involving industry, such as the EMA/IFAH Europe info day in March 2016. ITF was also continuously promoted in pre-submission meetings, and in response to individual queries. Four ITF meetings took place in 2016.
	Evaluate the impact of measures, recently put in place to support innovation (ADVENT,	100%	Analysis of existing pre-authorisation procedures was conducted during 2016, with the aim of providing recommendations for

Objective	Activity	% complete	Achievements/results
	ITF) and plan improvements in measures to support innovation.		additional support, if such need is identified. The report on implementation of measures in place to support access was prepared in the second half of the year, and will be finalised with an action plan for further development in Q1 2017.
	Develop regulatory guidance in priority areas for technologies, that are new to veterinary medicine (including cell-based therapies, monoclonal antibodies for veterinary use).	80%	Further to the agreement on the new working methodology, ADVENT has published for consultation five problem statements on the priority topics of stem cells and monoclonal antibodies. The consultation phase has ended for all statements, and the topic groups are developing answers to the comments on the problem statements. Q&A documents, based on the problems statements, are estimated to be finalised in Q2 and Q3 2017.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners.	Analyse the outcomes of the survey on recipients' views regarding the usefulness and quality of the scientific advice received, and decide on the potential for improvement.	10%	Planning for the analysis started in second half of 2016. However, veterinary medicines industry portfolio reviews were conducted during 2015-2016, aiming to understand the current developments and industry initiatives in developing veterinary medicines, as well as the usefulness of the support provided by the Agency. This provided user feedback on the scientific advice from the Agency, that will be incorporated in a forthcoming analysis.
	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 has been actively promoted in early contacts, business meetings with companies, pre-submission meetings, and ITF meetings. Analysis of the existing pre-authorisation procedures was being conducted throughout 2016, and included recommendations concerning parallel scientific advice. An action plan to develop parallel scientific advice procedure with the FDA is included in the planned improvements of scientific advice procedure in 2017.
Support the development and availability of veterinary medicines.	Identify (2016) and implement (2016-2020) EMA's contribution to the EU Network Strategy to 2020, in the area of promoting availability of vaccines within the EU, with particular emphasis on vaccines against transboundary diseases and	100%	A Network action plan on the availability of veterinary vaccines was developed in the first half of 2016. The mandates of the HMA steering group and the CVMP ad hoc group on veterinary vaccine availability (CADVVA) were adopted in Q1. Impact analysis of measures, proposed by industry for promoting the availability of

Objective	Activity	% complete	Achievements/results
	diseases with limited markets.		vaccines, was started by the HMA steering group and CADVVA in the first half of the year, and adopted by CVMP and HMA in November 2016. The results of the analysis of industry recommendation in improving vaccine availability were presented at a stakeholders meeting in December 2016. Further actions will start in in Q1-Q2 2017, including the organisation of a focus group on field efficacy trials. The website on veterinary vaccines availability was launched in August 2016.

Initial evaluation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Initial evaluation applications	23	12	10	28	21
New MRL applications	6	4	4	5	6
MRL extension and modification applications	6	2	3	1	1
MRL extrapolations	1	2	1	1	0
Art 10, Biocides	0	0	0	2	0
Review of draft Codex MRLs	0	5	0	7	5

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of procedures completed within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality and consistent scientific opinions to EC.	Finalise development (2016) and promote uptake (2016-2017) of the revised guideline, procedures and templates for	85%	The guidance and templates for pharmaceutical products that were adopted by the CVMP in December 2015, were implemented for electronic use in the first half of 2016. Training

Objective	Activity	% complete	Achievements/results
	CVMP assessment reports.		on the use of these took place in 2016, and is now available to assessors through web recording. Development of a template, including guidance for immunological products, also started in the first half of the year and the templates were adopted by the CVMP in December 2016. Implementation for electronic use and training is foreseen in 2017.
Ensure the establishment of MRLs supports the safe use of veterinary medicines with regard to their impact on human health.	Provide technical support to the European Commission in drafting the implementing acts specified in Regulation (EC) No 470/2009.	85%	Technical support on three draft implementing measures, prepared by the Commission and based on CVMP recommendations, continued in 2016, including participation at Standing Committee meetings in Q2 and Q4 2016. Two draft implementing measures were finalised in Q4, with favourable opinions adopted by the Standing Committee (November 2016). Public consultation on the third implementing measure is expected shortly. Preparation of a fourth implementing measure (methodological principles for risk-assessment and risk-management in the establishment of MRLs) was initiated in Q1 2016, and continued throughout the year. In September 2016, it was agreed with the Commission to extend the deadline for completion of the work, from December 2016 to the end of Q1 2017.
	Review the approach on genotoxic substances in the establishment of MRLs, and authorisation of veterinary medicinal products.	85%	A draft guideline on limits for genotoxic impurities (now called DNA reactive impurities) in veterinary medicinal products was prepared in Q2 2016, and submitted for consultation to the QWP and EWP (veterinary). Comments were received in Q4 2016, and the draft guideline was revised accordingly, followed by another round of consultation with the working parties that ended in December 2016. The draft guideline is expected to be adopted by CVMP for public consultation in Q1 2017.
	Finalise, in collaboration with ECHA and EC, the procedure for the establishment of MRLs for 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 discussions continue at the Commission level; the Agency will progress on the topic once the EC finalises its position.

Post-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Variations applications, of which:	315	340	373	350	410
Type IA variations	175	175	196	180	243
Type IB variations	108	118	116	125	126
Type II variations	32	47	61	45	41
Line extensions of marketing authorisations	5	6	3	3	3

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of 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.	Start a review of post-authorisation procedures other than variations, and introduce necessary improvements.	100%	The review and implementation of improved post-authorisation procedures has been incorporated in the veterinary change programme and will be carried out within this project. SOPs on processing type-IA variations, type-IB applications, renewals, annual reassessments and handling of veterinary applications inbox were reviewed and finalised during the year.

Referrals

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Arbitrations and Community referral procedures initiated[1]	10	7	7	8	8

[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	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of 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 antimicrobials and other classes of products.	Engage with the EC and Member States to identify and, where possible, prioritise referrals 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.	100%	In 2016, CVMP updated its joint advice with the CHMP on the use of colistin in veterinary medicine, and the final document was published in July. Five of the eight referral procedures started in 2016 concerned antimicrobials or other substances with antimicrobial activity (i.e. zinc oxide).

Pharmacovigilance activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Periodic safety-update reports (PSURs)	149	158	159	150	175
Total adverse-event reports, of which:	22,326	28,404	31,467	29,400	38,162
Adverse-event reports (AERs) for CAPs	8,166	11,878	14,387	13,000	18,419
Adverse-event reports (AERs) for NAPs	14,160	16,526	17,080	16,400	15,257

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of PSURs evaluated within the established timelines	97%	97%	99%	90%	98%
Percentage of AERs for CAPs monitored within the established timelines	100%	95%	98%	95%	96%

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.	Develop an approach to systematically ensuring quality-control and data verification of product data in the common European database of veterinary medicinal products, and link these data to adverse event information, related to CAPs and non-CAPs in the EudraVigilance Veterinary data warehouse, to allow signal detection in preparation for the new veterinary legislation.	100%	Bilateral meetings with eighteen NCAs took place throughout 2016, to provide support for the compilation of data and to prepare for uploading of data on national products into the common European database of veterinary medicinal products. A procedure and a best practice guide were established by Q4 2016. The software, that supports the upload and recoding procedure, was updated and tested in Q4 2016 and awaits release in production, pending EVHuman updates which have been prioritised first. The actual quality control of new product data received will start on release of the updated software.
	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species.	50%	A stakeholder focus group meeting for experts, industry and veterinarians to discuss the reasons for under-reporting AERs of veterinary medicinal products took place in November 2016. Following the meeting, the reflection paper is being revised and a draft for consultation is expected by Q2-Q3 2017.
	Revise the surveillance strategy for centrally authorised products to link signal-detection and PSURs, and to ensure better use of pharmacovigilance resources.	85%	Following the public consultation on the concept paper for revision of the Recommendation of basic surveillance of EVVet data, the Pharmacovigilance Working Party (veterinary) adopted a draft revised recommendation outlining a surveillance strategy, and integrating surveillance, using EVVet data and PSUR evaluation for CAPs for more efficient use of resources. The adoption of the draft revised recommendation by CVMP for consultation is expected in Q1 2017, once feasibility of related EVVet change request to allow re-routing of reports is confirmed.
Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners.	Publish the veterinary pharmacovigilance annual bulletin.	100%	The veterinary pharmacovigilance bulletin 2015 was published in February 2016.

Other specialised areas and activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
n/a					

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Support an increased availability of veterinary medicines.	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation.	100%	Throughout 2016, EMA provided technical advice to the EC during the Council Working Party discussions on new veterinary legislation.
Promote the uptake of harmonised standards at international level.	Participate in training events that raise awareness, and enhance uptake of VICH standards by non-VICH countries.	100%	In June, the Agency co-chaired the 7th VICH Outreach forum in Brussels, attended by 22 delegates from 12 countries around the world, 3 international organisations, as well as the 7 VICH member countries. EMA also chaired the 33rd VICH steering committee meeting. EMA contributed to the 5th Global Animal Health Conference in India in Q4, and to the associated workshop on good regulatory practice.
	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes.	100%	Two liaison meetings with JECFA took place in March and September, to discuss differences in specific scientific approaches for the establishment of MRLs. A third meeting is planned for Q1 2017.
Contribute to minimising the risk to humans and animals from the use of antibiotics in veterinary medicine.	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine, and publish the outcome in the annual ESVAC report.	100%	During the first half of 2016, the data from Member States were received and validated. The final annual ESVAC report that now also includes data from Croatia, Romania and Switzerland, was published in October 2016.
	Prepare and deliver a joint EMA-EFSA opinion on how to reduce the need for antimicrobials in	100%	A targeted consultation of interested parties (in the form of a questionnaire) was conducted in the first half of 2016, and the input was used by

Objective	Activity	% complete	Achievements/results
	food-producing species.		experts working on the scientific opinion. Close collaboration between EMA and EFSA (biohazards panel) continued throughout the year to progress the work on the opinion. 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 as scheduled.
	Draft and validate a methodology to measure the use of antimicrobials in poultry.	85%	The DDDvet and the DCDvet for poultry, pig and cattle were published in Q2 2016. The Expert Advice working group started drafting the guidance covering cattle, pigs and poultry in Q2; and a target internal consultation with NCAs was held in the second half of the year. Following the discussions with NCAs, the guideline is expected to be ready for consultation during Q1 2017. Also in Q2, the Agency started preparing an inventory of currently existing systems used to collect data on consumption in poultry in the EU. This was completed in Q4 2016, and the reports will be published in Q2 2017.
Effectively manage risks to the environment, arising from the use of veterinary medicines.	Continue scientific reflections on the management of risks related to the use of veterinary medicines, where concerns have been raised regarding the potential for harmful effects on the environment.	100%	A reflection paper on the authorisation of veterinary medicinal products, containing (potential) persistent bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances, was adopted for consultation at the February 2016 CVMP. Following the end of consultation (in May 2016), a revision of the reflection paper was initiated to take into account the comments, and is expected to be finalised in Q1-Q2 2017. A workshop on aquaculture with experts from regulatory authorities on environmental risk-assessment for aquaculture took place in June 2016. A reflection paper is being drafted as outcome of the workshop and will be finalised by the Environmental Risk Assessment Working Party by Q3 2017, for submission to CVMP and decision on the need for further environmental risk-assessment guidance with regard to aquaculture.
Contribute to minimising the need for testing of	Contribute to the development of internationally harmonised guidance by VICH, on applying	100%	The work on VICH international guideline GL50 'Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for

Objective	Activity	% complete	Achievements/results
veterinary medicinal products on animals.	the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas.		veterinary use', and the draft VICH international guideline GL55 'Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use', was led by the EU and these were published for consultation in Q1 2016, with a deadline for comments on 1 August 2016. The comments received are currently being evaluated by the VICH experts group. The activity is expected to be completed in 2017.
	Improve the guidance available on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches.	75%	A reflection paper, providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs, was adopted by the CVMP in Q2, and published for a six-month consultation, ending on 31 October 2016. The comments received will be reviewed by the relevant working parties and the new joint 3Rs working group that will meet for the first time in Q2 2017. A draft guideline, for individual laboratories for transfer of quality-control methods validated in collaborative trials with a view to implementing 3Rs, was finalised in the first half of the year and adopted by the CVMP and CHMP in July 2016 for a six-month consultation, ending in January 2017.

In addition to the above activities, the Agency provided input and leadership in the 2nd International Symposium on alternatives to antibiotics, organised by the OIE in December 2016, with a view to improve availability of alternatives. Review article to follow up in collaboration with the FDA. A review article on regulatory pathways to enabling the licencing of alternatives to antibiotics is being prepared in collaboration with the FDA.

Horizontal activities and other areas

Committees and working parties

Workload indicators

Procedure		2013 result	2014 result	2015 result	2016 forecast	2016 result
	Number of reimbursed meetings	354	397	437	484	441
	Number of teleconference meetings[1]	2,737	3,215	4,273	5,000	4,969
	Number of reimbursed delegates	6,869	7,488	8,226	9,000	7,972

[1] Total audio, video and web-conference meetings.

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Percentage of delegate satisfaction with the service level provided by the secretariat	-	n/a	93%	90%	n/a
	Percentage of up-to-date electronic declarations of interests submitted by committee members and experts, prior to participating in a committee, SAG or other meeting	-[1]	100%	99%	100%	99%
	Percentage of first-stage evaluations of conflicts of 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	-[1]	100%	100%	100%	100%
	Percentage of ex-ante verifications of declarations of interests for new experts completed within two weeks after upload of the DoI in the experts database	-[1]	94%	100%	90%	100%

[1] New performance indicators, introduced in 2014.

Achievements

Objective	Activity	% complete	Achievements/results
Improve collaboration and communication between committees, working groups and SAGs to increase quality, efficiency and consistency of outputs.	Analyse involvement of scientific advisory groups in evaluation activities, to identify gaps and improve guidance.	90%	A monitoring mechanism has been implemented and the data is being collected regularly. The analysis of the data is ongoing and the presentation of results at CHMP and PRAC is planned for Q1 2017.
	Develop and embed in the Agency the concept of therapeutic-area-specific communities (starting with the Oncology community) to facilitate knowledge exchange, and create knowledge development on therapeutic-area aspects within the Agency.	75%	A pilot for the oncology community was completed in May 2016, and is now transformed into an established community, continuing the ongoing activities and further developing active cooperation in priority areas (PRIME, CMA, AA). The experience gained was reviewed and the potential extension of communities based on therapeutic areas was discussed internally in 2016. This will be further explored in 2017.
Provide up-to-date, timely, state-of-the-art guidance documents on relevant topics in medicines'	Explore opportunities for collaboration with HTA organisations on the development and revision of methodological and disease-specific guidelines.	0%	Activity not progressed due to lack of capacity/interest from EUnetHTA.

Objective	Activity	% complete	Achievements/results
development.	Develop scientific guidance for the development of medicines in the elderly.	75%	Six-month consultation on the frailty guideline closed at the end of May 2016. The comments received were evaluated and incorporated, and the first review of the revised draft guideline is now taking place in the Agency.
	Support the finalisation of the revised dementia guideline by the Central Nervous System Working Party.	100%	The draft guideline was published for public consultation in February 2016. The consultation ended in July and, following the review of the comments, the final guideline is expected to be released in 2017.
	Provide administrative and scientific support to the drafting/revision of BSWP guidelines on adjustment for baseline covariates, multiplicity, and the investigation of subgroups in clinical trials.	80%	A guideline on adjustment for baseline covariates in clinical trials was published in January 2016. A guideline on multiplicity issues in clinical trials was adopted by CHMP in December 2016, and will be published for a 3-month consultation in early 2017. Questions and answers on data-monitoring committees, and a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development, were drafted and put under internal review by other EMA scientific groups. A guideline on the investigation of subgroups in clinical trials was put on hold until the ICH E17 guideline on multi-regional clinical trials is finalised.
	Draft a paper to summarise progress and to suggest new areas of guidance/training on the use of modelling and simulation methodology.	80%	Extrapolation workshop was held on 17-18 May 2016. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development was published for public consultation, and will be finalised in 2017. Guideline on the development and reporting of physiologically based pharmacokinetic (PBPK) models was published for public consultation on 29 July 2016. The consultation will end in January 2017 and the guideline is expected to be finalised during 2017. PBPK workshop was held on 21 November 2016.
	Draft a paper to summarise progress and to suggest new areas of guidance/training on the use of extrapolation methodology.	100%	A draft reflection paper on extrapolation of efficacy and safety in paediatric medicine development was published in April 2016. A regulators' workshop was held, as well as a stakeholders' workshop, in May 2016. The reflection paper was updated, based on the

Objective	Activity	% complete	Achievements/results
			outcome of the workshops, and is currently with the working parties and committees for consultation. Draft guideline is expected to be released for public consultation in April 2017.

