EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Annual activity report 2014

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1. Work programme achievements of the year

1.1. Key achievements

- One-year report on human medicines pharmacovigilance tasks of the European Medicines Agency (EMA) was published on 20 May 2014.
- The revised EMA policy on handling of declarations of interests of experts was adopted by the Management Board in March 2014 and published on the Agency's website in November, with 30 January 2015 as its implementation date. The e-DoI form and the related guidance documents were updated in line with the revised policy, and published in November. All European experts were requested to submit an up-to-date e-DoI by 30 January 2015.
- The pilot project on adaptive pathways was launched in March, and 9 proposals were reviewed in depth during the first round of candidate reviews in June. In total, 34 applications were reviewed in 2014, 10 of which were selected for Stage I discussions. Stage I applications will close end of February 2015.
- During the first half of 2014, the Agency started preparing for the implementation of the upcoming Clinical Trials Regulation. This included formal initiation of the Clinical Trials Regulation programme, which includes 4 projects (Pre-inception; EU Portal and Database, including Workspace; Safety Reporting and EudraCT; and EU-CTR legacy).
- Work on EU Portal and Database for submission and regulatory management of clinical trials commenced at the end of Q2, following publication of Clinical Trials Regulation on 27 May 2014. EMA Management Board adopted the functional specifications in December.
- The EMA policy on publication of clinical data was endorsed by the Management Board at its October meeting and was published on the Agency's website, along with the questions-and-answers document. The policy will come into force on 1 January 2015.
- To prepare for the future revision of the general fee legislation, a Management Board Steering Group was created in the first half of 2014, involving representatives of the European Commission, the Agency and the Member States. Analysis of the tasks and activities of the EMA and the NCAs was started, identifying 19 fee-generating and 12 non-fee-generating major activity areas where further data-collection is required. A pilot to test and validate the data-collection methodology will start in January 2015, collecting data on scientific advice and protocol assistance procedures.
- Business requirements for enhanced EudraVigilance system functionalities were finalised in May and implementation of the requirements began in Q3 2014.
- The first release of the PSUR repository was finalised in December, allowing the system to go into a pilot phase in January 2015.
- The tender for a service provider for monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance was re-launched in November, following an unsuccessful award procedure of the initial tender. The repeated tender closed in December and the results will be finalised in Q2 2015.
- The first product targeting a nonsense mutation in Duchenne muscular dystrophy, Translarna, was granted a positive opinion by the CHMP in May.
- The first stem-cell therapy, Holocar, for limbal stem-cell deficiency was granted a positive CHMP opinion in December.

- In October CHMP granted a positive opinion for Scenesse, the first medicine for prevention of phototoxicity in patients of erythropoietic protoporphyria (EPP), a rare genetic disease causing intolerance to light.
- 21 research proposals were submitted to IMI in January 2014, to support addressing public health needs with corresponding research. Some of the 21 proposals were subsequently merged, and 8 of the merged proposals were presented at the 4th IMI Regulatory summit in Washington, USA, in December 2014.
- The MUMS policy was reviewed in 2014, including consultation with the CVMP on the refined MUMS criteria. The revised policy was presented and adopted by the Management Board in December.
- With the status of the first MUMS products expiring in October 2014, a review of classification as MUMS was started in the first half of 2014. In the absence of request for renewal, the status of four products was allowed to expire in 2014.
- The EMA Innovation Task Force considered its first two veterinary products in 2014, following the procedure being made available to veterinary products in 2013.
- Draft responses to the remaining three of four questions of the European Commission related to the risk to man from the use of antimicrobials in veterinary medicine were finalised and published for a two-month public consultation in August. Final revised answers were adopted by the CVMP and CHMP and sent to the European Commission in December 2014.
- A progress report on the TransAtlantic Task Force on Antimicrobial Resistance (TATFAR) work was published in May, recording good progress in 15 out of 17 recommendations, and the addition of a new recommendation to identify knowledge gaps in the area of limiting transmission of resistance from animals to man.
- The EU Telematics Strategy was adopted by the EU Telematics Management Board in May and endorsed by the EMA Management Board in June. Heads of Medicines Agencies endorsed the strategy at their July meeting.
- In order to set up the EU Network Training centre, the mandate of the Training Centre was endorsed by the Agency management team in March and by HMA in May. The vision, road map and project plan of the Training Centre were endorsed by EMA and HMA in November.
- The project to relocate the Agency to new premises continued according to plan in 2014. The pilot move was carried out on 16 June. The premises were practically completed on 1 July, the first move took place on 2 July and the final move was completed on 30 July, with the Agency fully relocated on 1 August.
- In order to increase efficiency of project management, control and delivery in the Agency, a new project governance structure was put in place and a Programme Management Office was established in April 2014.
- Following an extensive bottom-up exercise involving all staff of the Agency, a set of core EMA values were selected in February. The new core values were launched in May, with implementation activities started in the second half of the year.
- An exercise on best-practice benchmarking within the European medicines regulatory network (BEMA III) began in early 2014. The self-assessment was finalised in Q2, followed by the assessors' visit in September. The Agency received a high range of best ratings, identifying it as an effective driving agency in its coordinating role in the EU network.

1.2. Work programme implementation

This section highlights the progress achieved in implementing the Agency's work programme 2014. It mirrors the structure of the work programme.

The work programme consists of four parts: human medicines evaluation, veterinary medicines evaluation, horizontal and corporate governance, and support 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 covers a set of objectives, with the relevant activities and results outlined. Highlights (results above or below the forecast) of workload and performance indicators are also outlined below: workload indicators refer to volumes of procedures, applications, requests etc. that drive the workload, while performance indicators measure how well an activity has been performed against certain criteria (time, quality etc.). Full details of the workload and performance indicators are included in Annex 1.