Inspections and compliance

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
GMP inspections[1]	397	420	567	525	672
GLP inspections	0	0	1	0	0
GCP inspections	70	66	86	120	121
Pharmacovigilance inspections	13	20	14	10	8
Notifications of suspected quality defects	178	147	164	180	181
Other GMP inspections-related notifications	-[2]	-[2]	18	60	17
Number of medicinal products included in the sampling and testing programme	45	46	48	48	48
Standard certificate requests	3,137	3,338	3,221	3,369	3,787
Urgent certificate requests	297	535	785	450	487
Parallel distribution initial notifications received	2,532	2,492	2,838	3,100	2,850
Parallel distribution notifications of change received	2,563	1,295	2,096	2,300	1,847
Parallel distribution notifications of bulk change received	1	9	13	10	8
Parallel distribution annual updates received	1,279[3]	2,339	4,550[4]	4,400	3,815[5]

[1] Includes plasma master file inspections.
[2] Previously included under suspected quality defects.
[3] Parallel distribution annual updates introduced in May 2013.
[4] Includes 560 parallel distribution annual update notifications that were received in 2014, but processed in 2015.
[5] Excludes approximately 1,000 notifications received, but not processed in 2016.

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%
Percentage of standard certificates issued	51%	30.4%	91%	90%	91.6%

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	within the established timelines					
	Average days to issue standard certificate	11	13.7	7	10	7
	Percentage of urgent certificates issued within the established timelines	100%	100%	100%	100%	100%
	Percentage of parallel distribution notifications checked for compliance within the established timeline	90%	97%	99%	90%	99%
	Number of training activities organised in the area of inspections (minimum number)	-	7	10	4	10
	Additional GCP inspections addressed through information exchange on inspections carried out by international partners	-	29%	46%	35%	34%
	Additional routine GMP re-inspections of manufacturing sites, addressed through exchange of information with international partners	-	8%	14%	10%	19%
	Percentage of 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.	Continue practical implementation of the risk-based inspections programme for third-country manufacturing plants of centrally authorised products, focusing EU inspectional resources on sites of highest risk.	100%	Risk-based approach to inspections planning for third-country manufacturing plants of centrally authorised products is fully implemented since Q3 2014, and routinely used by EMA.
	Identify (2016) and develop (2016-2017) 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%	As part of EMA-FDA GCP initiative, regular teleconferences for exchange of information took place throughout the year. Five joint EMA-FDA inspections and thirteen observational inspections were coordinated. Regular exchange of information and extensive discussions on bioequivalance inspections (product and/or sponsor related) took place as part of the EMA/MSs FDA bioequivalance initiative. In 2016, inspections coverage of pivotal clinical

Objective	Activity	% complete	Achievements/results
			trials submitted in marketing authorisation applications was improved by 34%, through information exchange on inspections carried out by international partners. Discussions with the WHO took place on potential collaboration on training activities on GCP inspections for bioequivalence studies, including at the Bioequivalance Forum organised by EMA in Q3 2016. In April 2016, the first ad hoc pharmacovigilance inspections information exchange with Swissmedic took place under the confidentiality arrangement.
	Deliver training and capacity-building activities for inspectors and assessors on inspection-related activities.	100%	The Agency participated in two capacity-building events in India in the first half of 2016. An online GCP training course (one webinar for EU, and one webinar for non-EU participants) took place in May 2016. In the second half of 2016, the Agency further supported training and workshops on GMP and GCP data integrity in China (1 GMP + 2 GCP). A training course on advanced quality risk management for GMP inspectors was held at the Agency in September. The annual GCP IWG workshop, Bioequivalence inspection forum, and the Pharmacovigilance IWG training course (human and veterinary) were held in October 2016 in the EU. The online training on bioequivalence was finalised and will be launched for EU/EEA inspectors in Q1 2017.
	Develop the plan to further extend cooperation with Member States in coordinating third-country inspections.	70%	Collaboration with Member States on coordinating third-country inspections and the GMDP IWG continued in 2016. A document on cooperation between EMA, EEA NCAs and EDQM on inspection planning was agreed. Instructions and rules on data entry into the EudraGMDP about the planned third-country inspections were adopted by GMDP IWG in September and will be published on the EudraGMDP portal in Q1 2017.
	Continue work to establish a mutual reliance framework with the FDA, to increase the scope of EU international inspections activities.	90%	During 2016, the Agency continued to support the work on the mutual recognition agreement between EU and the FDA.

Objective	Activity	% complete	Achievements/results
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects.	Implement process improvements on the handling of quality defects and non-compliance issues.	90%	A new form for reporting quality defects/suspected falsified medicinal products was completed in 2016. Two SOPs and related documents were also revised in the second half of 2016 and will be finalised in Q2 2017.
	Continue researching the root causes of quality defects.	90%	The new form for reporting quality defects, along with a user guide and instructions, were completed in 2016, incorporating the agreed MEdDRA terminology. The form was presented to EU NCA's and international partners in November 2016. A pilot phase with industry stakeholders will take place in Q1 2017.
	Develop statistics and metrics for measuring disruption in supply leading to shortages.	90%	EMA is working with the Member States on implementing the actions identified in the Network strategy regarding supply issues and availability of medicines. The SOP on 'Dealing with reports of suspected defective medicinal products' was reviewed in 2016 to incorporate instructions on how to deal with reports of stolen medicines, when these are received by the EMA.

In addition to the above activities, work on preparing a pilot phase with the FDA on sharing pharmacovigilance inspections information started in 2016, with the drafting of a document that outlines the aims and objectives of the EMA-FDA pharmacovigilance inspection initiative. Ad hoc exchange of information on pharmacovigilance inspections took place in the second half of the year, mainly with regard to planned inspections.

Partners and stakeholders

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Requests for SME qualification	401	499	793	650	582
SME status renewal requests	808	813	994	1,400	1,185
Requests for access to documents	293	416	701	750	823
Documents released following requests for access to documents	n/a[1]	1,771	2,972	2,300	2,876
Requests for information	5,840	4,625	4,573	4,500	4,843
Number of patients involved in EMA activities[2]	551	633	743	650	750

[1] Access to documents service only established in Q3 2013.
[2] Refers to number of instances of patient involvement in EMA activities (the same patient can be involved on several occasions).

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Satisfaction level of patient and consumer organisations	n/a	95%	n/a	80%	97%
	Satisfaction level of SMEs	97%	80%	92%	80%	94%
	Percentage of responses to ATD requests provided within set timelines	-[1]	-[1]	94%	90%	97%
	Percentage of responses to RFI requests provided within set timelines	-[1]	-[1]	97%	97%	100%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	-[1]	-[1]	81.7%	70%	77%

[1] New indicators, introduced in 2015.

Achievements

Objective	Activity	% complete	Achievements/results
Enhance cooperation within the European medicines regulatory network.	Develop training courses, to be provided through the Network Training Centre (EU NTC).	80%	Over 150 training courses (face to face and webinars) where made available through the EU NTC Training catalogues in 2016. 70 of these courses were organised by the EU Network, and the EU NTC reimbursed directly 24 of such courses, making them available to the wider network. The online learning management system was delivered in 2016, and currently has over 2,000 registered users. Progress was made in the development of further nine curricula, including Clinical Trials, GCP Inspections, Pharmacovigilance, Veterinary and ATMPs.
	Conduct horizon-scanning to identify emerging trends at an early stage and to ensure appropriate expertise is available, and to improve regulatory preparedness, including through supporting the work undertaken by the Innovation Network and EU Network Training Centre.	20%	An awareness session was organised with the NCAs, and the trends from the ITF were analysed in the first half of 2016. Ad hoc learnings are being used to identify opportunities for increasing effectiveness of the support provided to the companies. Development of a more structured approach to horizon-scanning was started. A pilot was started at the end of 2016, where all EU-funded research projects are invited to an ITF briefing meeting at the project start, to enhance our

Objective	Activity	% complete	Achievements/results
			awareness of research in innovative medicines, and to signpost innovators to opportunities for interactions with regulators, such as qualification advice, scientific advice, protocol assistance and others. In 2017, a pilot to incorporate the ITF data in a client reference manager will start, to help achieve more effective horizon scanning opportunities.
	Complete the data-gathering initiative for fee-generating activities (2016) and non-fee generating activities (2016-2017).	75%	All the data collection cycles for the review of all human and veterinary fee-generating procedures, as well as non-fee generating activities (e.g., PDCO, COMP, working parties), was launched during 2016. Interim analysis of the human medicines data set was presented to the Management Board in December. Report on veterinary scientific advice was also completed.
Further strengthen the Agency's transparency and open-data commitments.	Implement necessary processes for clinical data publication, including processes for document receipt, redaction consultation and conclusion, public access process, and others.	100%	External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use was published in March. Updated version of the guidance was published in December. The clinical data website was launched on 20 October 2016.
	Initiate reflection on providing access to individual patient data.	5%	During the first half of the year, the Agency provided input to the initiative on collecting individual patient data in relation to direct-acting oral anti-coagulants, which will contribute to the reflection on providing access to individual patient data. No further progress was made in second half of 2016 due to the need to prioritise the EMA preparedness for Brexit.
	Publish, for public consultation, the transparency policy.	10%	A new approach towards future transparency at EMA, taking into account identified drivers for change since 2009, and transparency initiatives undertaken by other regulatory authorities and other EU agencies, was agreed by management in September 2016, but due to the need to prioritise the EMA Brexit preparedness, the project is currently put on hold.
	Develop principles for public consultation of EMA core scientific and corporate documents, and implement	100%	Draft principles for public and targeted consultation of EMA core and scientific documents were prepared in Q1-Q2 2016, and were circulated internally for comments in

Objective	Activity	% complete	Achievements/results
	them in a guidance document.		November 2016.
	Publish, for public consultation, the revised policy on access to documents.	95%	The revised policy and two 'output tables' (one covering documents relating to medicinal products for human and veterinary use, and the other one relating to corporate documents) were adopted by the Management Board in December 2016. The public consultation will be launched in Q1 2017.
	Finalise and publish the policy on handling falsified data/information on medicines.		It was decided to include the issue of handling falsified data in the EMA policy on the handling of information from external sources concerning EMA activities on the authorisation, suspension and maintenance of human and veterinary medicinal products. The policy has been finalised and discussed with both the EC and OLAF, and will be submitted to the Management Board in March 2017.
	Publish a report on coordination of safety announcements within the Network, and revise EU guidance on safety communication.	80%	The public consultation on the revised EU guidance on safety communication ended in February 2016. The comments received were reviewed and are being implemented into the final guidance, which is expected to be published in Q1 2017.
Provide stakeholders and partners with consistent, high-quality, timely, targeted, and accessible information on the Agency's work, outputs and medicinal products.	Develop a crisis communication strategy.	25%	An internal draft version of the crisis communication strategy was prepared in the first half of 2016. The learnings on corporate crisis situations, gathered from the recent experience with Brexit, will be taken into account when finalising the strategy. The crisis communication strategy is expected to be finalised in Q3 2017 and tested in Q4 2017.
	Develop a framework for communicating the scientific output of EMA scientific committees.	80%	In the first half of the year, all committees were interviewed and a mapping exercise was completed. An initiative with recommendations to streamline communication of EMA committees was prepared, based on the results of both the interviews and the mapping exercise. The initiative is expected to be agreed by the Scientific Coordination Board in Q1 2017.
	Publish product-related communication guidance on 'what' information and 'when' EMA publishes on products.	100%	The guidance was published in May 2016.
	Expand user-testing by patients for all product-related communications that include	10%	Based on the feedback received from stakeholders, the Agency initiated a reflection on how to user-test various communication

Objective	Activity	% complete	Achievements/results
	patients as a target audience.		products targeting the general public. Following the EMA Annual training day for patients in 2016, where one break-out session is dedicated to review of documents, the Agency took the opportunity to recruit and train new reviewers for documents destined for the public. A call for expression of interest was sent to training day participants from 2015 and 2016 as well as those who had expressed interest via the individual expert database. A training webinar will be organised in March 2017.
Strengthen stakeholder relations, focusing on patients and consumers, healthcare professionals, industry associations and academia.	Adopt (2016) and implement (2017) a framework for collaboration with academia.	75%	Public consultation on the proposal of a framework for collaboration with academia was conducted in the first half of the year. The draft framework was discussed at a Scientific Coordination Board meeting and the HCPWP meeting with academia in June, and was presented to the Management Board in December. Adoption of the framework is expected in March 2017, once the comments from the MB are incorporated.
	Implement a framework for interacting with industry stakeholders.	100%	Eligibility criteria were adopted by the Management Board and published in June 2016. The review of the eligible organisations is expected to be completed and published by January 2017.
	Publish annual report on EMA's interaction with industry associations.	100%	The 2015 annual report was presented at the June Management Board meeting, and subsequently published on the Agency's website.
	Publish annual report on EMA's interaction with patients, consumers, healthcare professionals, and their organisations.	100%	The 2015 annual report was presented at the June Management Board meeting, and subsequently published on the Agency's website.
	Conduct a joint PCWP/HCPWP workshop on the use of social media, to further engage with patients, consumers and healthcare professionals.	100%	The social media workshop took place on 19 September 2016. A report on the workshop and its outcomes has been published on EMA website.
	Publish a 10-year report on PCWP operations.	100%	A dedicated workshop to mark 10 years of the PCWP took place on 14 June 2016. Recording of the workshop, interviews, and articles are published on a dedicated page on the EMA website.

Objective	Activity	% complete	Achievements/results
	Explore processes to capture patients' input on the value of evidence during benefit-risk evaluation, based on the outcome of the pilot phase of patients' involvement in benefit-risk assessments.	90%	An article on incorporating patient preferences into drug development and regulatory decision making was published in May 2016. A study to explore the process to capture patient input on the value of evidence during benefit-risk evaluations was completed in June. An article on the study was submitted to 'Clinical pharmacology and therapeutics' journal in December 2016.
	Develop (2016) and implement (2017) recommendations to promote GPs' interactions with EMA.	70%	A workshop with GPs was held in April, and this identified areas for mutually beneficial collaboration between GPs and EMA. A report with the outcomes of the workshop was published in June. In addition, draft recommendations to promote interactions with GPs are being developed.
	Implement a revised framework for EMA interaction with patients.	90%	A study to explore the process for capturing patient input on the value of evidence during benefit-risk evaluations was completed in June. An article on the study was submitted to 'Clinical pharmacology and therapeutics' journal in December 2016. Training of patients on EMA activities took place on 29 November 2016.
Further develop support to, and strengthen stakeholder relations with, SMEs.	Develop an action plan arising from the 10-year report on the implementation of SME Regulation.	80%	The action plan was developed and is under internal review. It is expected to be discussed at management level in Q1 2017.
	Enhance communication and outreach to SMEs, to increase regulatory awareness and promote the use of new approaches and tools in development.	100%	An SME workshop on statistical perspectives in regulatory clinical developments was held on 5 February 2016. A second SME workshop on non-clinical development, including a topic on PRIME, was held in October. Regular communication through mailings and quarterly newsletters to SMEs continued throughout the year.
	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.	90%	In the first half of 2016, SME webpages were revised to become more user-friendly and to facilitate access to support measures. An SME user guide was revised and published on the EMA website. In addition, revised SOPs on SME status assignment, and renewal and conditional fee exemption, were finalised and published. The e-SME declaration is also being revised, and version 1.5.0.0 is expected to be finalised in Q1

Objective	Activity	% complete	Achievements/results
			2017.
	Develop a plan for further development of the network of SME and innovation support structures of EU agencies and organisations, including greater work-sharing and exchange of best practices with bodies offering support to SMEs in the national, European and international context.	100%	In the first half of 2016, a meeting to share best practices with the EU agencies' SME offices took place in Brussels. Regular interactions on the SME definition took place with DG Growth, the Research Executive Agency and EU Agencies' SME support structures. The Agency also interacted with DG Research on queries relating to Horizon 2020. The plan for further development of the network of SME and innovation support structures of EU agencies and organisations is under development, and will be delivered as part of the action plan arising from the 10-year report on the implementation of SME regulation.

International activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
n/a					

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Ensure the best use of resources through promoting mutual reliance and work-sharing.	Enhance cooperation between international regulators in all therapeutic areas, including paediatric medicines, biosimilars, orphan medicines, veterinary medicines, generics, and medicinal products derived from blood.		Alongside regular cluster activities with non-EU regulators, cooperation with international regulators continued in all therapeutic areas, including paediatric medicines, biosimilars, orphan medicines, veterinary medicines, generics and medicinal products derived from blood. In the first half of 2016, the International API programme and the pharmacovigilance cluster were expanded to include Japanese regulators.

Objective	Activity	% complete	Achievements/results
			A strategic review of paediatric approaches with the FDA was completed in September, and PASIBs were published in the context of the IPRF Biosimilars working group. Three new clusters were successfully established in 2016 — a patient engagement cluster, a pharmacometrics/modelling cluster, and a rare diseases cluster, bringing the total number of clusters to 14. Work on mutual recognition agreement with the FDA took place in 2016, and the document is expected to be signed in early 2017.
	Implement and review the IDGRP information-sharing pilot to the centralised procedure.		No applications were received in 2016 as part of the IDGRP information-sharing pilot. To raise awareness of the data-sharing pilot among generic-medicines applicants, the eligibility outcome letter was amended, to include a statement on the data-sharing pilot.
	Establish additional collaborations with FDA on patient engagement and pharmaceutical quality.	50%	A draft report with the feedback on the learnings from the EMA-FDA 'quality by design' pilot was prepared and sent to FDA for comments, to officially close the pilot. A quality fellowship with the FDA took place in Q3, where the possibility to set up a quality cluster with different work streams, including a potential program on innovative technologies, was discussed, and where draft terms of reference were prepared. Official feedback from the FDA on these is awaited.
	Optimise Article 58 scientific opinion activities, to include enhancing collaboration with the WHO and concerned regulators, and developing additional communication tools.		The Article 58 procedure was presented at the DIA Euromeeting 2016 in Hamburg in April, and a revised infographic, describing the procedure, was published. A study, looking at stakeholder awareness, experience, and views on the Article 58 procedure, was published on the EMA website in April 2016. During 2016, EMA participated in several international events, including ICH/IPRF (November) and ICDRA (December), to present and promote the Article 58 procedure and other reliance mechanisms, such as the WHO-EMA Collaborative Registration Pilot, and sharing of assessment reports. Internal action plan for increasing perception and use of Article 58 was drafted in the first half

Objective	Activity	% complete	Achievements/results
			of the year, and work on several work streams started in 2016. Article 58 guidance and Q&A for sponsors were reviewed and submitted to CHMP for comments, in December 2016. Consultation with the Commission and WHO is expected to take place in 2017, prior to finalising the revised documents. Umbipro CHMP opinion was adopted in April, and Pyramax (antimalarial) was the first Article 58 product included in the WHO-EMA collaborative registration pilot with low- and middle-income countries in Africa. No new article 58 opinions were adopted in the second half of the year. However, there are indications of increased interest in the Article 58 procedure, with a small increase in scientific advice and eligibility requests. EMA also took an active part, and provided comments, in drafting a new WHO guideline on good regulatory practices, which should be finalised by WHO in 2017.
	Update existing guidance on the Article 58 scientific opinion procedure.	75%	A draft guideline on EMA procedural advice for medicinal products, intended exclusively for markets outside the European Union under Article 58 of Regulation (EC) No 726/2004, was finalised and presented to the Committees in 2016. It is expected to be published in 2017.
	Explore mechanisms to enhance involvement of non-EU regulators in EMA scientific reviews, to facilitate work-sharing.		The assessment report for a centralised product was shared with regulators in Israel, who also participated, as observers for the first time, in part of the May CHMP meeting during the discussion on the list of questions. Colleagues from Israel were also invited to join the Day 120 discussion for the product in question at the November CHMP meeting. A template, intended to help companies when giving consent to EMA to share assessment and inspection documents with regulators outside the EU, has been published on the EMA public website. EMA also took active part and provided comments in drafting a new WHO guideline on good regulatory practices, which should be finalised by the WHO in 2017.
	Provide input to activities aimed at greater mutual reliance, such		Assessment reports for four products (three CAPs and one Art. 58) were shared with African

Objective	Activity	% complete	Achievements/results
	as the mutual reliance initiative with the FDA and ICMRA GMP, and exploring mechanisms for confidential exchange of trade secret information.		regulators in 2016, as part of the pilot with WHO for collaborative registration, where the assessment and inspection work carried out by the EU assessors and inspectors is available to regulators in low- and medium-income countries, while allowing these regulators to retain their regulatory responsibilities. Discussions with WHO on improving the pilot to benefit further patients in African countries continue. An FDA MRI procedure, based on observation of the activities of the Joint Audit Programme, was completed in the first half of 2016. The FDA template for sharing trade secret information was reviewed by the Commission in 2016. An article, discussing models for reliance by regulators on the work carried out by other regulators, co-authored by EMA staff, the CHMP chair and the CMDh chair, has been published in the WHO Drug Journal in December 2016. The ICMRA GMP pilot was also launched. EMA also took an active part, and provided comments in drafting a new WHO guideline on good regulatory practices, which should be finalised by the WHO in 2017.
Promote convergence of global standards and contribution to international fora.	Provide assistance to candidate countries in aligning their standards and practices with those established in the European Union, to further foster their integration process.	100%	Following the IPA meeting in Copenhagen in April 2016, beneficiaries' NCAs were informed of the EMA involvement in the second phase of the IPA programme and that one representative per beneficiary would be invited to participate as an observer in selected meetings in 2017. A list of selected meetings was sent to all beneficiaries, requesting nominations of representatives.
	Conduct gap analysis of existing regulatory frameworks in paediatrics and dementia, and organise workshops to improve understanding of the frameworks, and to facilitate the development of medicines in these areas.		The manuscript titled 'Paediatric Medicine Development: An Overview and Comparison of Regulatory Processes in the European Union and United States' was submitted in Q4 2016, and has been accepted for publication by the journal Therapeutic Innovation and Regulatory Science. An FDA-EMA workshop was held in September. The meeting report has been published on the Agency's website. Comparative work on FDA and EMA guidelines on Alzheimer's disease was initiated in 2016. A data-sharing initiative between companies and

Objective	Activity	% complete	Achievements/results
			regulators, sharing data from failed trials, was completed in 2016. The report on this learning exercise is expected to be published in Q2 2017.
	Support relevant external activities in dementia/Alzheimer's disease with international partner agencies and intergovernmental initiatives.	100%	A joint presentation with the FDA's Neurology division, and also on behalf of Health Canada and PMDA, on the update of the multilateral cooperation work stream activities, was given at the integrated development initiative meeting, facilitated by OECD and hosted by BfArM in Bonn, in June 2016.
Assure product supply chain and data integrity.	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries.		In the first half of the year, a mechanism to improve cooperation with Indian and Chinese regulators on observing GMP inspections, was agreed and implemented. Throughout the year, EMA continued acting as the EU contact point, informing Chinese and Indian authorities of planned EU inspections in their respective territories, in order to facilitate their participation as observers.
	Develop training and communication materials on the importance of data integrity, in collaboration with other regulators, such as the FDA.		Joint training activity with the FDA on data integrity was organised, and took place in October and November in China. EMA staff and Member States' inspectors participated in the trainings.
	Contribute to ICH activities on starting materials and lifecycle management.		The Q&A (ICH Q11) on starting materials were amended, following the receipt of comments by constituents. The revised document was adopted as step IIB document at ICH plenary in November, and was published for a 3-month public consultation in December. Drafting of ICH Q12 on lifecycle management continued in 2016. It is expected to be discussed at QWP/BWP in Q1 2017, and finalised at the ICH expert working group in Q2. Consultation is expected in June 2017.
	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.		A draft paper, aimed at promoting alignment and interconnectivity of track and trace systems globally, was developed by a drafting group and led by EMA. The paper was presented to the ICMRA management committee in June 2016. Track and trace topic is discussed at the monthly teleconferences with ICMRA supply chain. A questionnaire has been distributed.
Support training and capacity-	Increase involvement of non-EU regulators (including candidate		Non-EU regulators have been invited to, and have participated in, selected EU NTC events

Objective	Activity	% complete	Achievements/results
building, and promote the EU regulatory model.	countries) in other training activities, and the work of the EU Network Training Centre.		and other training activities throughout the year. EMA worked with the Commission and WHO to ensure funding for some regulators. A total of 143 non-EU participants have attended 15 different workshops or trainings (in person or remotely) in 2016, representing a 20% increase from 2015. In addition, the Agency worked with WHO on a pilot, to include selected EU NTC training opportunities in the WHO online training portal.
	Identify training priorities, and explore how to address these with key regulators outside the EU.		In the first half of the year, India and China working groups on pharmaceuticals identified GMP/GCP training requirements for Indian and Chinese regulators. In October and November 2016, EMA participated in GMP and GCP training seminars in China, together with the FDA and EDQM.
	Increase involvement of experts and observers from concerned regulators in Article 58 activities.		In this reporting period, the Agency engaged with WHO and DG Sant, to address operational and regulatory issues, such as expert nomination and the eligibility process. Internal action plan for increasing perception and use of Article 58 was drafted in the first half of the year, and work on several work streams started in 2016. Article 58 guidance and Q&A for sponsors were reviewed and submitted to CHMP for comments, in December 2016. Consultation with the Commission and WHO will take place in 2017, prior to finalising the revised documents.

Data-management support

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Number of Telematics information services provided by EMA	n/a	16	20	21	22
Number of ongoing Telematics IT projects where EMA is the delivery organisation	n/a	19	18	7	13
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	n/a	15	11	5	6

Performance indicators

Performance indicators related to core business		2013 result	2014 result	2015 result	2016 target	2016 result
	Satisfaction of external customers of Telematics information services provided by EMA (% satisfied or very satisfied)	-[1]	-[1]	-[1]	80%	94%
	Satisfaction of EMA internal customers of information services (% satisfied or very satisfied)	-[1]	-[1]	-[1]	80%	94%

[1] New indicator introduced in 2016.

Achievements

Objective	Activity	% complete	Achievements/results
Deliver information technology solutions required by EU law.	Deliver information systems according to the EU Telematics roadmap.	80%	The PSUR repository was delivered according to plan. Clinical trial system is broadly on track, and has been handed over to a new contractor. New timeline for EudraVigilance was agreed by the Management Board in June 2016, to further strengthen performance of the new EV system prior to its go-live date. Organisation and referentials management services are delayed and a new go-live date has been agreed for Q2 2017.
	Implement the ISO IDMP roadmap with EU NCAs and industry.	85%	Work on the new version of ISO IDMP standards continued during 2016, and the new standard is expected to be published in late 2017. Over the first half of the year, extensive work was undertaken to publish versions 1 and 2 of the substance technical specifications, and comments on the medicinal product and pharmaceutical product technical specifications were addressed. Product-related technical specifications were approved in late 2016, and are expected to be published in late 2017. Substance technical specification is delayed due to high complexity, and is now expected to be published in Q4 2017. Two HL7 messaging standards (SPL7 and CPM3) were also published in 2016.
	Develop and implement common policies, procedures and standards, to maximise the sharing of, and optimise investment in, data.	35%	During 2016, a number of documents (data models, application programming interface specifications, target operating model, use cases, etc.) were developed, adopted and published externally, for industry and NCAs to

Objective	Activity	% complete	Achievements/results
			use in relation to RMS and OMS. Work on policies, procedures, and standards is now aligned with the implementation plans of SPOR roadmap. Work on EU implementation guides, in collaboration with our stakeholders, continued in 2016, and is expected to be finalised in the first half of 2017.
	Implement effective communication systems to support the Network's readiness in using and integrating Telematics systems.	100%	During the first half of 2016, the EU Telematics website was revamped, adding a dedicated ISO IDMP/SPOR page, in order to strengthen communication with stakeholders. Ten webinars and seven surveys were conducted for the Network, during 2016. Monthly bulletins have been published since October 2015, providing the Network with an overview of Telematics news. Industry's participation in EU Telematics at a strategic level was agreed in February, with two meetings per year to take place with the pharmaceutical industry associations. In 2016, industry associations took part in the February and November meetings. Further streamlining of the Telematics maintenance structure and optimisation of the Telematics governance structure, continued in 2016, and creation of a single Change management board was agreed by HMA and EMA Management Board in December 2016.
Share information on medicines.	Implement information provision and analytics information services, to increase the value of information through web access, business intelligence, and analytics.	95%	During the first half of 2016, an internal reflection document on data analysis, with a vision for management reporting (e.g. dashboards on budget, FTEs utilisation) and scientific data analytics (e.g. big data, real-world evidence), was agreed. Work on prototype of management dashboards started in late 2016, and will continue in 2017. Operational tools, such as the BIACC (Business Intelligence & Analytics Competence Centre) and the RACI, were established at the end of Q2 2016. Transition architecture for the Data Warehouse and Business Intelligence was approved by the Architecture Board in July 2016, and improvements were deployed in all environments. The long-term target

Objective	Activity	% complete	Achievements/results
			architecture is awaiting input from the Data centre strategy, and is expected to be discussed at the Architecture Board in March 2017. Following the feedback from NCAs, an enhanced version of the 'Article 57 Publication' dashboard report was released in the EudraVigilance Data Analysis System (EVDAS) production environment, in June 2016. Full implementation of Article 57 reporting requirements has been released to EMA staff in December 2016, and the reports will be open to NCAs in February 2017. Revision of SAS architecture and technology rationalisation for analytics took place in October-November 2016. The improvements will be implemented in the first half of 2017. New eRMR format was finalised and implemented in November for the whole Network. A revised statistical guidance and a user manual were also published along with the new eRMR.
Establish and improve EMA information services.	Establish a set of standard information services, to support efficiency and effectiveness of scientific and other core activities.	90%	All planned EMA information services and service maintenance processes were established during 2016. All information services are now operational, except the Master Data Management service, where technical difficulties of OMS and RMS projects have delayed the go-live date until May 2017.
	Develop and start implementing improvements in the management of electronic documents and records.	80%	New strategies for record management and archiving, as well as a record management target operating model, were completed in the first half of 2016. A review of the electronic content management (ECM) tool available in house was done in 2016, and a new ECM system was selected. The decision on the new ECM system is expected early in 2017. Retention policies for financial records were also reviewed in Q1-Q2. The new policies will become operational once the new ECM is implemented. The document classification policy and implementation plan were approved in December.
	Improve EMA's technology landscape by means of	100%	Simplifications of the application landscape were identified and agreed with the business in the

Objective	Activity	% complete	Achievements/results
	enterprise architecture.		first half of 2016. New process to de-commission obsolete applications was implemented, and 11 applications were de-commissioned in 2016.
	Develop and implement an information security management system, to protect data assets and strengthen information security.	100%	In Q1-Q2 2016, an information classification scheme methodology was developed and the EXB approved document classification policy in December 2016. The Agency's technology security controls were enhanced with additional systems, to detect and prevent security attacks and incidents. Seminar to Agency's staff on security matters was held in November.

Support and governance activities

Workload indicators

Procedure	2013 result	2014 result	2015 result	2016 forecast	2016 result
Requests for interviews and comments by media representatives	1,987	2,384	2,268	2,200	2,149
Number of press releases and news items published	271	224	190	200	187
Number of reports, brochures and leaflets produced	3	2	7	6	25[1]
Number of documents published on the EMA website	14,866	4,858	7,154	10,000	7,369
Number of pages published and updated on the EMA website	1,553	2,201	2,911	5,000	4,790

[1] Sharp increase in 2016 due to high demand for graphic representation of reports, posters and infographics.