Evaluation activities for human medicines

Pre-authorisation activities

Workload and performance indicators

Workload indicators	Performance indicators
• Pre-authorisation scientific advice and protocol assistance increased by 20% (14% increase, if considering all SA requests) • Orphan designation applications reached 329, a 54% increase over the forecast • Requests for ATMP classification increased by 40%	• Performance indicators on target • 17% increase in scientific advice requests was observed, exceeding the target of 9%

Achievements

- A common application form with the FDA for qualification of novel methodologies was finalised in June. A joint letter of intent to be used with the common application form was made available on the websites of both agencies in December 2014.
- As part of developing a framework that would satisfy the needs of the EMA, regulators and HTA bodies, the exchange of guidelines for mutual input started in early 2014.
- To increase engagement of HTA bodies in the lifecycle of medicines, best-practice guidance on EMA HTA parallel scientific advice procedures was prepared and published for a three-month public consultation in April 2014. The comments received during the public consultation were discussed by the EMA HTA process working group in Q4 2014.
- In order to support development of new approaches and medicines, a reflection paper for ATMP classification was revised and public consultation was conducted between June and October. The finalised relfection paper is expected to be published in Q2 2015. A reflection paper on clinical aspects of tissue-engineered products was adopted in September.

- A workshop with a scientific society (DGTI) was held in September, in order to reach out to academic and hospital developers of ATMPs and raise their awareness of the ATMP development framework and support available.
- In the area of collaboration on nanotechnologies, three meetings with the US-EU Nanotechnology Characterisation Laboratory (NCL), Joint Research Centre (JRC) and European Commission (EC) were held in 2014, in order to share experience with the US-NCL and facilitate the EC decision on the establishment of an EU-NCL.
- The EMA organised and chaired a webinar of International Regulators on Nanomedicines in May. Participants included the FDA, Health Canada, MHLW, TGA and Swissmedic. The webinar focused on: exchange of ongoing and submitted marketing-authorisation applications (MAAs) and major issues discovered; an international definition of nanotechnology and nanomedicines; and agreement on draft rules for participation of additional regulators in the exchange forum.
- At the November ICH Steering Committee meeting, the establishment of a new International Nanomedicines Working Group was adopted, and the first teleconference to discuss the mandate and work programme of the group was held in Q4 2014.
- 21 research proposals were submitted to IMI in January 2014, to support addressing public health needs with corresponding research. Some of the 21 proposals were subsequently merged, and eight of the merged proposals were presented at the 4th IMI Regulatory summit in Washington, USA, in December 2014.
- As part of developing scientific guidance for the development of medicines for specific target segments, the Agency and the Geriatric Expert Group prepared a draft 'Points to consider on frailty evaluation instruments for baseline characterisation of clinical trial populations' in 2014. It is expected to be finalised in early 2015, with public consultation planned for the second half of 2015.
- A report on European collaboration between regulators and HTA organisations on the data presentation in EPARs, underlining the relevance of EMA/HTA collaboration, was prepared by the EMA and representatives of EUnetHTA. The article, titled 'Improving the Contribution of Regulatory Assessment Reports to Health Technology Assessments — A Collaboration between the European Medicines Agency and the European network for Health Technology Assessment', was published in Value in Health, the Journal of The International Society for Pharmacoeconomics and Outcomes Research, in June.
- In addition, discussions with EUnetHTA to identify specific EPAR sections relevant for rapid REA by HTA bodies in the context of EUnetHTA Joint Action 2 and WP5 pilots were held.
- The pilot project on adaptive pathways was launched in March, and nine proposals were reviewed in depth during the first round of candidate reviews in June. In response to the high interest raised by the launch of the pilot, a question-and-answer document was published in September, and an updated application form was published in October 2014. In total, 34 applications were reviewed in 2014, ten of which were selected for Stage I discussions. Stage I applications will close at the end of February 2015.

Initial evaluation activities

Workload and performance indicators

Workload indicators	Performance indicators
Number of applications received is slightly lower than expected (100 vs 118), yet still shows an increase over 2013 (88) • New non-orphan medicinal product applications saw a slight decrease (38 applications vs forecasted 48) • Similar biological product applications remain at a stable low level • Generic applications saw an unexpected increase in 2014, reaching a high total of 25 applications	Performance indicators on target

Achievements

- As part of implementing updated benefit-risk assessment methodology, use of the 'effects table' was piloted in the first half of 2014, and used for 17 products, from D80 AR to D120. Detailed guidance on the effects table was developed, based on the feedback from the pilot. A decision on further implementation of the effects table was taken at the December CHMP and the effects tables will be implemented for all MAAs and extensions of indications in February 2015.
- A workshop on best practice in preparing the benefit-risk section of the assessment reports was prepared, in collaboration with senior assessors from the network. The workshop will take place in January 2015.
- In order to improve standards and support the robustness and consistency of scientific assessments, the review of the initial marketing-authorisation assessment process started in Q1 2014. A number of improvements, ranging from strengthening pre-submission meetings to increasing the focus of the peer-review process on major objections, were identified and will be gradually implemented.
- In addition, a specific regulatory and scientific support framework for the committees was implemented in Q1 2014.
- A draft guideline on the investigation of subgroup analyses in confirmatory clinical trials was published for public consultation in January. It received a large number of comments, which were discussed with stakeholders at a workshop in November. The guideline is expected to be finalised and published in 2015. The Biostatistics Working Party (BSWP) also commented on a number of therapeutic-area guidelines, with regard to biostatistical input in the review process.
- Statistical methodology for the comparative assessment of quality attributes in medicines development was discussed with the FDA in the second half of 2014, not only between the statisticians, but also with the FDA Biosimilar cluster, the Biosimilar WP and Health Canada.
- A draft reflection paper on comparison of methods to assess analytical biosimilarity was started and an information exchange between the BSWP and FDA took place in the second half of 2014.
- A pilot on further integrating patient values in benefit-risk evaluations started in September, with patients taking part in the CHMP discussion of Scenesse.

- The test-run of the project on improving data scrutiny was completed in Q1.
- The first product targeting a nonsense mutation in Duchenne muscular dystrophy, Translarna, was granted a positive opinion by the CHMP in May.
- In October, the CHMP granted a positive opinion for Scenesse, the first medicine for prevention of phototoxicity in patients of erythropoietic protoporphyria (EPP), a rare genetic disease causing intolerance to light.
- The first stem-cell therapy, Holocar, for limbal stem-cell deficiency, was granted a positive CHMP opinion in December.

Post-authorisation activities

Workload and performance indicators

Workload indicators	Performance indicators
• Variations have seen an average increase of 18% against the forecast across all types of variations	Performance indicators on target

Achievements

- Collaboration with scientific advice to optimise PRAC input on non-imposed, non-interventional PASS procedures and deliver high-quality advice to companies was discussed at the PRAC meeting in November. As a result, a call for nomination of PRAC members for the Scientific Advice Working Party will be released in Q2 2015, and a 12-month pilot for the new business process is planned to start by Q3 2015.
- In order to develop scientific guidance on post-authorisation efficacy studies, a rapporteurs' group from PRAC/CHMP/CMDh was formed in June. The structure and scope of the guideline was agreed upon and drafting the guidance began in June. The draft guidance will be presented at the Pharmacovigilance Stakeholder Platform in January 2015, and is planned to be released for public consultation in Q3 2015.
- Exploring the use of various data sources, the collection of additional data on European data sources on drug consumption (with integration of additional countries) continued over the first half of the year, with the third revision of Drug Consumption inventory finalised in Q4 for publication on the PROTECT website in 2015. A report on ENCePP activities in 2014 was prepared, outlining the number of data sources on drug consumption.
- A pilot on the sources and processes on gathering best evidence to support PRAC decision-making was agreed in Q4 2014, and will start in early 2015.
- In order to facilitate the collection and analysis of high-quality data informing regulatory decisions and the evaluation of the benefit-risk profile of medicines, an initiative to establish a collaborative EU framework for patient registries was agreed by the Committees in Q4 2014. A strategy paper on the patient registries is expected to be finalised in Q2 2015.
- The WebRADR project was launched in September 2014, with the MHRA and EMA co-leading the work package on policy and governance.
- To explore opportunities for extending the use of peer-review in assessment procedures, development of a best-practice guide started in Q1 2014. The business process for type II

variations was redesigned in Q1. The possibility for peer-review in assessment of major changes to marketing authorisations will be reviewed in Q1 2015.

- Systematic peer-review of environmental risk assessment for all centrally authorised medicines was implemented in January 2014.
- Summaries of risk-management plans for newly authorised medicines have been published since March 2014, as part of a one-year pilot. Analysis of the pilot will be conducted in 2015.

Arbitration and referrals

Workload and performance indicators

Workload indicators	Performance indicators
• Number of referrals started has decreased by 36%, as compared to the forecast for 2014	Performance indicators on target

Pharmacovigilance activities

Workload and performance indicators

Workload indicators	Performance indicators
• Number of both reviewed and validated signals has fallen slightly, compared to 2013, yet the results are at the level forecasted for 2014	Performance indicators on target

Achievements

- The third revision of the ENCePP guide on methodological standards in pharmacoepidemiology was published in July 2014, updating most of the contents, adding a new chapter on design and analysis of pharmacogenetic studies and data in pharmacoepidemiology, and integrating the final results of PROTECT WP3 on duplicate detection and assessment of masking effects.
- The third revision of the ENCePP code of conduct, providing further clarifications on the key concept of scientific independence and conditions for the ENCePP Study Seal, was published in March 2014.
- In order to develop a programme for studying public-health impact, several meetings with stakeholders were held in 2014 to develop the business case as well as scope and methodology of the programme. An outline of the programme was presented and discussed at the PRAC in Q4, and a concept paper and implementation plan were being drafted. These will be finalised in the first half of 2015.
- A one-year report on human medicines pharmacovigilance tasks of the European Medicines Agency was published on 20 May 2014.
- A recommendations report on methodology and visualisation techniques to be used in benefit–risk assessment was published in the journal Pharmacoepidemiology and Drug Safety in May and June 2014, and presented to the informal PRAC meeting in May 2014.
- Tools and methods of the VISUALizE Study (assessment of patients' preferences) were finalised in June 2014. A survey to help improve communication of benefits and risks of medicines was

conducted for patients and healthcare professionals in the second half of 2014. The results of the survey are being analysed and a report on the outcomes will be published in the final PROTECT report to IMI in Q2 2015.

- The process for assessing risk-management plans as part of the initial MAA evaluation was reviewed in Q2 2014, and principles for redesigning this process and related tools (e.g. templates) were agreed. The redesign of the process started in Q3 2014.
- The signal-detection process was reviewed in the first half of 2014, finding the process to be well established. No major changes are required.
- Updating the guidance on signal-detection methodology, and the development of new, complementary guidance combining an amended statistical guide on the use of statistical methods in EudraVigilance (based on PROTECT research outcomes) and signal-detection guidance for specific topics (medication errors, lack of efficacy, etc.) started in Q2 2014. Public consultation on statistical guidance is foreseen in Q2 2015, once results on the pilot phase of eRMR are incorporated in the guidance. Signal-detection methodology guidance is expected to be finalised for public consultation by Q4 2015.
- A pilot survey of 21 ENCePP centres' experience with HTA and their capacity to generate data useful for HTA bodies was conducted in April. The complete survey was sent to 150 centres in June, and the results were presented at the International Conference of Pharmacoepidemiology (ICPE) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in November 2014.
- A survey of ENCePP centres on the use and understanding of the ENCePP database of studies (also known as the EU PAS register) and the ENCePP Seal was conducted and the results reported to the ENCePP Steering Group at the end of June.
- A report on the survey of researchers coordinating EC-funded multi-database drug-safety projects was published in October 2014.
- Business requirements for enhanced EudraVigilance system functionalities were finalised in May. Implementation of the requirements began in Q3 2014 and is expected to continue until Q3 2015.
- Business requirements for essential auditable requirements for the PSUR repository were finalised in Q2 2014. The first release of the PSUR repository was finalised in December, allowing the system to go into a pilot phase in January 2015. Preparations for the audit foreseen by the pharmacovigilance legislation took place in the second half of 2014, with the audit planned in February 2015.
- The tender for a service provider for monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance was re-launched in November, following an unsuccessful award procedure of the initial tender. The repeated tender closed in December and the results will be finalised in Q2 2015.
- A draft guideline on literature-monitoring for case reports to be entered in EudraVigilance was prepared and published for a two-month public consultation in June. Finalisation of the guideline was postponed, due to the delay in the tender procedure for the literature-monitoring service provider.
- The final audit report on the quality system of the pharmacovigilance system was released in May. A report on all pharmacovigilance audits conducted in the past two years was presented to the Management Board in October.