Performance indicators

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Percentage of posts on the Agency establishment plan filled	95.4%	97%	98%	97%	98%
Percentage of revenue appropriations implemented	95.6%	96%	98.7%	97%	100%
Percentage of expenditure appropriations implemented	96.8%	94%	95.8%	97%	96%
Percentage of payments against appropriations carried over from year N-1	96%	97%	94%	97%	96%
The maximum rate of carryover to year N+1, of total commitments within the title:					

Performance indicators related to core business	2013 result	2014 result	2015 result	2016 target	2016 result
Title 1	0.9 %	1.2%	0.9%	1%	0.9%
Title 2	11.6%	22.5%	7.6%	15%	7.9%
Title 3	24.6%	28.0%	23.1%	25%	25.9%
Percentage of payments made within 30 days time	-[1]	98%	99.7%	98%	99%
Satisfaction level of partners/stakeholders with EMA communications	-[2]	-[2]	80%	n/a	n/a
Key messages included in media articles generated by EMA press releases:					
At least one key message	-[3]	-[3]	100%	95%	100%
At least two key messages	-[3]	-[3]	100%	70%	51%
Quote included	-[3]	-[3]	60%	60%	0%[4]
Average rating of pages on corporate website during the year	-[5]	-[5]	-[5]	3	3.6
Availability of Telematics IT systems (% of time)	n/a[6]	n/a[6]	99.4%	98%	100%
Availability of corporate IT systems (% of time)	n/a[6]	n/a[6]	100%	98%	100%
Availability of corporate website (% of time)	n/a[6]	n/a[6]	99.7%	98%	100%

[1] 2013 results not comparable due to change in indicator (30-day vs 45-day timeline in 2013).
[2] The survey, first conducted in 2015, is done every two years.
[3] New indicator, introduced in 2015.
[4] No monitoring was done for quotes.
[5] New indicator, introduced in the 2016 work programme.
[6] 2013-2014 results not comparable due to change of indicator (a single combined indicator replaced with three more detailed ones).

Achievements

Objective	Activity	% complete	Achievements/results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities.	Develop the Agency's multiannual programming, to implement the Network strategy 2016-2020.	100%	The EMA multiannual work programme was adopted by the Management Board on 16 June 2016. It follows the structure of the Network strategy and translates the strategy into more specific medium-term objectives and key initiatives to deliver the objectives. The multiannual work programme is expected to be reviewed annually, to ensure it is up to date and reflects all key priorities and developments.
	Conduct self-assessment of the Agency's quality management system against the new ISO 9001:2015 standard.	100%	Gap analysis between ISO 9001:2008 and ISO 9001:2015 was carried out in the second half of the year. The opportunity for improvements identified will be addressed in 2017-2018.

Objective	Activity	% complete	Achievements/results
	Develop a corporate communication strategy.	100%	A framework strategy for external communications (previously 'corporate communication strategy') was developed in the first half of 2016 and was endorsed by the Management Board at its June meeting. A communications plan for 2016 was adopted by EXB in May 2016.
	Develop a social media strategy.	50%	A reflection paper, setting out the different options for a social media strategy, was completed in Q1 2016. A report, assessing internal capacity and appetite for social media, was completed in Q4 2016. Social media strategy will be developed, based on the recommendations in the report.
Maintain high level of independence, integrity and transparency in all aspects of the Agency's work.	Implement the conflicts-of-interests policy for Management Board members and EMA employees.	100%	The policy on competing interests for Management Board members was adopted in December 2015, and came into effect in May 2016. The revised version of this policy was adopted at the October Management Board meeting, alongside the revised EMA policy on the handling of declaration of interests of scientific committees' members and experts. Guiding principles for the revision of the decision on the rules, concerning the handling of declared interests for the Agency's staff, were agreed at the March Management Board meeting, and a revised decision on the rules, concerning the handling of declared interests of EMA staff members, was adopted at the October Management Board meeting.
	Conduct annual reviews of the Agency's handling of independence.	100%	During the first half of 2016, the Agency conducted the annual assessment of handling of independence, and prepared a report, which was discussed at the Management Board in October.
Align the Agency with the highest European standards in environmental performance.	Prepare and implement an action plan to register the Agency for EMAS certification.	100%	The Green group, created in 2015, launched its first action in January, to improve the Agency's waste-management system, by including food waste. This was followed by other initiatives in the area of electricity consumption, by adjusting the lighting system, and replacing non-recyclable coffee-mugs in the catering services. In preparation for EMAS certification, an environmental consultant reviewed and verified the Agency's strategy, policy, and action plan during 2016.

Objective	Activity	% complete	Achievements/results
			The first version of the EMA Environment System Manual was finalised in December, defining EMA's environmental policies and processes. The manual includes references to the relevant clauses in the EMAS regulation (ISO14001 as appropriate), to demonstrate meeting of their requirements. Internal audit of the Agency's environmental system took place, in preparation for a verification audit. The tender for the verification audit is due to be launched in 2017.

2. Management

2.1. 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's 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 do not represent any government, organisation, or sector.

In 2016, 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:

- Election of Christa Wirthumer-Hoche in March as chair of the MB for a three-year period.
- Election of the Grzegorz Cessak as vice-chair of the Board for a three-year period.
- Adoption of the Multiannual Work Programme to 2020.
- Adoption of the work programme and budget for 2017.
- Revision of the budget structure from financial year 2017.
- Adoption of the Annual Report 2015.
- Adoption of the Assessment of the Executive Director's Annual Activity Report 2015.
- Revision of the implementing rules to the Fee Regulation.
- Revision of the Rules of Procedure of the Management Board.
- Revision of the rules of procedure on the organisation and conduct of public hearings at the PRAC.
- Endorsement of the 6th Annual Report Veterinary MUMS/limited market.
- Endorsement of the EMA Stakeholder Relations Management Framework.
- Revision of the EMA Code of Conduct.
- Endorsement of the criteria for EMA involvement in externally funded projects.
- Review of the EMA independence policies and ensuing actions.
- Revision of the EMA policy on the handling of declarations of interests of scientific committees' members and experts, management board members, and EMA staff.
- Revision of the framework of interaction with healthcare professionals.
- Endorsement of the revision of the Access to documents policy.

- Endorsement of the Multinational assessment team concept.
- Endorsement of the new EU Telematics governance model.

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 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.

2.2. Major developments

Brexit

Following the UK Referendum, the Agency set up an Operations and Relocation Preparedness (ORP) taskforce, as a direct response to the Brexit outcome of the UK referendum. The main aim of the taskforce is to ensure preparedness for any possible scenario following the referendum, and the UK's eventual exit from the EU.

In 2016, the taskforce was focused on the assessment of impact on the Agency, with the aim to identify the main risks, and propose possible mitigating measures; to answer specific questions; to manage preparations relating to support for staff and delegates, financial matters, security issues, infrastructure, and related issues that fall within its remit; and to compile a list of facts and features about the Agency, in the event of relocation to another country.

The UK's withdrawal from the Union is likely to have implications for certain contractual arrangements, which have been concluded between the Agency and third parties. An increase in both internal and external queries related to this withdrawal, as well as changes to certain contract management operations, cannot be excluded.

Scientific committees regulatory science strategy division

In 2016, the Agency further recognised the need for a body that would support its strategic coordination of innovation in regulatory sciences, and between the scientific committees of the Agency in their objectives of delivering the EU Medicines Agencies Network strategy 2020, including the conduct of consolidated horizon scanning, and impact assessment studies. For this purpose, the Scientific committees regulatory science strategy division was created.

Clinical data publication

The clinical data website was launched on 20 October 2016. The first six dossiers were published in 2016, with more dossiers to follow in 2017.

The Agency provided exhaustive guidance on the process, which was first published in March 2016.

Based on the experience gained, the Agency updated its external guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use, on 20 December 2016.

The implementation of the policy is still a learning curve, for both EMA and industry. To ensure the published dossiers are in line with the EMA redaction conclusions, a final check pre-publication of the dossier has been introduced.

Access to documents

The Access to documents policy and the 'output table' were revised during 2016, taking into account experience gained. The Management Board endorsed the revised policy and two 'output tables' (the existing one covering documents relating to medicinal products for human and veterinary use, and a new one, relating to corporate documents) for public consultation, which will be launched in Q1 2017.

The Agency handled 823 requests for access to documents (380,911 pages released), and 97% were handled within the legal timeframes. In 2016, 4,843 requests for information were received, and 100% of the requests answered were handled within the set timeframes.

Anti-fraud strategy

The Agency's Anti-fraud office delivered on the targeted actions, outlined in the EMA Anti-fraud strategy for 2016. All EMA temporary agents and contract agents were requested to attend the EMA e-learning course, covering anti-fraud related matters, and entirely prepared in-house by the Anti-fraud office. In addition, interims, trainees, seconded national experts, and all new staff recruited in 2016, were asked to complete the same exercise.

During 2016, the office provided a timely response to OLAF, in relation to three new cases in which the co-operation of the Agency was required. EMA's responsiveness to all requests was particularly appreciated by OLAF.

Seeking operational excellence

In 2016, EMA pursued the reorganisation of its human medicines divisions, which was initiated in 2013, to further improve the efficiency and effectiveness of its operations, and to achieve a leaner, more streamlined architecture. The new structure binds more tightly to the medicine lifecycle, with one operational division responsible for support to medicines developers; one for the evaluation of medicines, bringing scientific and procedure management under one umbrella; and one for the oversight of medicines, including pharmacovigilance and inspections. The changes also introduced the creation of a new function, dedicated to strengthening the collaboration between EMA and the national competent authorities, by overseeing the implementation of the joint network strategy to 2020.

On the operational side, the Agency has optimised its model for the management of evaluation procedures for human medicines, which builds on recent efforts to streamline and simplify internal processes, to focus on value-adding activities. With the new model, procedure managers and procedure assistants are now assigned to a product, rather than to a procedure, whilst maintaining a consistent approach across a given regulatory procedure. This is expected to improve the coordination of regulatory activities regarding individual products, particularly where multiple regulatory procedures are run in parallel for the same product.

A similar review is currently ongoing for the veterinary medicines division, aiming to optimise the use of existing resources, thereby laying the foundation for the changes that can be expected to arise as a result of the ongoing review of the legislation governing veterinary medicines.

Staff engagement survey 2016

The Agency conducts a staff engagement survey every two years, with the last one taking place in November 2015. In total, 76.4% of EMA staff took part in the survey, and the results showed improvement across most topics and areas. The overall staff engagement level was 67% — an increase of 4%, compared to the 2013 survey.

Following the results of the 2015 staff engagement survey, the Agency has set in place a methodology for improvement actions. While most indicators have improved, compared to 2013, a few areas of improvement remain: collaboration across divisions, objectivity in decision-making processes, and trust in senior management.

To better understand the root causes of specific division and department results, and to identify most efficient ways to address them, qualitative analysis took place in each division. This resulted in tailored action plans, led by each management team.

At the Agency level, a series of focus groups were held to gain better understanding of the results. Volunteers from both management and staff were recruited, to form the Staff Engagement action

group. The volunteers analysed the results and in-depth interviews from the focus groups, and proposed eight improvement actions for the three areas of improvement. Six of the proposals were endorsed by the Executive Board, and implementation started in Q4 2016, in collaboration with the relevant teams across the Agency. The action group will continue tracking implementation of the improvements through 2017, and report regularly to the Executive Board. Two of the proposals require further consideration, and are to be presented again in 2017. The final report is expected in Q2 2017, after which the next staff engagement survey will take place in Q4 2017.

2.3. Budgetary and financial management

Financial highlights for 2016

The European Medicines Agency is a fee-funded agency, with 89.34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry, for services provided.

Following the referendum on the UK's membership of the EU, the pound weakened considerably, resulting in major exchange rate gains on payments made in pound sterling, in particular salary and rent, and building maintenance payments. As a consequence, the budget was reduced by EUR 16.3 million through an amending budget, adopted by the Management Board at its October 2016 meeting.

The budgetary outturn — a surplus of approximately EUR 10.23 million — was caused in part by the continued weakening of the pound throughout the year, as well as a higher collection rate for fee income, in the final weeks of December 2016.

In order to comply with the provisions of the Financial Regulation, and in particular Art 69 and 70; and on the advice of the European Court of Auditors (ECA) in late 2016; the Agency 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. This increased the amount of appropriations carried forward to 2017, and will also have an impact on the level of carry-forward in future years.

The Agency managed to comply fully with the ceilings/KPIs set by the EC for the amounts carried forward: title I (10%), title II (20%) and title III (30%), with the following percentages achieved: title I: 0.86%, title II: 7.93%, title III: 25.86%.

Budget overview

Authorised appropriations in the European Medicines Agency's initial budget for 2016 totalled EUR 324,711,000; representing a 7.5% increase compared to the 2015 initial budget (EUR 302,117,000).

One amending budget was processed in 2016. This addressed two general issues:

- Reduction in fee income, with a knock-on effect on payments to rapporteurs.
- Considerable reduction in the euro (EUR) value of expenditure incurred in pound sterling (GBP), due to the weakening of the pound against the euro, in particular in the second half of the year. This also impacted staff salaries, and the weighting which is paid as part thereof.

Revenue from cash, received for services rendered, was reduced by EUR 6,371,000; and the EU contribution was reduced by EUR 9,918,000; bringing the budget total to EUR 308,422,000; representing a 0.1% increase over the 2015 final budget (EUR 308,097,000).

To balance the budget, expenditure appropriations related to expenditure carried out in pound sterling, and those linked to rapporteur commitments, were decreased by the same total amount.

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; for post-authorisation activities; as well as for various administrative activities.

Revenue entered in the accounts as at 31 December 2016 amounted to a total of EUR 305,098,697.55.

Of the total revenue, 89.34% derived from the evaluation of medicines and other business related activities; 5.49% from the European Union budget to fund various public health and harmonisation activities, including positive outturn of previous year; and 5.01% from external assigned revenue, as described in the work programme (2015: 83.1%/11.1%/5.8%).

Expenditure (commitments and payments)

Commitments totalled EUR 297,012,705.56, or 96.30% of final appropriations (2015: 94.05%). Payments totalled EUR 253,980,400.73, or 85.51% of commitments entered into (2015: 87.09%).

Appropriations carried forward from 2016 to 2017

Automatic carry-forward to financial year 2017 totalled EUR 43,032,304.83, or 13.71% of appropriations (total carried forward from 2015 to 2016, both automatically and non-automatically: EUR 48,818,970.14, or 13.90%).

There was no non-automatic carry-forward to 2017.

Implementation of appropriations carried forward from 2015 to 2016

Automatic carry-forward from financial year 2015 to 2016, i.e. fund source C8, totalled EUR 37,420,970.14. Payments against the C8 appropriations equalled EUR 35,753,697.89, or 95.54% (2015: 93.95%), and EUR 1,667,272.25 were cancelled.

Non-automatic carry-forward from financial year 2015 to 2016, i.e. fund source C2, totalled EUR 5,398,000.00. A total of EUR 4,301,705.10 was paid in 2016, and EUR 115,974.90 was carried forward for payment in 2017, resulting in the cancellation of appropriations totalling EUR 980,320.00. The cancellation was mainly due to the fact, that some of the contracts were not ready for signature and commitment by the end of March 2016 — the final date for commitment under the Financial Regulation.

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 2016, an amount of EUR 15,230,149.24 was recognised as assigned revenue from landlord inducements, related to the project for the new headquarters. This amount covered all rent cost incurred in 2016. The remainder of the inducements will cover rent cost for most of 2017, depending on the strength of pound sterling against the euro.

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 per se are not an indicator of deficiencies in financial management, but are a necessary tool to adjust 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 2016, twelve transfers were made. All were adjustments within the limits of Article 27(1) of the Financial Regulation, i.e. transfers within titles, and therefore approved by the executive director. They totalled EUR 9,268,000, or 3.00% of final appropriations. All involved expenditure appropriations.

The transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development; increased appropriations for rapporteurs and pharmacovigilance services; and reduction of appropriations, where expenditure is mainly paid in pound sterling.

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, and should rather be consider as the result of stringent monitoring of actual revenue and adjustments to the expenditure.

In budget 2016, expenditure appropriations totalling EUR 11,397,694.44 remained unused, corresponding to 3.70% of final appropriations (2015: EUR 12,927,191.98, 4.20%).

This unused amount must be seen in conjunction with collected revenue being EUR 3,323,302.45 (1.08%) 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 7,970,017.09, or 2.58% of final appropriations (2015: 8,964,611.10, 2.9%).