Other specialised areas and activities

Workload and performance indicators

Workload indicators	Performance indicators
• Number of new and revised herbals remained at the same, stable level as before, meeting the forecast for 2014 • 1 public statement was finalised in 2014	Performance indicators on target

Achievements

- Scientific-advice applications for new antibiotics for MDR pathogens were discussed with the FDA, in order to streamline data requirements and optimise development support.
- During the first half of 2014, the Agency started preparing for the implementation of the upcoming Clinical Trials Regulation. This included formal initiation of the Clinical Trials Regulation programme, which includes 4 projects (Pre-inception; EU Portal and Database, including Workspace; Safety Reporting and EudraCT; and EU-CTR legacy).
- Work on the EU Portal and Database for submission and regulatory management of clinical trials commenced in Q2, following publication of the Clinical Trials Regulation on 27 May 2014. Monthly meetings of the EU Clinical Trial Information System subgroup (composed of representatives of ten Member States) have taken place since January. The first meeting with stakeholders to discuss the requirements for these systems took place in June and the functional specifications were adopted by the EMA Management Board in December.
- A draft proposal for an addendum on transparency to the 'Functional specifications for the EU portal and EU database to be audited' was prepared and shared with the EC and Member States. Public consultation will start in January 2015 and the adoption of the technical addendum by the EMA Management Board is expected in March 2015.
- A business case for safety-reporting was approved in October, following which gathering of the business requirements for SUSAR and annual safety-reporting (in collaboration with Member States, the EC and stakeholders) started. This will be finalised in 2015.
- Business requirements for an enterprise-wide case and workflow management tool were agreed in December, and potential vendors identified.
- The proposal for the establishment of an Ethics Advisory Group was discussed by the CHMP in May/June. A follow-up meeting with CHMP representatives took place in December. Finalisation of the proposal, including agreement on the criteria for selecting members of the Ethics Advisory Group, is expected in 2015.
- Pandemic preparedness plans were put to the test by the Ebola virus crisis, with the EMA acting as a hub for coordination of network and international activities.
- A review of the strategy for rapid responses to pandemic crises started in Q4 2014, including a proposal for enlarging its scope so as to address wider public-health threats.
- In relation to influenza-pandemic preparedness, a draft clinical and non-clinical guideline on influenza vaccines was prepared in the first half of 2014, with the draft guideline released for a six-month public consultation in July. The guideline is expected to be finalised in Q1 2015.

Evaluation activities for veterinary medicines

Pre-authorisation activities

Workload and performance indicators

Workload indicators	Performance indicators
• Scientific advice requests have returned to the 2012 level of activity • Requests for MUMS classification have exceeded the forecast by 61%	Performance indicators on target, with minor deviation in finalising 1 scientific advice procedure

Achievements

- The MUMS policy was reviewed in 2014, including consultation with the CVMP on the refined MUMS criteria. The revised policy was presented and adopted by the Management Board in December.
- With the status of the first MUMS products expiring in October 2014, a review of the classification for MUMS products was started in the first half of 2014. In the absence of a request for renewal, the status of four products was allowed to expire in 2014.
- The EMA Innovation Task Force considered its first 2 veterinary products in 2014, following the procedure being made available to veterinary products in 2013. The number of initial queries received about ITF shows an increasing interest in the procedure.
- The pilot to increase interaction with and provide further support to applicants requesting scientific advice for novel therapies continued in 2014.
- The EMA Management Board endorsed creation of an Ad hoc Expert Group on Veterinary Novel Therapies (ADVENT) at its June meeting. The HMA endorsed the group in July 2014, with a view to the group becoming operational in 2015. The focus of the group will be on generating guidance for applicants seeking to bring to market innovative technologies previously not seen in the veterinary domain.

Initial evaluation activities

Workload and performance indicators

Workload indicators	Performance indicators
• 12 initial applications were received in 2014 (vs the forecast of 18) • New MRL applications, extensions, modifications and extrapolations have remained at the level forecast	Performance indicators on target

Achievements

- In order to embed more clearly the benefit-risk methodology in the assessment process of antimicrobials used in animals, work continued with the Antimicrobials Working Party of the CVMP on a guideline on the benefit-risk assessment of veterinary antimicrobials in 2014. The draft guideline is expected to be adopted and published for public consultation in Q1 2015.

- Work continued on revision of assessment-report templates for veterinary medicinal products, including the review of a dedicated section on benefit-risk assessment. A revised draft was discussed by the CVMP in Q4 2014, and work will continue in 2015.
- A system for routine internal peer-review was implemented in Q4 2014, as part of efforts to increase the quality and consistency of scientific opinions.
- A new approach implemented by the EMA in the evaluation of MRL applications and subsequent MRL recommendations was adopted by the EC in February 2014. The reflection paper detailing this scientific approach will be finalised, taking into consideration the EC's response to an issue related to residue control at national level, raised by one NCA.

Post-authorisation activities

Workload and performance indicators

Workload indicators	Performance indicators
• Number of type I variations increased by 47% vs the forecast, while type II variations exceeded the forecast by 18% (47 vs the forecast of 40)	Performance indicators on target

Arbitration and referrals

Workload and performance indicators

Workload indicators	Performance indicators
• 7 referral procedures were initiated in 2014	Performance indicators on target

Achievements

- Informal procedural advice on referrals to the CVMP was endorsed by the HMA in March 2014.
- CVMP, at the request of the EC, confirmed the risk that exposure to veterinary medicinal products containing diclofenac may pose to vultures and other necrophagous birds and proposed a range of measures to minimise the risk.
- In 2014, 9 referrals relating to antibiotics were completed. Three of these were related to colistin and enrofloxacin, antimicrobials considered particularly important in relation to the risks posed to human health (antimicrobial resistance).
- One referral was completed and one started related to the risk to the environment from veterinary medicines reflecting the increased concern on the impact on the environment of human and veterinary medicines.

Pharmacovigilance activities

Workload and performance indicators

Workload indicators	Performance indicators
• Number of adverse event reports has increased against both the 2014 forecast and	• Performance indicators on target • 97% of PSURs were evaluated within the

Workload indicators	Performance indicators
the results of 2013. • Total adverse event reports have increased by 26%, while AERs for CAPs have seen a 65% increase in 2014 against the forecast (45% increase against 2013)	established timeline, exceeding the target of 90%

Achievements

- As part of deliverables of the veterinary IT and data roadmap, the first EU Veterinary Medicinal Product Database was developed by December 2014, and will be delivered in Q1 2015, encouraging competent authorities to provide outstanding product data and increasing Member States' ability to use existing signal-detection facilities of the central data warehouse.
- IT tools used for pharmacovigilance surveillance were migrated to a new system in July 2014, and the necessary training was provided in Q3 2014.

Other specialised areas and activities

Achievements

- Draft responses to the remaining three of four questions of the European Commission related to the risk to man from the use of antimicrobials in veterinary medicine were finalised and published for a two-month public consultation in August. Final revised answers were adopted by the CVMP and CHMP, and sent to the European Commission in December 2014.
- A methodology to measure the use of antimicrobials was drafted in 2014 and tested throughout the second half of 2014, collecting data from 45 pig farms from 10 volunteer Member States. The methodology will be updated according to the experience gained, and a pilot project to measure the use of veterinary antimicrobials will start in 2015.
- In order to establish technical units of measurement (DDDA and DCDA) for veterinary antimicrobials, data on dosing from 9 Member States was collected during July-August 2014. Preliminary technical units of measurement were established and the first draft principles for assignment of DDDA and DCDA were circulated among the working group in December 2014. Assignment of the technical units of measurement is expected to start in September 2015.
- In order to facilitate the supply of data to the ESVAC database, work started on development of an IT solution for web-based collection of data in January. The web-based tool for data collection was tested in Q4 2014, with the pilot use of the system starting in 2015.
- A progress report on TransAtlantic Task Force on Antimicrobial resistance (TATFAR) work was published in May, recording good progress in 15 out of 17 recommendations, and the addition of a new recommendation to identify knowledge gaps in the area of limiting transmission of resistance from animals to man.
- A VICH revised guideline on the safety of veterinary drug residues in human food was adopted by the CVMP in November. A VICH draft guideline on electronic exchange of documents was released for a four-month public consultation in March, and is expected to be finalised in Q1 2015.

Horizontal activities and other areas

Committees and working parties

Workload and performance indicators

Workload indicators	Performance indicators
• Workload indicators related to committees and working parties have slightly exceeded the 2014 forecasts	• Performance indicators on target • 87% of delegates were satisfied with the service level provided by the secretariat, exceeding the target of 80%

Achievements

- The centralised Committees Secretariat for human medicines was established in April 2014, along with the Experts and Declarations of Interests Management Team. A Scientific Coordination Group to support the Scientific Coordination Board was also formed.
- As part of harmonising administrative processes of the Committees Secretariat, a best-practice guide for the organisation of committee meetings, harmonised templates for committee agendas and minutes, and a DoI-tracking tool and membership checklist were developed in December 2014.
- Work on establishing a coordinated secretariat for the working parties started in Q3, with implementation foreseen in 2015.
- The mandate of the Inter-committee Oncology Scientific Advisory Group started in July 2014. The new group held three meetings in 2014, with two of these initiated by the PRAC. Analysis of the results of this initiative will be carried out in July 2015, after one year of operation.
- The revised EMA policy on handling of declarations of interests of experts was adopted by the Management Board in March 2014 and published on the Agency's website in November, with 30 January 2015 as its implementation date. The e-DoI form and the related guidance documents were updated in line with the revised policy, and published in November. All European experts were requested to submit an up-to-date e-DoI by January 30, 2015.

Inspections and compliance

Workload and performance indicators

Workload indicators	Performance indicators
• GMP and pharmacovigilance inspections have exceeded the forecasts by 17% and 43% respectively, with a total of 20 pharmacovigilance inspections conducted in 2014 • No GLP inspections were requested in 2014 • Number of quality defects reported has reduced by 18% both, vs the 2014 forecast and last year's results • Urgent certificate requests have exceeded the forecasts by 19%, reaching a total of 535	• Only 30% of standard certificates were issued within the timeline of 10 working days. Average time to issue standard certificate in 2014 was 13.7 days • 97% of parallel distribution notifications were checked for compliance within the standard timeline • Additional 29% of GCP inspections and additional 8% of routine re-inspections of manufacturing sites were addressed through information exchange with international

Workload indicators	Performance indicators
requests • Parallel distribution notifications of change continue to diminish (results reached 80% of the 2014 forecast) due to introduction of the annual updates procedure	partners • Other key performance indicators on target