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 2016, 466 payments out of a total of 57,738, i.e. 0.81% of all payments, were made later than 30 days after receipt of a valid invoice (2015: 0.27% of all payments). This resulted in default interest of EUR 1,208.00 being paid to suppliers and contractors.

[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, administrative expenditure is mainly paid in pounds sterling. Throughout 2016, 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. This resulted in decreased euro expenditure, in particular in titles 1 and 2 of the budget.

The weakening of sterling, and the reduced estimate of fee applications, were the main justification for one Amending budget in 2016, which decreased expenditure appropriations on budget items 1190 (weighting on salaries) and 2000 (rent), as well as on items 3010 and 3013 (evaluation activities).

2.4. Human resources management

During 2016, the Agency recruited 170 members of staff (25 temporary agents [TA], 19 contract agents [CA], 14 national experts [SNE], 43 interims [INT], and 69 trainees [TR]), and had 157 staff (19 TA, 26 CA, 13 SNE, 39 INT, and 60 TR) leaving the Agency.

The occupancy rate for temporary agents was 98%.

2.5. Assessment by management

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 multi-annual work programme. The annual work plans are derived from the multi-annual 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 updating the multiannual work programme, setting the priorities, and 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

In September 2016, the project governance and gated procedure were revised and implemented as a result of the deployment of the P3i methodology. The project budget approval process remains unchanged.

The Executive Board 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 has been delegated with the following competences: overall responsibility to oversee the Agency's programme and project portfolio, including making 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. The latter retains responsibility on taking decisions concerning initiatives (programmes or projects) to include 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.

While the project governance was revised and simplified by having a single board, and shorter times for approval at gates and change requests, the previous gated procedure remains almost unchanged.

In the gated approval process, the idea or concept for a project (i.e. Gate 1 request) has to be approved or declined by PB, taking into account the portfolio, priorities and budget agreed by the EXB, before resources are assigned to deliver the project business case. The preliminary business case, with identified benefits and costs, is subject to approval by the PB. The PB receives and considers advice on business design and process review, from the relevant business areas and the Medicines leadership team. Advice on technology and IT architecture matters is provided by the Enterprise Architecture Board, when relevant. Particular attention is given to the business needs 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 it 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 a new optional check-point for large projects, to ensure completion of deliverables and business readiness prior to closure. At the end of the project a closure report is presented to PB for assessment and approval.

Bi-monthly reports are presented to the PB, to review the status of the portfolio, programmes and projects, and to monitor the delivery of the portfolio as a whole, during their entire lifetime. The same reports are presented to EXB twice a year, in January and in July. The EU Telematics Management Board receives, on a quarterly basis, a summary 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 the 'EMA internal notice on project-related ex-post and ex-ante evaluations - Guiding principles in relation to programmes and projects', that came into effect on 1 February 2015.

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 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; in the October meeting, covering the period 1 July to 31 December.

2.6. Assessment of audit results during the reporting year

Internal Audit Service (IAS)

The final report for the audit on Paediatric Regulation procedures was received on 18 May 2016; it confirmed that the Agency deploys and uses adequate systems for the management and control of Paediatric Regulation procedures. A strong emphasis on internal effectiveness and compliance with legal deadlines contributes to meeting the objectives of timely delivery of high-quality opinions and decisions, and to compliance with the Paediatric Regulation. The Agency ensures legal soundness of the final opinions and decisions, by involving legal and regulatory experts in the process.

The audit did not identify any critical or very important issues.

Internal audit capability (IAC)

In 2016, 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 the 'Recruitment procedure', the 'Business continuity management system', 'Project management', 'Request for information procedure', 'Missions and training management', 'IT governance', 'Pharmacovigilance', 'Medical Literature Monitoring', and the 'Innovative Medicines Initiative joint undertaking (IMI-EU2P)'.

Based on the results of 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 conducted its annual audit of the Agency's 2015 accounts, and adopted its report on 4 October 2016. In the report, the European Court of Auditors expressed the following opinions:

- The Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2015, and the results of its operations and its cash flows for the year in accordance with the provisions of its Financial Regulation, and the accounting rules adopted by the Commission's accounting officer.
- Transactions, underlying the annual accounts for the year ending on 31 December 2015, are legal and regular in all material respects.

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

Internal Audit Service

Neither critical, nor very important recommendations were open as of 31 December 2016.

Internal audit capability

At the end of 2016, ten very important recommendations, stemming from audits carried out up to 31 December 2015, were still open; all of them were within the timeline agreed with IAC; no critical recommendations remain opened.

2.8. Follow-up of observations from the discharge authority

EMA reported on the follow-up of the observations, made by the discharge authority for 2014, 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.

On 27 April, the European Parliament voted positively on the discharge of EMA's 2015 accounts. This is the final approval of the budget implementation for 2015, and the decision is based on a review of the annual accounts, and the ECA annual report.

3. Assessment of the effectiveness of internal control systems

3.1. 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 2016, 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.

As regards to the assessment of risks related to 'Brexit', this has been performed separately by the ORP taskforce. In 2016, the taskforce was focused on the assessment of the impact on the Agency; on identifying the main risks; proposing possible mitigating measures; answering specific questions; managing preparations, related to support for staff and delegates; financial matters, security issues and infrastructure and related issues that fall within its remit; and compiling a list of facts and features about the Agency, in the event of relocation to another country.

3.2. Compliance and effectiveness of internal control standards

As in the previous years, the Agency reviewed the implementation of the internal control standards (ICS) in 2016. This was done via an internal questionnaire, addressed to the Agency management. In 2016, 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 three areas for improvement were highlighted; namely — staff allocation and mobility; objectives and performance indicators; and operational structure.

Measures have been taken to further improve the efficiency and application of the standards above, and an action plan to rectify the above areas has been drafted (Annex 10) and it will be implemented in 2017.

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

3.3. 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 2016, the Verifying office performed its duties and achieved all objectives. No delays were reported. All transactions, without any 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 2016 budget year, 500 (993 in 2015) rejections were recorded, of which 260, or 52% (601 and 61% in 2015) were related to manual adjustments, technical rejections or interface issues following the decentralised verification. The balance of 240 (48%) rejections reflects the effective rejection rate for less than 0.5% of the total transactions being checked.

Out of the 240 rejected payments, 58% did not present a materiality, and 42% did not show a noticeable individual financial risk.

Eight commitments were rejected following initiating agents' requests. The balance was rejected for various financial reasons (incorrect currency, calculation errors, wrong allocation, etc.), or procedural issues (missing document, change of requirement, wrong cost centre, etc.); however, none of them has 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.

Six commitments deemed to be recorded into the register of exceptions. All were financial commitments showing a date oversight, a weakness in the procurement procedure, or a lack of follow-up (renewal of contract); however, their low materiality did not expose EMA to a real financial risk. None of these records revealed any breach of rules or of contract provisions.

3.4. 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, and under the Agency's internal control standard (n.8) on processes and procedures which, under its requirements, states: 'The processes and procedures comply with applicable provisions, in particular the Financial Regulation (e.g. ex-ante and ex-post controls), and the EMA policies'.

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. As such, controls check compliance with procedures, and help to detect and correct potential errors.

In 2016, the Agency completed several ex-post controls. The areas subjected to financial ex-post controls were:

- GMP inspection process.
- Procedures in place for post-authorisation fee incentives for epizootics.
- Application of fee incentives for pharmacovigilance-related Type IA variations, for medicinal products for veterinary use.
- Collection of fees and payments for the evaluation of PSURs.

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

- Compliance of the process of acquisition and information exchange within the Business pipeline, with procedures in place.

- Correct application of the criteria for Regulatory affairs office involvement in products.
- Efficiency of Emerging safety issues (ESI) process, and correct categorisation of notifications received in the ESI mailbox.
- Correctness of CHMP/PRAC/CAT rapporteur appointment in the centralised procedure.
- Correct evaluation of the declarations of interest of experts involved in EMA activities.
- Reliability of automatic renewal of SME status, in place since 2014.
- Validation of user-access rights, granted in SAP FIN.
- Compliance with sensitive posts guidelines.
- Accuracy of the authorisation process for procuring licences, services and hardware in IT.

Overall, the ex-post controls did not highlight any major weaknesses of the processes analysed, although areas with potential for improvement were identified, and they are being addressed by specific improvement action plans.

3.5. Advisory Committee on Procurement and Contracts and procurement management

The Advisory Committee 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 2016, the ACPC gave its opinion, in an advisory capacity:

- on all proposals for a negotiated procedure over EUR 60,000, prior to the procedure being launched by the responsible delegated authorising officer;
- on all proposed contracts (excluding specific contracts derived from framework contracts) for works, supplies, or services involving amounts exceeding the value of the Public Procurement Directive;
- on specific contracts, derived from framework contracts at the discretion of the ACPC according to a risk-analysis, as set out in the opinion of the corresponding framework contract;
- on any agreement, supplementary to the above-mentioned contracts, irrespective of the amount involved, which would raise the total contract value to an amount above the limits, or change the deliverables, value, or duration of the contract;
- prior to the start of the tendering procedure, on all procurement decisions that anticipate a presentation by the tenderer in the evaluation process, or a contract duration in excess of the period prescribed by the general Rules of Application;
- at the request of the responsible delegated authorising officer or the ACPC chair, on proposed contracts, other than those mentioned in first three paragraphs, if the contracts are considered to involve questions of principle, or are of a special nature.

During 2016, 30 new procurement contracts exceeding EUR 15,000 in value were concluded by the Agency, following procurement procedures and one service concession; compared to 27 in 2015, and 28 in 2014. The total value of all such new contracts and service concession was EUR 97,175,639.16. In addition, the Agency signed up for 31 inter-institutional framework contracts run by other EU institutions or agencies. There were 230 specific contracts concluded from framework contracts,

making an overall total of 261 new contracts (including the service concession) concluded in 2016. There were also 112 contract amendments/renewals.

The number of opinions given by the ACPC decreased from 2015 to 2016 mainly due to the change in ACPC scope, whereby specific contracts derived from framework contracts are reviewed only if ACPC has requested this with the opinion on the framework contract. This decrease is expected to continue in 2017. At the same time, the Agency is included in an increasing number of procurement procedures and subsequent framework contracts that are carried out by the EC. These framework contracts are provided to the ACPC for information only.

The Agency uses the Early Warning System of the European Commission and has access to a database that enables the EMA to check the financial status of potential contractors. Any risks identified would be alerted to the ACPC and the relevant authorising officer.

3.6. Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2016, 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.

3.7. 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.

There are currently 82 processing operations in the data protection register, maintained by the EMA DPO. Seven new processing activities were registered in the course of 2016. One new processing activity, concerning the collection of data for the organization of Public Hearings, triggered a notification to the EDPS for prior check under Article 27. The Prior Check Opinion has been received, and the recommendations are being implemented. The processing activities of medical data of EMA staff by the medical service provider have also been reported to the EDPS.

In terms of activities related to data protection, the DPO has followed very closely the issues related to the adoption and implementation of the new General Data Protection regulation (GDPR), which will enter into force in 2018, and its possible impact on the implementation of Clinical Trial Regulation. The DPO also coordinated a consultation with the EDPS with regard to the methodology and risk assessment for the use of cloud-based services. Throughout the year, DPO offered data protection training sessions on the GDPR to members of EMA staff, in particular for procurement and human resources activities, and provided support within the Big data taskforce, for addressing the challenges stemming from the application of personal data legislation to new analytical tools and big data.

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, projects of the Information management division, and to the Anti-fraud office.

Quarterly bilateral meetings took place between the DPO and the executive director/deputy executive director, in 2016.

3.8. Management of conflicts of interests

Management Board

The revised policy on the handling of competing interests of the Management Board members came into effect on 1 May 2016, to achieve a better balance in managing declarations of interests of the Management Board members versus the specific role and responsibilities of the Management Board, and to maintain alignment with the EMA policy on the handling of declarations of interests of scientific committees' members and experts. Following the revision of the policy on the handling of declarations of interests of scientific committees' members and experts during 2016, the policy on the handling of competing interests of the Management Board members was further revised in October 2016.

Involvement 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.

The implementation of the revised policy now 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 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 conflict of interest which has been identified, and the applicable restriction to their involvement at the meeting. At the start of each meeting, members are further asked to declare any specific interests which could be prejudicial to their independence with respect to the items on the agenda.

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

No breach of trust procedures were initiated for Management Board members in 2016.

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 entered into force on 1 December 2016. The update includes a clarification on the restrictions regarding the expert's potential employment in a pharmaceutical company; and the alignment of the rules relating to close family members' interests for scientific committee and working party members, with those for the Management Board members.

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. Guidance on inclusion of declared interests in the e-DoI, and on how to submit the e-DoI and e-CV, is available to experts. To

facilitate updating of the e-DoIs, experts receive automated reminders from the Experts database, to update their e-DoI one month prior to its expiry.

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 with 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 continues to be 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. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are stricter than those for the other committee members.

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

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

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

EMA has in place a breach-of-trust procedure, which sets out how the Agency deals with incorrect or incomplete e-DoIs by experts and committee members. The Agency last updated the procedure in April 2015, to align it with the policy on handling competing interests, and to take into account experience gained since it was first endorsed by the EMA Management Board in 2012.

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.

As of 2015, EMA reviews, on an annual basis, all of its policies on independence and rules for handling competing interests and their implementation, and publishes an annual report. The report includes results of breach-of-trust procedures, any controls carried out, initiatives planned for the following year, and recommendations for improvement.

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 Articles 11, 11a and 13 of the Staff Regulations, concerning the handling of declared interests of staff members of EMA and candidates before recruitment, was revised as a result of the review of both the policy on the handling of declarations of interests of scientific committee members and experts, and the policy on competing interests of the MB members. The revised Decision rules were adopted by the EMA Management Board in October 2016, and become effective as of 1 January 2017.

Staff declarations are available in an internal database, 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 website).

Following completion of a declaration of interests, and depending on the nature of the declared interests, if any; a risk level (1-3) is assigned to the staff member and/or candidate by the reporting officer evaluating the declaration. Staff members and/or candidates at risk 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 conflict of interests must be declared by selection committee members and procurement evaluation committee members, and action must be taken accordingly.

External consultants and contractors

Conflicts of interests for external consultants and contractors are covered by the standard framework contract provisions[3], 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.

[3] Article II.3

- The Agency reserves the right to verify that such measures are reasonable, and may require additional measures to be taken, if necessary, within a time limit which it shall set. The contractor shall ensure that the contractor's staff are not placed in a situation which 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 declaration 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 (i.e., ACL in DREAM – staff only), 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.

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 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;
- a 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;
- a 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.

5. 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, 22 May 2017

[signature on file]

Guido Rasi

(Executive Director)

Annexes

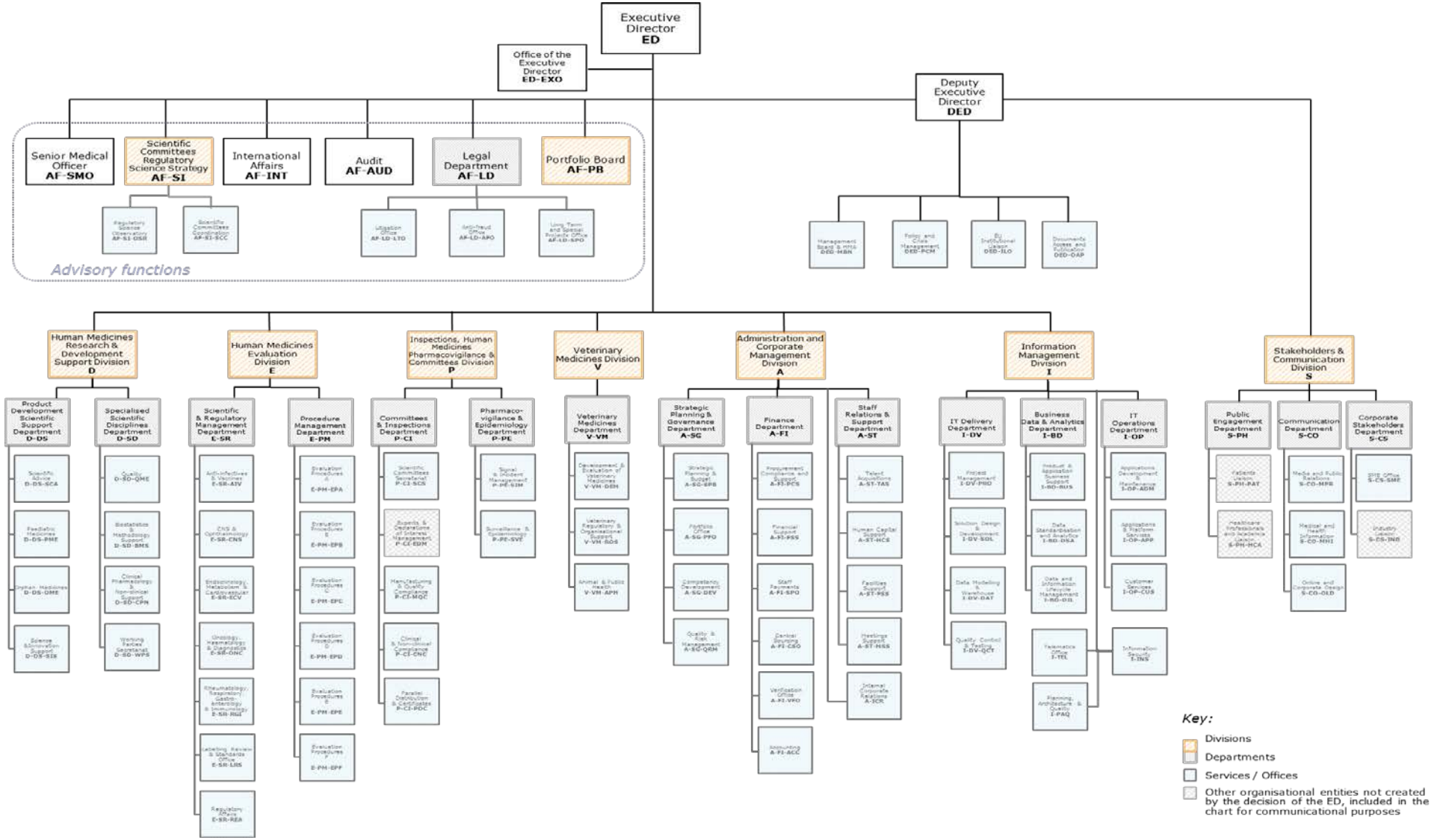
Annex 1. Core business statistics

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 2016



Annex 4. Establishment plan

Category and grade	Authorised for 2015		Occupied as of 31/12/2015			Authorised for 2016		Occupied as of 31/12/2016			Authorised for 2017	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts
				Grade fillled	Actual grade				Grade fillled	Actual grade		
AD 16	-	0	-	0	0	-	0	-	0	0	-	0
AD 15	-	4	-	3	2	-	4	-	2	1	-	4
AD 14	-	6	-	5	1	-	6	-	6	1	-	6
AD 13	-	9	-	9	10	-	9	-	9	10	-	11
AD 12	-	42	-	41	24	-	42	-	39	27	-	40
AD 11	-	37	-	36	22	-	38	-	37	25	-	40
AD 10	-	40	-	39	33	-	44	-	44	31	-	43
AD 9	-	36	-	36	33	-	37	-	37	35	-	42
AD 8	-	52	-	51	51	-	54	-	54	52	-	53
AD 7	-	52	-	51	50	-	54	-	54	56	-	61
AD 6	-	36	-	36	77	-	37	-	37	74	-	37
AD 5	-	26	-	26	20	-	18	-	18	18	-	3
Total AD	***0***	***340***	***0***	***333***	***323***	***0***	***343***	***0***	***337***	***330***	***0***	***340***
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	5	-	5	3	-	5	-	5	3	-	6
AST 9	-	7	-	6	2	-	7	-	7	3	-	7
AST 8	-	16	-	16	5	-	16	-	16	4	-	16
AST 7	-	19	-	18	14	-	19	-	17	12	-	19
AST 6	-	39	-	38	19	-	39	-	39	21	-	43
AST 5	-	42	-	42	33	-	43	-	42	30	-	43
AST 4	-	49	-	49	33	-	49	-	49	35	-	52
AST 3	-	43	-	41	65	-	47	-	46	78	-	45
AST 2	-	37	-	37	34	-	32	-	27	34	-	23
AST 1	-	0	-	0	56	-	0	-	0	37	-	0
Total AST	***0***	***259***	***0***	***254***	***264***	***0***	***259***	***0***	***250***	***257***	***0***	***256***
AST/SC1	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC2	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC3	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC4	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC5	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC6	-	0	-	-	0	-	0	-	-	0	-	0
Total AST/SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Grand subtotal	***0***	***599***	***0***	***587***	***587***	***0***	***602***	***0***	***587***	***587***	***0***	***596***
Grand total	**599**		**0**	**587**	**587**	**602**		**0**	**587**	**587**	**596**	

Information on the entry level for each type of post

Interims: from 1 January 2016 to 31 December 2016, there have been 100 interims, and on average their interim assignment was for 7.03 months during 2016.

Contractors: from 1 January 2016 to 31 December 2016, there have been 409 different contractors under IT budget, and on average their contract duration was for 6 months.

The entry grades for recruitment of **temporary agents** are AST 1, AST 3, AD 5, AD 6, AD 8 (Senior Scientist/Administrator), AD 6 (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 2016

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.

The first phase of the implementation process for agencies consists of a staff screening exercise, categorising human resources according to the organisational role each job is serving. 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	2015 (%)	2016 (%)
Administrative support and coordination	**17%**	**16%**
Administrative support	16%	16%
Coordination	1%	1%
Operational	**79%**	**79%**
Top-level operational coordination	1%	1%
Programme management and implementation	23%	20%
Evaluation and impact assessment	41%	43%
General operational	14%	15%
Neutral	**4%**	**5%**
Finance/control	4%	5%
Linguistics	0%	0.00%
Total	**100%**	**100%**

Annex 6. Human and financial resources by activity

Activities	FTEs[4]	Staff expenditure	Infrastructure, IT and project exp.	Meetings cost (incl. overhead)	Evaluation cost (NCAs)	Other operational expenditure[5]	TOTAL[6]
		€'000	€'000	€'000	€'000	€'000	€'000
1 Evaluation activities for human medicines	**403**	**58,702**	**31,583**	**11,423**	**103,565**	**9,285**	**214,558**
1.1 Pre-authorisation activities	87	12,780	3,078	4,086	16,244	76	36,264
1.2 Initial evaluation activities	80	12,347	2,346	1,553	13,888	817	30,952
1.3 Post-authorisation activities	95	13,639	5,845	1,520	62,202	1,508	84,715
1.4 Referrals	8	1,011	219	427	0	286	1,942
1.5 Pharmacovigilance activities	111	14,893	13,614	1,994	11,230	3,699	45,430
1.6 Other specialised areas and activities	23	4,032	6,480	1,843	0	2,899	15,255
2 Evaluation activities for veterinary medicines	**45**	**5,976**	**1,793**	**1,739**	**3,996**	**451**	**13,955**
2.1 Pre-authorisation activities	2	303	89	648	215	3	1,258
2.2 Initial evaluation activities	15	2,110	521	414	1,720	86	4,851
2.3 Post-authorisation activities	17	2,082	838	470	2,061	179	5,630
2.4 Referrals	2	335	71	188	0	170	764
2.5 Pharmacovigilance activities	2	211	53	0	0	0	264
2.6 Other specialised areas and activities	6	935	221	19	0	14	1,188
3 Horizontal activities and other areas	**147**	**20,573**	**7,066**	**3,941**	**6,948**	**1,310**	**39,838**
3.1 Committees and working parties	22	2,490	726	1,129	0	1	4,345
3.2 Inspections and compliance	39	4,076	1,682	1,109	6,948	28	13,843
3.3a Partners and stakeholders	35	5,936	1,226	1,680	0	676	9,518
3.3b Transparency and access to documents	21	2,920	1,064	23	0	0	4,007
3.3c Information	15	2,176	1,902	0	0	605	4,683
3.4 International activities	14	2,975	467	0	0	0	3,441
4 Corporate governance and support activities	**175**	**24,884**	**7,089**	**315**	**0**	**791**	**33,080**
4.1 Governance, quality management and internal audit	25	4,406	859	315	0	135	5,715
4.2 Finance	27	3,574	1,316	0	0	135	5,025
4.3 Information technology	43	7,557	1,893	0	0	133	9,583
4.4 Human resources	39	4,509	1,696	0	0	139	6,345
4.5 Infrastructure services	15	1,704	481	0	0	2	2,188
4.6 Communication (corporate)	26	3,134	844	0	0	247	4,224
Total	**769**	**110,135**	**47,531**	**17,418**	**114,509**	**11,837**	**301,430**

[4] Full-time equivalents (FTEs) represents the establishment plan adjusted for part-time schedule, long-term absences. In 2016, the hours worked in excess of the standard time (8 hours per day) were equivalent to 32 FTEs, which means that 769 staff worked the equivalent of 801 FTEs.
[5] Other operational expenditure includes items such as translation carried out by the Centre de Traduction, other translations carried out by the Member States and business consultancy.
[6] Contrary to the previous years, the expenditure is based on commitments and payments made against 2016 budget (€297 million) and non-automatic carry-forward (€4.4 million).

Annex 7. Statistics on flexi leave according to grade

Grade	Staff members on 31.12.2016	Total flexi leave days taken	Average flexi leave days per staff member
AD15	1	0	0
AD14	1	0	0
AD13	9	0.5	0
AD12	27	27	1
AD11	25	47.5	2
AD10	31	60	2
AD09	34	93.5	3
AD08	52	107.5	2
AD07	56	80	1
AD06	74	162.5	2
AD05	18	48	3
AST10	3	8.5	3
AST09	3	1	0
AST08	4	1.5	0
AST07	12	8	1
AST06	21	33.5	2
AST05	30	10.5	0
AST04	35	19.5	1
AST03	76	89	1
AST02	34	19	1
AST01	37	15	0

Grade	Staff members on 31.12.2016	Total flexi leave days taken	Average flexi leave days per staff member
FGII.04	29	20	1
FGII.05	38	18.5	0
FGII.06	7	20.5	3
FGIII.08	6	2	0
FGIII.09	8	2.5	0
FGIII.10	1	0	0
FGIV.13	13	22.5	2
FGIV.14	36	42.5	1
FGIV.15	2	2.5	1
FGIV.16	2	0	0
FGIV.17	1	8	8
SNE	38	51.5	1

Annex 8. Report for 2016 on staff engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

For the period from 1 January 2016 to 31 December 2016, a total of 21 applications were made, resulting in 16 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; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at the Agency; 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. Other individual restrictions are applied on a case-by-case basis. Information on restrictions applied to applications in 2016 is given below.

Engaging in an occupational activity within two years of leaving the service - restrictions applied to applications in 2016:

Case No	Job title / Function at EMA	Length of service	Date of application	Joint Committee opinion	Date of Joint Committee's opinion	Decision of Executive Director	Date of Executive Director's decision
1	Trainee + Contract agent / Legal department	10 months + 1 year	26/07/2016	Authorisation with restrictions	18/08/2016	In line with professional ethics applied at the level of bar associations throughout Europe, the staff member should not, on a permanent basis, represent/assist a third party in any case lodged with the European Court of Justice, national or international courts which she dealt with while in service at the Agency.	25/08/2016
2	Temporary agent / Scientific & Regulatory Management department	6 years + 6 months	05/09/2016	Authorisation with restrictions	04/10/2016	Holds that during a period of six months to be counted as of the date of leaving the 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 s/he may have dealt with in the performance of his/her responsibilities at the Agency during the 6 years and 6 six months of service.	12/10/2016
3	Contract agent +Temporary agent / Finance department	1 year + 8 months 3 years + 7 months	09/11/2016	Authorisation with restrictions	08/12/2016	Holds that during a period of six months from leaving the service, s/he should refrain from individually liaising with any staff member of the European Medicines Agency with regard to any professional activity s/he may	09/12/2016

Case No	Job title / Function at EMA	Length of service	Date of application	Joint Committee opinion	Date of Joint Committee's opinion	Decision of Executive Director	Date of Executive Director's decision
						have dealt with in the performance of his/her duties at the Agency during the 5 years and 3 months of service.	
4	Trainee, Contract agent + Temporary agent / Product Development & Scientific Support department	5 months 7 months 8 years	07/12/2016	Authorisation with restrictions	23/01/2017	Six month 'distance clause' provision extended to a further six months with respect to interactions on the specific products the staff member worked on within the last three years. Holds that during a period of six months from leaving the 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 s/he may have dealt with in the performance of his/her responsibilities at the Agency during the 9 years of service.	27/01/2017
5	Temporary agent / Product Development & Scientific Support department	10 years + 1 month	20/12/2016	Authorisation with restrictions	23/01/2017	Six-month 'distance clause' provision extended to a further six months with respect to interactions on the specific products s/he has worked on within the last three years; Holds that during a period of six months from leaving the service, s/he should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during the 10 years and 1 month of service at the Agency.	27/01/2017

Annex 9. Risks

Operational activities

Risk	Mitigating actions and controls
Product assessment – procedure management	
Incorrect scientific opinions due to lack of required competences and expertise of experts	In place: • Legal requirements regarding expertise and competence • 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 and PRAC • 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 limited controlled role • Revised policy on CoI to improve balance between reducing risk for CoI and using best available expertise In progress: • Joint EMA-HMA training strategy
Product assessment – Conflicts of interests / independence	
NCA experts participating in the assessment work at the level of national agencies influence the outcome due to a failure to disclose conflicts of interests	In place: • Legal requirements for independence • Contractual arrangements and memorandum of understanding with NCAs • Agreement by HMA that EMA standards should be the minimum standards applied at NCAs
Experts attending and providing advice or opinions during EMA committees, working parties and other groups influence the outcome due to a failure to disclose conflicts of interests	In place: • Legal requirements for independence • Code of conduct and Guidance on handling declaration of interests in case of a committee or other scientific forum member's intention to become employee in a pharmaceutical company • Framework for decision-making process at CxMP • Policy on handling declarations of interests of scientific-committee members and experts • Check of interests declared by members and experts participating in meetings • Publication of DoI and e-CV of committee members and experts on Agency website • Breach-of-trust procedures on conflicts of interests for scientific-committee members and experts • Comparing e-CVs and DoIs to uncover discrepancies regarding conflicts of interests • KPIs to monitor conflicts of interests declared Planned: • Improvements to the Experts database to incorporate DoI evaluation forms and overview of involvement of the experts
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

Risk	Mitigating actions and controls
	In progress: • Active publication of clinical trials data post authorisation • 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
Inspections	
Inadequate quality of medicines due to framework for compliance with GxP from non-EU countries not meeting the EU standards at all times	In place: • EU network / cooperation (inspection working wroups, inspections planning – EudraGMDP planning module, PhV inspection programme, CMDh subgroup on Bioequivalence trials) • International cooperation in GxP area: – The ICH process (GMP, GCP, PhV) – The OECD programme (GLP) – Mutual-recognition agreements and agreement on conformity assessment (GMP) – International collaboration on GMP inspections of API manufacturers – EMA-FDA GCP initiative and EMA/EU MS/FDA initiative on inspections for generic applications – Exchange of inspections information and reports with non-EU authorities with confidentiality agreements or other bilateral relations – Joint inspections with non-EU authorities – Training and capacity-building activities • Legal and regulatory requirements • Risk-based approach for GxP inspections allowing better use of available resources In progress: • Mutual reliance initiative between FDA and EU on GMP inspections
Pharmacovigilance	
Lack of additional post-marketing authorisation data on human medicines to proactively identify, qualify and quantify risks	In place: • Launch of post-authorisation studies using ENCePP network • Independence, transparency and methodological standards of ENCePP studies ensured • Implementation of pharmacovigilance legislation (PASS and PAES) • 'Best evidence' procedure to support PRAC discussions In progress: • Longitudinal patient record databases used for EMA studies (in-house and commissioned studies) • Registries initiative
Inability of the Agency to effectively conduct veterinary pharmacovigilance if suitable IT system is not developed to replace EVVet2	In place: • Maintain expertise and knowledge in house to ensure EVVet2 can continue to operate until a replacement system is developed Planned: • Replace existing technology for EVVet2 with more modern technology as a first step to a complete revision/replacement of the system