Achievements

- The EMA–FDA initiative on exchange of information on GCP inspections was extended to generics, starting January 2014. A first joint GCP inspection on generics took place in September/October 2014.
- In November, the Agency, in collaboration with the ANSM (Agence nationale de sécurité du médicament et des produits de santé), held a Bioequivalence Forum dedicated to senior GCP inspectors, and a bioequivalence inspections basic training course to train new EU BE inspectors. The WHO also participated in these two events.
- The EMA, together with the GCP IWG, developed an online basic training course for GCP Inspectors, accessible to the EU Network via EudraPortal and to non-EU GCP inspectors via secure links. The first webinar took place on 27 June and, following positive feedback from the participants, another webinar was held later in the year.
- The annual GCP IWG workshop, with an extended invitation to the international GCP inspectors' network, was held in November.
- The EMA also participated in the APEC LSIF MRCT/GCP inspections workshop in May.
- A draft proposal for the visiting experts' training programme was being developed in 2014.
- To improve public information on GCP inspections, a proposal on publication of GCP/PhV/GLP inspections that also harmonises the information on GCP inspections in the EPAR was prepared in January.
- A draft concept for a joint pharmacovigilance inspections programme with the FDA was developed in November. The concept will be further discussed in 2015 and the pilot will be initiated once agreement is reached.
- Procedures for inspections of wholesale distributors and EU-based manufacturers, importers and distributors of active substances were developed. However, in December 2014, the GMDP IWG decided to delay implementation of these procedures, in order to assess and address their impact on the corresponding GMP procedure (on serious GMP non-compliance requiring coordinated measures to protect public or animal health), which was published in December 2014.
- The Agency oversees development of the plan to address medicines shortages due to manufacturing issues (through receiving regular progress updates from industry associations). In 2014, industry associations prepared their implementation plans to address the medicines shortage issue, and a report on the work done is planned to be discussed in detail in Q1 2015.
- The revised procedure for dealing with serious GMP non-compliance requiring coordinated measures to protect public or animal health was sent to the EC in June and published in the 'Compilation of Community Procedures on Inspections and Exchange of Information' in December.

- Additional information was provided to the Japanese authorities throughout 2014 to support the EC initiative to expand the mutual recognition agreement to sterile and biological medicinal products and active pharmaceutical ingredients.
- A workshop for quality-defect contact points took place in June 2014. Three working groups were formed to explore the three key areas in international cooperation of managing quality defects: communication, cooperation and coordination. Other potential improvements to the EU system for managing defects were identified at the workshop and considered by the GMP/GDP IWG in September.
- Meetings with various parallel distribution companies were held throughout the second half of 2014, with a meeting with the parallel distribution association expected in early 2015.
- A Quality by Design workshop took place in February and a workshop on quality defects was held in June. The pharmacovigilance IWG training took place in October.
- The Agency is cooperating with the EC and Member States to implement the provisions of the Falsified Medicines Directive regarding identification of authorised internet pharmacies. This includes development and introduction of a logo (in June) and conducting awareness campaigns.
- A checklist on risk indicators for shortages (manufacturing and quality) for assessors to use during the assessment of MA applications in order to identify potential future supply risks was agreed with the BWP and QWP in January. Discussions on the best approach to introduce the checklist into Day-80 quality assessment reports took place in 2014, with the agreement expected in early 2015.

Partners and stakeholders

Workload and performance indicators

Workload indicators	Performance indicators
• Rate of SME status renewals is slightly lower than forecast, with 81% of the forecast achieved in 2014 • Access-to-documents requests exceeded the forecast by 19%, showing a near-60% increase over 2013 results • Number of pages released has also increased significantly (67% increase) against the forecast for 2014	n/a

Achievements

- In order to set up the EU Network Training centre, the mandate of the Training Centre was endorsed by the Agency management team in March and by the HMA in May. The vision, road map and project plan of the Training Centre were endorsed by the EMA and HMA in November.
- The first EU Network Training centre training champions' workshop was held in September, to identify and agree common needs for scientific and regulatory training. The list of training needs and offers per NCA, and the guideline for training budget allocation and reimbursement of scientific and regulatory training events for the EU network were endorsed by the Training Steering Group in December 2014.

- To prepare for the future revision of the general fee legislation, a Management Board Steering group was created in the first half of 2014, involving representatives of the European Commission, the EMA and the Member States. Analysis of the tasks and activities of the EMA and the NCAs was started, identifying 19 fee-generating and 12 non-fee-generating major activity areas where further data collection is required.
- Scientific advice and protocol assistance was chosen as a pilot procedure to test and validate the data-collection methodology, with the planned pilot start date in January 2015.
- A framework for interacting with pharmaceutical industry organisations was developed and discussed by the Management Board in December 2014. Following a formal consultation with the Commission, the framework is expected to be adopted by the Management Board in Q2 2015.
- The revised framework for interaction with patients'/consumers' organisations was adopted by the Management Board in December 2014.
- The first annual report on the EMA's interaction with patients, consumers and healthcare professionals was presented to the EMA Management Board in October.
- The EMA policy on publication of clinical data was endorsed by the Management Board at its October meeting and was published on the Agency's website, along with the questions-and-answers document. The policy will come into force on 1 January 2015.
- The process for handling requests for access to documents was reviewed in the first half of the year. As part of this exercise, a centralised team to coordinate ATDs and manage RFI requests was established, and an ATD public guide was prepared and published in November. The AskEMA IT tool was implemented to help manage ATD/RFI process.
- The EMA chaired the VICH international conference in Brussels in June 2014.
- As part of the measures delivered by the Agency, training activities on bioequivalence and for assessors in the Environmental Working Party were delivered in relation to veterinary medicines.
- Support relating to the reform and reorientation of ICH governance and scientific harmonisation activities was provided to the EC in ICH and IPRF meetings in the US in June and November 2014.
- As part of the support to the EC on scientific and technical aspects of trade negotiations with third countries, the EMA participated and provided input in TTIP meetings in Brussels, as well as FTA and CETA discussions.
- To develop further Article 58 activities, rules for involvement of WHO experts and observers in Article 58 procedures were finalised and implemented in June 2014.
- A project to develop a new EMA extranet (to facilitate cooperation with delegates and other NCA groups) was started in August 2014. The initial research phase with the users was completed by the end of 2014, and the project entered the design stage.
- The proposal to establish a web managers' network with Member State authorities was discussed at the Working Group for Communications Professionals.
- Work to review the process for coordination of medicines information, especially safety information, started in Q2. The GVP module XV on safety communication was revised in 2014, and the draft is expected to be released for public consultation in Q2 2015.
- Surveys relating to coordination of medicines information were sent to the Member States in June. Drafting the report began in 2014, and the final report is expected to be presented to the PRAC

and EMA Management Board in the second half of 2015, following the EMA communication perception survey in Q2 2015.

Data management support

Workload and performance indicators

Workload indicators	Performance indicators
n/a	• 15% of substance and referentials data were registered within 24 hours, and 18% of the data were registered in 48 hours in 2014 • Stakeholder survey was not carried out in 2014

Achievements

- Internal (EMA) and external with NCAs (EU Network) Data Boards were created in Q1 2014. A forum with industry (i.e. ISO IDMP Taskforce) is expected to be created in Q1 2015, completing the data-governance structure that includes the Agency and its partners and stakeholders, and allows for a more encompassing data management.
- The centralised substance-management service has been operational since Q1, following the completion of the IT solution for the Substance Management Service in January. A data-management service for products and organisations will be developed in 2015.
- The operating model for business data and support processes was approved in September.
- Based on the analysis done in the first half of 2014, and considering the chosen solution for the data-management system, the EMA was preparing a data-integration roadmap for the next 3-5 years in 2014. The draft roadmap is expected to be approved in early 2015. The roadmap will focus on two main areas: master-data management and data-quality management.
- Preliminary analysis of the opportunities to use centralised services for collection and maintenance of data related to veterinary medicines was conducted in the second half of 2014, revealing benefits of common data-management services for veterinary referentials, organisations and substances.

Process improvements

Workload and performance indicators

Workload indicators	Performance indicators
n/a	• 100% of the targeted procedures were reviewed in 2014, exceeding the goal of reviewing 80% of regulatory procedures

Achievements

- By the end of 2014, all procedures within the scope of the Agency's efficiency improvement programme were redesigned and consultations with NCAs were completed, with the exception of the referrals and renewals procedure, where NCA consultation is expected to be finalised by Q1 2015.

- The reviewed processes were implemented for variations, MA transfers, PSURs/PSUSAs and PASS in the first half of the year, and for initial MAAs, EPARs, paediatrics, signal management and inspections in the second half of 2014. Implementation of the redesigned processes continues for scientific advice, orphans, referrals and renewals, and is expected to be completed by Q3 2015.
- In order to extend the benefits of Agency-level centralised services to procedures related to authorisation of veterinary medicines, the changes required for centralisation of the fees were being implemented in 2014, with finalisation expected in Q2 2015.
- Defining key performance indicators for each procedure started in Q4 2014 and is expected to be finalised in the second half of 2015.
- An evaluation of the redesigned processes started in Q4 2014 and will continue until Q3 2015, to review whether additional optimisation activities are needed.

Support and governance activities

Workload and performance indicators

Workload indicators	Performance indicators
n/a	• 46% of critical and 50% of severe IT issues were resolved within the set time (target: 80%) • 91% and 99% of important and minor IT issues (respectively) were resolved within the set time, exceeding the target of 80% • 23% of total commitments within Title 2 were carried over to 2015 • Other key performance indicators on target

Achievements

- The project to relocate the Agency to new premises was completed according to plan. The fit-out of the new premises was completed in the first half of the year and the pilot move was carried out on 16 June. Premises were practically completed on 1 July, as planned. The first move took place on 2 July and the final move was completed on 30 July, with the Agency fully relocated on 1 August.
- In order to increase the efficiency of project management, control and delivery at the Agency, a new project governance structure was put in place and a Programme Management Office was established in April 2014.
- Following the staff engagement survey that was carried out in October 2013, the results were presented to the Agency management in Q1. The action plan stemming from the survey results was presented to the management, and implementation of a series of actions started in Q3, including a team briefings pilot, vision and values deployment, and the annual appraisal exercise.
- An inter-agency benchmarking report and further recommendations were presented to senior management in October 2014. As a result, further analysis of survey results will be carried out in Q1 2015, in order to better understand the issues and fine-tune the next steps of the action plan for implementation before the next staff engagement survey in November 2015.

- Following an extensive bottom-up exercise involving all staff of the Agency, a set of core EMA values was selected in February. The new core values were launched in May, and the activities to embed the values throughout the organisation (staff workshops) started in Q3. Embedding the values in the Agency's processes started in Q4.
- An exercise on best-practice benchmarking within the European medicines regulatory network (BEMA III) began in early 2014. The self-assessment was finalised in Q2, followed by the assessors' visit in September. The Agency received a high range of best ratings, identifying it as an effective driving agency in its coordinating role in the EU network.
- An audit on the quality system of the pharmacovigilance system was conducted in March, and the final report released in May. An audit on SAP took place in May, with the final report released in July. Audits on record management and MRLs took place in October and November 2014, respectively. The final reports for these two audits will be released in Q1 2015.
- A project to develop a prototype of a new EMA intranet (to support staff and management communications) was started in August 2014. The initial research phase with users was completed by the end of 2014, and the project entered the design stage.
- As part of the review of regulatory content on the EMA public website, the paediatrics section was re-written in July 2014 and provided to the content owners for review and comments.
- In order to streamline the Agency's web-publishing processes, a proof-of-concept for the new web-publishing software was conducted in 2014.
- The existing social media strategy was updated to take into account the new corporate website requirements. Development of an appropriate search engine marketing strategy was postponed to 2015, in order to account for the requirements emerging for the European medicines web portal.
- To reinforce the Agency's media relations, existing press distribution lists were reviewed in the first half of 2014, to identify gaps in media contacts in individual Member States. New media contacts were gradually introduced after verification by the Member States, resulting in an active press distribution list of over 2,500 journalists by the end of 2014.

2. Governance, management and control systems

This section broadly describes the main characteristics of the Agency's organisation and administrative structure, reports on major internal and external events during the reporting year, and gives an overall picture of the implementation of sound management at the Agency.

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU with the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The Agency works with the Member States' national competent authorities (NCAs), which provide scientific experts for the work of EMA scientific committees and working parties, and rapporteurs and co-rapporteurs in assessments of applications.