Support activities

Risk	Mitigating actions and controls
Data management – data protection and security	
Accidental leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • IT security policies implemented 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 • Declaration of confidentiality and conflicts of interests for staff and for IT contractors • Annual checks to validate the control of access to database by users • Security tools against data leak (EudraLink to secure package, End point security) In progress: • Security road map project
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 • DataCentre access limited to relevant resource • Access control lists to restrict contractors' data access; checklist to manage contractors' access to IT systems • Data encryption tools to allow data transfer between parties outside the EMA network • Each new system account given appropriate level of access and necessary access restrictions applied In progress: • Data logs activated on all systems (where possible) and red flags set up and actively monitored • Access rights reviewed on regular basis to ensure permissions are appropriate Planned: • Policy on data security across EMA • Proactive markings on sensitive documents
Sensitive and/or confidential data intentionally accessed or removed from EMA premises by external suppliers	In place: • Security awareness training CCTV • Access control • Printing control • Confidential waste stored in locked confidential bins Planned: • Guidance on 'clear desk policy'
Data-protection issues due to non-compliance with the regulation	In place: • Legal requirements for identification and regular management review of systems to be notified • Appointment of Data Protection Officer within the Agency • Training programme for existing and new members of staff • Creation of data-protection network within the Agency • Regular bilateral meetings between Executive Director and Data Protection Officer Planned: • Review of the system of EMA management responsibilities for processing

Risk	Mitigating actions and controls
	personal data
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-analytics tool and processes for monitoring data quality • Governance structure for data management In progress: • Data-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 a service • Data quality-control level based on risk assessment of individual data assets
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 • 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 In progress: • Identification of dataset owners and definition of clear roles and responsibilities • KPIs to monitor compliance with EMA records-management policy Planned: • Records management embedded in redesigned human medicines evaluation processes • 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 In progress: • Review of IT operating model to insource further critical skills and knowledge Planned: • Outsourcing less critical skills and services, managed by strict contracts and SLAs
Finance - revenue collection and treasury management	
Loss of revenue due to inability/difficulty collecting pharmacovigilance fees from new customers	In place: • Proactive communication/engagement with stakeholders, including guidance/workshop with industry • New SAP technology for debt collection Planned: • Establishment of acceptable level of non-payment/to write off debts (waiver of recovery)
Loss on currency exchange rate fluctuations	In place: • Hedging, other exchange mechanisms

Risk	Mitigating actions and controls
	• Forward exchange contracts • Treasury policy • Minimum cash-flow level kept • Subsidy claimed only as required • Regular meetings with treasure committee
Agency operation interrupted due to significant system failure	In place: • Monitoring, preventive maintenance and resilience • Trained teams to repair/fix systems, external support from companies In progress: • Tested disaster-recovery systems and procedures
Clinical-data publication	
Non-compliance of MAHs/pharmaceutical industry with the policy	In place: • Information sessions with industry prior to implementation • Consultation with stakeholders • Targeted consultations with stakeholders In progress: • Identification of non-compliance scenarios and remedial actions Planned: • Annual report on implementation experience, including non-compliance data
Stakeholder relationships	
Failure to meet stakeholder expectations	In place: • Framework for interaction with patients and consumers • Frameworks for interaction with healthcare professionals • Framework for interaction with academia • SME surveys and other initiatives • Communication perception surveys • Targeted stakeholder meetings • Tools including website/media monitoring/Google alerts • Framework for interaction with industry stakeholders

In light of the outcome of the UK referendum on EU membership, the Agency is conducting impact and risk assessment. Among 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. Once the new seat becomes know, some staff will not be willing to relocate and the Agency may face significant loss of staff/expertise.
Currency volatility	High fluctuations of GBP to EUR exchange rate introduce instability in the Agency's cash flow and budget.

Annex 10. Implementation of the internal control standards in 2016 and actions planned for 2017

Standard	Actions planned for 2016	Actions planned for 2017
Mission	n/a	n/a
Ethical and organisational values	• The decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the EMA and candidates before recruitment is currently under revision. **Action fulfilled** - SOP on assessment of competing interests of Agency employees published.	• The Agency is now creating the basis for developing a competency framework through hiring an AD5 with experience in this area who will lead this initiative in Q2/Q3 and conclude it at the end of 2017.
Staff allocation and mobility	n/a	• In 2017, the Administration division will launch an initiative to develop a competency framework that, together with the consequent skills-mapping exercise, will offer a basis for consistent planning of learning and development needs for the present and future. • Work on a new policy for internal mobility progressed in 2016. The new policy will enter into force in 2017.
Staff evaluation and development	• Deloitte report published in January 2016 and disseminated to coincide with the appraisal process and support tighter objective writing. **Action fulfilled.**	• Put in place priority scientific and regulatory competency definitions in 2017, and remaining frameworks plus related mapping of competencies in 2017-2018.
Objectives and performance indicators	• To improve planning and reporting throughout the Agency, and in line with the recommendation from the audit on building blocks of assurance carried out in November-December 2015, a mechanism and templates/tools for improved cascading of strategy and the Agency's work programme in the divisions/departments will be considered within the scope of developing integrated planning and reporting in the Agency. • Work on a management dashboard started in 2016 **In progress.** • In 2016, the Agency embarked on reviewing its planning and	• The dashboard for management is expected to replace quarterly reports done previously, and possibly merge information currently reported in several other management reports. Work on the dashboard will continue in 2017. • The Agency is set to continue reviewing its planning and reporting processes over 2017-2018, to further integrate and streamline various components, ensure better cascade of objectives and activities throughout the organisation, and improve information support to management decision-making. • Introduction of more qualitative indicators establishing clearer

Standard	Actions planned for 2016	Actions planned for 2017
	reporting processes. **In progress.**	links between performance indicators and objectives would improve the ability to monitor progress and achievement of the set objectives. • The link between the MAWP and annual work programme needs to be clarified and further reinforced, to ensure proper and effective links and cascading of objectives and activities. • The cascading to division/department level is not implemented consistently across the Agency and needs to be improved (the division work plan template is being developed).
Risk-management process	n/a	n/a
Operational structure	• The revised Telematics governance adopted by EU TMB on 2 February 2016 and its further revision, including a new change-management governance model for Telematics systems in production, was endorsed by the HMA and EMA MB in December 2016 • Project-management framework (P3i) has been completed and is in full implementation. The IT delivery lifecycle part of the methodology is still to be delivered and subject to project prioritisation • An IM master plan was developed and approved by the EXB on 9 September 2016 • Implementation of prioritised COBIT processes was initiated	• 2017 revision of IM master plan • Continued implementation of COBIT processes • Follow up on recommendations from 2016 IT governance audit • Development of the IT delivery lifecycle part of the P3i methodology, subject to project prioritisation
Processes and procedures	• Quality framework to be reviewed, including the quality manual **Action fulfilled.**	n/a
Management supervisions	n/a	n/a
Business continuity	• An audit on business continuity and IT disaster recovery took place in April 2016 and pointed out 6 major findings, 2 of which rated very important and 4 important. • A plan for the implementation of the improvement actions was put in place.	Follow-up on actions closed.

Standard	Actions planned for 2016	Actions planned for 2017
Document management	• Full implementation of the Executive Director's decision on corporate controlled documents to be achieved by the end of 2016.	• Taking into consideration the technology decision for a new document/records management tool, an unstructured information management strategy and roadmap will be drafted and proposed for endorsement in 2017. • A work instruction on 'risk minimisation in handling personal data' is being updated to reflect the current organisational changes, and will be implemented in 2017.
Information and communication	Communication: • Develop new strategic framework for corporate communications for the period 2016-2020. IT systems: • Cloud policy to be approved in 2016. **In progress.** • Information classification policy to be approved in 2016. • Document classification policy endorsed by EXB in December 2016. • A full Pen Test was completed in March 2016 • Information security strategy 2016-2018 approved by Head of Division in Q1 2016 • The Agency's technology security controls were enhanced with additional systems to detect and prevent security attacks and incidents, such as: – BitLocker and DirectAccess implemented in April 2016 Enterprise Log Management system implemented in June 2016 – Intrusion Detection System implemented in October 2016 – Delivery of security awareness to Agency staff on security matters in November 2016	Communication: • Develop new strategic framework for corporate communication for the period 2016-2020. IT systems: • The cloud policy is to be completed in Q3 2017. • Risk-assessment on sensitive information to be completed by Q2 2017. • Guidelines on information handling & labelling to be completed by Q3 2017. • Follow up on the recommendations from cyber security and cloud readiness audit and ADR audit. • Development of a training course on IT security, which will be mandatory for all staff by Q4 2017

Standard	Actions planned for 2016	Actions planned for 2017
Accounting and financial reporting	n/a	n/a
Evaluation of activities	n/a	n/a
Assessment of internal control systems	n/a	n/a
Internal audit capability	n/a	• To address the scarcity of resources and improve effectiveness, new audit IT tools are under assessment, especially for data analysis. • To improve visibility of the auditors' work, a new communication strategy is planned. • In view of the external assessment of the function that will be conducted in 2017, the service completed a self-assessment in 2015. • An external assessment of IAC has been planned for 2017, as is required by the IIA standards.

Annex 11. Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2016

(Contracts signed during the reference period 1/1/2016–31/12/2016)

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/2016/02/HR	Framework service contract	ILX Group plc	First priority - training service in governance and portfolio, programme and project management in the Agency's P3i methodology	GBP 95,000	Negotiated middle value	Administration division
EMA/2016/13/FI	Service contract	Webb Valuations International Ltd	Physical inventory	GBP 39,500	Negotiated middle value	Administration division
EMA/2016/16/IS	Framework service contract	Wyse Solutions Ltd	Managed services consultancy	GBP 44,000	Negotiated low value	Administration division
EMA/2016/20/COM	Shortform contract	Charles Kendall Freight Ltd	Exhibition panels logistics	GBP 47,247	Negotiated low value	Stakeholders & communication division
EMA/2016/23/VM	Service contract	Norwegian Veterinary Institute	ESVAC study	EUR 15,000	Negotiated low value	Veterinary medicines division
EMA/2016/31/LD	Framework service contract	DS Avocats	Legal services: pre-litigation and litigation services	EUR 200,000	Negotiated - 134 1 (h) RAP	Legal – advisory function
EMA/2016/32/HR	Framework service contract	NopleProg Limited	Activiti training	EUR 115,000	Negotiated middle value	Administration division
EMA/2016/41/COM	Shortform contract	Laser Crystal Ltd	Corporate and staff service awards	EUR 15,000	Negotiated low value	Stakeholders & communication division
EMA/2016/42/COM	Shortform contract	Key Logo Limited	Promotional products	EUR 60,000	Negotiated low value	Stakeholders & communication division
EMA/2016/46/HR	Framework service contract	Everesta	Second priority - training service in governance and portfolio, programme and project management in the Agency's P3i methodology	n/a	Negotiated middle value	Administration division
EMA/2016/60/COM	Shortform contract	Royal Pharmaceutical Society of GB	Pharmaceutical e-books	EUR 124,256.39	Negotiated middle value	Stakeholders & communication division

Annex 12. Annual report 2016

Please see the Agency's 'Annual report 2016', attached as a separate document.

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 level 1 through to level 10
Surface area (in square meters)	26,450	
of which office space	18,448	
of which non-office space	8,002	
Annual rent	GBP 14.0 million : - Rent - GBP 11,759,937 Estimated Building Service Charge: GBP 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

There were no building projects in the planning phase in 2016.

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

There were no building projects likely to have significant financial implications submitted to the EP and the Council.

The fitting out of Level 10 has been included in the Agency's relocation project 'Project 2014' and is reflected in the figures above. The fitting-out works were completed and the Agency took possession of Level 10 in September 2015. The 12-month defects rectification period ended in September 2016, following which the project was closed.

The financial impact of 'Project 2014' over the term of the lease, including basement to level 10, is estimated to be EUR 565,218,810, compared to the initial EUR 554,600,000, which corresponds to an annual impact of EUR 424,752, in line with what was communicated to the European Commission in January 2015 in regards to the 2016 Preliminary draft budget. Note that the euro values are based on

a GBP/EUR exchange rate of GBP 0.858117/EUR, which corresponds with the European Parliament buildings questionnaire submitted by the Agency in April 2011.

Annex 14. Pharmacovigilance Fee Regulation, Article 15 (2)

Breakdown of costs to be covered by pharmacovigilance fees:

Description	2016 (€'000)	Forecast for 2017 (€'000)
Activities to be covered by the Annual Fee	21,076	19,907
Periodic safety update reports (PSUR & PSUSA)	13,078	15,683
Post-authorisation safety studies (PASS)	492	776
Referrals	1,966	1,969
Total	**37,612**	**38,336**

Annex 15. Environmental performance

Environmental management at the Agency

The Agency has adopted and endorsed a number of policies and activities with respect to environmental management, including an environmental strategy, an environmental policy, a Green Group mandate, and the launch of environmental activities and initiatives. The environmental strategy sets the scene for the re-initiation of environmental activities at the Agency, particularly in view of the move to new premises in 30 Churchill Place in 2014. The Agency's environmental policy was updated in May 2015 and sets out the scope, statement and roles and responsibilities for environmental management.

The Agency aims to register to the European Commission's Eco-Management and Audit Scheme (EMAS) in 2017, and in preparation for this performed an internal review of its environmental management system at the end of December.

EMAS is site-based and the scope of the environmental statement would cover EMA offices at 30 Churchill Place in Canary Wharf, London, which the Agency occupies since the summer of 2014. The building is classified as a Green Building by the UK Green Building Council, as well as according to EU standards. The landlord, Canary Wharf Management Ltd, is certified to ISO 14001:1996 for its environmental management system and to ISO 50001:2011 for its energy management, and is one of the founders of the UK Green Building Council. The Agency applies host-country legislation (UK) and requires that its contractors and suppliers do so too.

Environmental impact in running the Agency offices relates to resource consumption, waste, carbon emissions, and staff engagement and behaviour. The Agency aims to set objectives and targets to be monitored and achieved over the course of 2016, as well as for the longer term up to 2020.

Overview of EMA performance in 2016

The following table shows an overview of consumption, expressed also per workstation. The office space accounts for approximately 70% of the total space occupied, with a capacity of 1,300 workstations; the remainder being delegate and visitor, common and storage areas. Considering the Agency's relocation in the summer of 2014, the 2014 indicators are reported taking into consideration only the new offices in Churchill Place, and figures for energy and water consumption are extrapolated on the basis of the six-month data available for 30 Churchill Place.

Indicator	Units	2014		2015		2016	
		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
Water consumption	m^3	2,429	2.08	2,607	2.14	1,345	1,11
Paper consumption	kg	41,287	35.35	26,554	21.84	22,953	18.88
Waste[1]	kg	240,130	205.6	176,530	145.2	176,676	145.3
Work-related travel[2]	miles	9,229,023	7,902	9,785,507	8,048	8,848,604	7,277
Overall net CO_2e	kg CO_2e	2,724,461	2,333	2,842,558	2,338	2,854,120	2,347

[1] Including non-recyclable, recyclable and confidential waste.
[2] Including delegates, missions, training and candidates.

Annex 16. Project implementation

Project progress and delivery as of 31 December 2016 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 2016 in comparison to what was planned and approved at the end of 2015 (i.e. as noted in the work programme 2016). Notes explaining the changes are added.

In cases where the project start or end dates foreseen in the work programme 2016 were revised during 2016, the current dates are added in the relevant cells, with the original date from the work programme 2016 shown as crossed out.

Projects in human medicines evaluation activities

Programme / project	Project start	Project delivery target	Project delivery against Time	 Budget	 Scope	Results 2016
Pharmacovigilance programme						
Pharmacovigilance fees **(Completed)**	Q4 2013	Q1 2016				The project was completed and approved for closure by EXB on 26/04/16.
EudraVigilance auditable requirements	Q4 2013	~~2017~~ Q2 2018				• Communication to stakeholders on specifications, training and change-management plans delivered • Updated timelines endorsed by EMA Management Board • EMA internal test cycles completed ahead of EV audit • Updated/new EV web pages delivered on EMA website • Training material (e-learning) delivered • System tested by selected NCAs/MAHs/WHO-UMC (following EMA internal tests) • Release of software for audit delivered • Independent auditing company selected and preparations for audit fieldwork

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
						completed Fixes required following the tests, as well as transition to new IT supplier for system development, caused delays in project delivery. Switch to fixed-price contract sourcing strategy had significant impact on budget.
Clinical trials programme						
EU Portal and clinical trials database	Q3 2014	~~2018~~ Q3 2019				• Four development releases and user-acceptance testing with relevant stakeholders completed • Switch to fixed-price contract sourcing strategy completed • Development plan up to release 0.7 (for audit) produced • Work on the application programme interfaces specifications between national systems and the EU Portal and database progressed along the year The switch to the fixed-price contract sourcing strategy will have an impact on 2017 budget. Change in scope, in particular of the Auditable release version, to include non-auditable "must" requirements, was decided by MB in December 2015. Following this decision, project was re-baselined accordingly. No further change in scope or timeframe happened during 2016.
Safety reporting	Q4 2014	~~2017~~ Q 2018				Interaction with the network, in particular with Clinical Trial Facilitation Group, and with other projects' dependencies kept open. Delivery of the project delayed as a result of prioritisation of project resources within the CT programme.
eCollaboration programme						
eSubmission Gateway v3 **(Completed)**	Q4 2013	Q2 2016				• Submission Gateway able to generate and process the XML metadata delivery files required to process all submissions via the submission Gateway • Transition to maintenance completed • Communication, training and documentation updates completed The project closed successfully in June 2016.

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
PSUR repository **(Completed)**	Q4 2013	Q2 2016				• A repository for PSURs and the corresponding assessment reports was developed and deployed • Functionality required for mandatory use of the PSUR repository delivered • Transition to maintenance completed • Communication, training and documentation updates completed The project closed successfully in June 2016.
Standalone projects						
AddValue: raising the standard of scientific output	Q3 2015	Q4 2017				• Preliminary and detailed business cases approved during 2016 • Roll-out of the assessment report with revised benefit/risk section completed

Projects in veterinary medicines evaluation activities

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
Veterinary change programme						
Implementation of veterinary legislation	Q2 2016	2019				• Preliminary and detailed business cases approved during 2016 • 'As-is' and 'to-be' process mapping for all major procedures in the veterinary division involving internal and external stakeholders completed • Proposal of the revised organisational structure for the Division that supports the improved business processes agreed

Projects in horizontal activity areas

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
Data-integration programme						
Referentials management service	Q1 2015	~~2016~~ Q2 2017				• Internal RMS (release 1) go-live • EMA internal training completed Quality of software development and configurations by external supplier caused delays in project delivery.

Programme / project	Project start	Project delivery target	Project delivery against			Results 2016
			Time	Budget	Scope	
Organisations management services	Q1 2015	~~2016~~ Q2 2017				• Internal OMS (release 1) go-live • EMA internal training completed Quality of software development and configurations by external supplier caused delays in project delivery.
Identity and access management **(Completed)**	Q4 2014	Q2 2016				• Identity and access management (IAM) solution installation and configuration completed • Centralised view of users' access created, based on the integration of the Identity platform with the existing repositories (Corporate active directory and ECD/OID). • Self-service user registration and password management capabilities deployed. • Workflows regarding access requests, access approval and automated provisioning for SIAMED/OBIEE partially delivered for SPOR and CT • Reporting and access certification capabilities regarding user access for SIAMED/OBIEE partially delivered for SPOR and CT. • Governance structure for the user registration service created. • Training material for external and internal users developed. All Ping-related activities and tasks were de-scoped as the Ping Federate was deemed insufficient as a sole solution. The EudraVigilance application has not been on-boarded during the IAM project because of conflicting requirements with the SPOR applications. Project delivery was delayed due to compatibility issues between technological components and EMA infrastructure, which delayed deployment of the tool, and internal resource availability constraints. The project closed in December 2016.
ISO IDMP	Q4 2013	~~Q2 2016~~ Q4 2017				• Two international HL7 standards published (normative editions), namely: HL7 SPL v7, HL7 CPM v3 • One international ISO technical

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
						specification published, namely: ISO/TS 19844:2016 • Two international ISO standards reached the DIS status, namely: ISO/DIS 11615, ISO/DIS 11616 • Two international ISO technical specifications reached the final status for publication, namely: ISO/TS 20443, ISO/TS 451 • Draft EU implementation guide for ISO IDMP – products (based on information available in 2016) delivered • Draft EU implementation guide for ISO IDMP – substances (based on information available in 2016) delivered 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						
European Medicines Web Portal	Q1 2014	2019				• The reflection paper describing the vision for a future European medicines web portal was adopted by EMA Management Board on 6 October 2016, and by the HMA on 7 September 2016 A baseline plan will be defined as part of the business case.
Corporate website	Q1 2014	2019				• Reorganised and rewritten human and veterinary regulatory sections published in December 2016
Standalone projects						
EU network training centre **(Completed)**	Q2 2014	Q4 2016				• Learning management solution launched • Curricula for eight scientific and regulatory areas developed • Curricula for Telematics area developed • Clinical trials training programme launched The project closed successfully in December 2016.
Publication and access to clinical data	Q2 2014	~~Q4 2016~~ Q1 2017				• Portal enhancements deployed, including better read-only view of PDFs, support for withdrawn MA procedures,

Programme / project	Project start	Project delivery target	Project delivery against			Results 2016
			Time	Budget	Scope	statistical information on the most often viewed/downloaded dossiers, and user interface improvements • Interim tracking tool delivered Timelines were extended to complete tracking tool, as work has been more extensive than initially planned, and to deliver additional functionality supporting relevant business processes.
Rationalising working parties	Q1 2015	2017				• Data-gathering exercise finalised and presented to EMA senior management • Workshop with EMA management held to discuss findings and possible solutions • Presentation of the outcomes of the workshop given to the sounding board

Projects in corporate support and governance activities

Programme / project	Project start	Project delivery target	Project delivery against			Results 2016
			Time	Budget	Scope	
EMA portfolio/ programme/ project methodology (P3i methodology) **(Completed)**	Q3 2015	~~Q3 2016~~ Q4 2016				• Detailed business case approved • New methodology for portfolio/programme/project management deployed • Complete set of training materials delivered and one complete cycle of training for all P3i modules (governance, basic and advanced project management, programme management) deployed • Series of information sessions, complementing the training, delivered to ensure successful change-management • Microsite updated, providing complete framework of information on the new methodology • Framework for the evolution and continual improvement of the methodology developed Review of existing IT lifecycle was de-scoped due to resource unavailability and will be run

Programme / project	Project start	Project delivery target	Project delivery against Time	Budget	Scope	Results 2016
						as a separate project (or operational enhancement of the methodology) in 2017. As a result, the IT lifecycle within P3i remains unchanged and refers to the current IT lifecycle process. Project delivery delayed due to more extensive work throughout the project and on templates and guidelines following redefinition of project governance. In addition, the tender procedure for a training vendor took longer than expected and the delivery of the training plan was delayed due to the limited availability of the training vendor. The project closed in December 2016.
Desktop strategy and implementation **(Completed)**	Q2 2015	Q4 2016				• Pilot of new computing equipment completed to validate effective device selection and increase user acceptance • Repeatable and sustainable processes for the provisioning of new equipment developed • Knowledge transfer and training provided for IT service desk, primary support, infrastructure teams and end-users on the use of new equipment / systems • Equipment refresh policy and plan for future sustainability created • Rollout of new Agency computing equipment completed • Obsolete equipment donated/disposed of The project closed in December 2016.

Deprioritised projects

Programme / project	Status on 31 December 2016
Pharmacovigilance programme	
EudraVigilance critical requirements	Project on hold in 2016.
EudraVigilance Fixes	The project was deprioritised from the 2016 portfolio by EXB on 9/6/16 and rescheduled to start in 2017 due to lack of I-Division staff resources and delays in the award of the new DIMSIS framework contract.
Clinical trials programme	
EudraCT and EU Portal	The project was deprioritised from the 2016 portfolio by EXB on 9/6/16 and

Programme / project	Status on 31 December 2016
	rescheduled to start in 2017 due to lack of I- Division staff resources.
eCollaboration programme	
eCTD 4 pre-project activities	The pre-project activities were deprioritised from the 2016 portfolio by EXB on 9/6/16 and rescheduled to start in 2017 due to lack of I-Division staff resources.
Single submission portal	The external project activities were deprioritised from the 2016 portfolio by EXB and rescheduled to start in 2017.
Veterinary IT programme	
EudraVigilance veterinary v3.0	The project was deprioritised from the 2016 portfolio by EXB on 9/6/16 and rescheduled to start in 2017 due to lack of I- Division staff resources and delays in the award of the new DIMSIS framework contract.
Union database	The project was deprioritised from the 2016 portfolio by EXB on 9/6/16 and rescheduled to start in 2017 due to lack of I-Division staff resources and delays in the award of the new DIMSIS framework contract. In October 2016, it was decided to incorporate this project in the Substance & Product management services project within the Data-integration programme, in order to promote synergies in terms of data model, processes, infrastructure and shared technical team.
Data-integration programme	
Substances management service	Project was put on hold in December 2015 and scheduled to restart not before delivery of RMS and OMS. Project is now merged into Substances & Products management service.
Products-management service	Project was put on hold in December 2015 and scheduled to restart not before delivery of RMS and OMS. Project is now merged into Substances & Products management service.
Online programme	
Extranet	Work with the digital design agency was completed and wireframes and prototype were delivered in January 2016 The project was deprioritised from the 2016 portfolio by EXB on 9/6/16.
Standalone projects	
Building EU network capacity to gather and analyse information on clinical use	The project was deprioritised from the 2016 portfolio by EXB on 26/4/16 and will be managed as an initiative instead.
SIAMED systems integration phase I	The project was deprioritised from the 2016 portfolio by EXB on 9/6/16 and rescheduled to start in 2017 due to lack of I-Division staff resources.

Annex 17. Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AA	accelerated assessment
ACL	access control list
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
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	Ad hoc Expert Group on Veterinary Novel Therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
API	active pharmaceutical ingredient
Art.	article
AST	assistants function group
ATD	access to documents
ATMP	advanced-therapy medicinal product
AYUSH	Indian Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
BIACC	Business Intelligence & Analytics Competence Centre
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
BSWP	Biostatistics Working Party
BWP	Biologics Working Party
CA	contract agent
CADVVA	CVMP Ad hoc Group on Veterinary Vaccine Availability
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCI	commercially confidential information
CCTV	closed-circuit television, video surveillance system
CHMP	Committee for Medicinal Products for Human Use
CMA	conditional marketing authorisation
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CO2e	carbon dioxide equivalent
COBIT	Control Objectives for Information and Related Technologies, a good-practice framework for information technology management and IT governance
CoI	conflict of interests
Commission	European Commission
committee(s)	scientific committee(s) of the Agency

Term / abbreviation	Definition
COMP	Committee for Orphan Medicinal Products
Council	European Council
Court of Auditors	European Court of Auditors
CPAS	classification of post-authorisation studies
CPTR	Critical Path to TB Drug Regimens initiative
CT	clinical trial
CV	curriculum vitae
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	generic abbreviation for EMA scientific committees
DCDvet	defined course doses for animals
DCP	decentralised procedure
DDDvet	defined daily doses for animals
DIA	Drug Information Association
DIMSIS	'Development, Implementation, and Maintenance of Software and Information Systems' framework contract
DIS	draft international standard, a status of ISO standard
Division	organisational entity of 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
DNA	deoxyribonucleic acid
DoI	declaration of interests
DPO	Data Protection Officer at the Agency
DREAM	Document Records Electronic Archive Management – EMA's document management system
EC	European Commission
EC C3	Directorate C3 of the European Commission
ECA	European Court of Auditors
ECD/OID	Eudra Common Directory/ Oracle Internet Directory
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECM	electronic content management
ECNP	European College of Neuropsychopharmacology
eCTD	electronic common technical document
e-CV	electronic curriculum vitae
e-DoI	electronic declaration of interests
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
e.g.	exempli gratia, for example
EMA	European Medicines Agency

Term / abbreviation	Definition
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
ESI	emerging safety issue
e-SME	electronic SME application
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
etc.	et cetera, and so forth
EU	European Union
EU contribution	EU special contribution for orphan medicines
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
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	European network for health technology assessment
EU NTC	EU network training centre
EUR	euro
EU TMB	EU Telematics Management Board
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
EVHuman	Eudravigilance human
EVVet	EudraVigilance veterinary
EWP	Efficacy Working Party
EXB	EMA Executive Board
Executive Board	EMA Executive Board
FDA	United States Food and Drug Administration
FDA MRI	FDA mutual reliance initiative
FG	function group for contract agents
FTE	full-time equivalent
GBP	pound sterling
GCP	good clinical practice
GCP IWG	Good Clinical Practice Inspectors Working Group
GDRP	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
GMO	genetically modified organism

Term / abbreviation	Definition
GP	general practitioner
GRP	good regulatory practice
GVP	good pharmacovigilance practice
GxP	good practice (e.g. laboratory, clinical, manufacturing)
HCPWP	Healthcare Professionals Working Party
HIV	human immunodeficiency virus
HL7	Health Level 7 standard
HL7 CPM	Health Level 7 Common Product Model messaging standard
HL7 SPL	Health Level 7 Structured Product Labelling messaging standard
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
Horizon 2020	EU Research and Innovation programme
HTA	health technology assessment
IAC	internal audit capability of EMA
IAM	identity and access management
IAS	Internal Audit Service of the EC
ICDRA	International Conference of Drug Regulatory Authorities, a forum of WHO Member State drug regulatory authorities
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
IDWP	Infectious Diseases Working Party
i.e.	id est, that is
IFAH-Europe	International Federation for Animal Health Europe
IGDRP	International Generic Drug Regulators Programme
IIA standards	internationally accepted audit standards
IM	information management
IMI	Innovative Medicines Initiative
IMI-EU2P	Innovative Medicines Initiative – European programme of pharmacovigilance and pharmacoepidemiology
IMI GetReal	Innovative Medicines Initiative project on incorporating real-life data into drug development
I-MOVE	Influenza Monitoring of Vaccine Effectiveness network
Implementing Rules	implementing rules of the EMA Financial regulation
INT	interim
IPA	informal network of EU agencies working with pre-accession
IPRF	International Pharmaceutical Regulators Forum
IRM	Institute of Risk Management
ISO	International Organisation for Standardisation

Term / abbreviation	Definition
ISO IDMP	international standards for the identification of medicinal products
ISO/DIS	International Organization for Standardization / Draft International Standard
ISO/TS	International Organization for Standardization / Technical Specification
IT	information technology
ITF	EMA Innovation Task Force
IWG	Inspectors Working Group
JA3	Joint Action 3
JECFA	Joint Expert Group on Food Additives
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
m3	cubic metre
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
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
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

Term / abbreviation	Definition
	lifecycle
PAES	post-authorisation efficacy study
PASIB	public assessment summary information biosimilars
PASS	post-authorisation safety study
PB	EMA Portfolio Board
PBT	persistent bioaccumulative and toxic substance
PBPK	physiologically based pharmacokinetic model
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
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PRAC	Pharmacovigilance Risk Assessment Committee
PREDICT-TB	Model-based preclinical development of anti-tuberculosis drug combinations, IMI project
PrEP	pre-exposure prophylaxis
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
RACI	responsible, accountable, consulted, informed
Rev. (1,2,…)	revision
RFI	request for information
RGI	rheumatology, gastroenterology and immunology
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
SA	scientific advice
SAG	scientific advisory group
SAGE	Strategic Advisory Group of Experts on Immunization
SAP	Systems, Applications & Products (budgetary system)
SAP FIN	finance module of SAP
SAWP	Scientific Advice Working Party
SC	secretary/clerk function 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

Term / abbreviation	Definition
SNE	seconded national expert
SOP	standard operating procedure
SPOR	Substances, Products, Organisations, Referentials – and EMA programme
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
SWP	Safety Working Party
TA	temporary agent
TGA	Therapeutic Goods Administration, Australia
TIGRE	Team of International Global Rare Disease Experts initiative
TR	trainee
TTIP	Transatlantic Trade and Investment Protocol
UK	United Kingdom
Union	European Union
USA	United States of America
VE	Vaccines Europe
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
XML	extensible mark-up language – a text-based format used to share data on the internet, intranets and elsewhere