The main Agency partners include the European institutions, NCAs, EU regulatory agencies and international health authorities. Stakeholders include patients, healthcare and veterinary professionals, and industry associations.

In 2014, seven scientific committees conducted the main scientific work of the Agency, some of which are supported by several working parties and scientific advisory groups:

- Committee for Medicinal Products for Human Use (CHMP)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)
- Committee for Advanced Therapies (CAT).

These committees normally meet on a monthly basis, and are mostly comprised of members nominated by the EU Member States. Assessments are based on scientific criteria, and determine whether or not the medicines concerned meet the necessary quality, safety and efficacy requirements, in accordance with EU legislation. These processes ensure that medicines have a positive benefit-risk balance in favour of patients and users of these products once they reach the marketplace.

2.1. Governance of the European Medicines Agency

2.1.1. Executive Director

The 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.

2.1.2. Management Board

The Management Board is the Agency's integral governance body. It has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.

The 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 2014, significant items adopted or endorsed by the Management Board were:

- Annual report 2013
- Analysis and assessment of the Executive Director's annual activity report 2013
- Opinion on the Agency's annual accounts for the financial year 2013
- Amending budget 01-2014
- Amending budget 02-2014
- Preliminary draft work programme 2015
- Work programme 2015-2016
- Preliminary draft budget and establishment plan 2015
- Draft budget and establishment plan 2015
- Resource programming 2016
- Preliminary draft budget and establishment plan 2016
- Revised implementing rules to the Fee Regulation as of 1 April 2014
- PSUR single-assessment procedure for nationally authorised products (NAPs)
- Draft revised EMA policy on the handling of declarations of interests of scientific committees' members and experts
- Addendum to Cooperation Agreement between the EMA and NCAs
- Revised rules for reimbursement of delegates and experts attending meetings
- Harmonisation of payments to NCAs for applications with fee reductions
- Telematics strategy
- EMA policy on the publication of and access to clinical-trial data
- Clinical Trials Portal and database functional specifications
- EMA anti-fraud strategy
- Proposal for the establishment of an Ad hoc Expert Group on Veterinary Novel Therapies (ADVENT)
- Fourth annual report on the veterinary MUMS/limited-market scheme
- Revised policy for MUMS/limited market
- Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA eligibility

- Joint annual report on the interaction with patients', consumers' and healthcare professionals' organisations
- Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations
- Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency activities
- Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency activities
- Mandate for the Executive Director to sign the lease and all associated documents for 30 Churchill Place
- EMA internal audit charter.

Furthermore, in March 2014 the Management Board established a steering group on the data-gathering initiative to collect evidence needed by the European Commission in drafting the future legislative proposal on fees. (see section 2.2.5.)

2.1.3. Strategy Board

The Strategy Board is a governing body that considers long-term strategic issues of the Agency. These include setting the strategy, priorities and strategic goals, assessing new legislation and its impact, and making policy and resource decisions.

The Strategy Board is chaired by the Executive Director (Deputy Executive Director in his/her absence) and consists of the:

- Deputy Executive Director
- Principal Adviser in Charge of Strategy
- Chief Policy Adviser
- Senior Medical Officer
- Head of Programme Design Board
- Head of Corporate Governance Department
- Head of Legal Department
- Head of International Affairs
- Heads of division
- Deputy heads of division

2.1.4. Executive Board

The Executive Board (EEB) is a decision-making body. It decides on horizontal operational matters such as implementation of strategy, planning, project approval and implementation, project pipeline, and work programme monitoring, as well as finance, HR, KPIs, risk and audit reporting. The EEB also decides on critical operational divisional/departmental issues that require escalation.

The Executive Board is chaired by the Executive Director (Deputy Executive Director in his/her absence). The EEB is composed of the Strategy Board members and, depending on agenda topics, also includes:

- Head of Communication
- Head of Audit
- Head of Management Board and HMA Service
- Head of Internal Corporate Relations.

Heads of department can join the meetings and participate in the discussions of topics relevant to their field.

2.1.5. Human Medicines Leadership Team

The Human Medicines Leadership Team (HMLT) is the key governance and decision-making body of the human medicines operational divisions. It considers product-related issues (pre-PRAC or pre-CHMP), as well as organisational, procedural or regulatory matters.

The HMLT is comprised of:

- Heads of human medicines divisions
- Heads of department within the above divisions.

Advisory functions and product or project team members are invited to attend, depending on the topics discussed. The Veterinary Medicines Division participates in discussions on topics of common concern.

2.1.6. Management meetings

Management meetings are called to ensure communication and feedback across the Agency on various issues, including strategic and operational matters, business priorities and performance.

Management meetings comprise the whole management team of the Agency — the Strategy Board members, heads of department and managers of services/offices.

2.1.7. Programme governance bodies

The Programme Design Board (PDB) is in charge of the oversight and review of the initial phases of any project of the Agency. The PDB has particular responsibility for improved quality, efficiency and effectiveness of the Agency's procedures and processes.

The Programme Implementation Board (PIB) is responsible for programme prioritisation and portfolio management, including planning, monitoring and reporting activities in relation to programmes and projects. The PIB reports to the EEB on a quarterly basis.

The PIB is chaired by the Deputy Executive Director and consists of:

- Accountable executives of the programmes in the Agency's portfolio
- Head of Information Management Division
- Head of Programme Design Board
- Head of Corporate Governance Department.

2.2. Major events in 2014

The year 2014 was once more characterised by great changes, repeatedly demonstrating the ever-changing nature of the environment in which the EMA operates, continuously presenting the Agency with new challenges.

2.2.1. Decision of the Civil Service Tribunal

On 13 November 2014, the European Union Civil Service Tribunal gave a judgment that annulled, on formal grounds, the 2011 decision of the Agency's Management Board to appoint Guido Rasi as the Executive Director of the Agency.

The Deputy Executive Director took over responsibility for the management and operations of the Agency. Although the judgment had no immediate effect on the EMA's day-to-day operations, the sudden loss of its Executive Director had an impact on many of the Agency's strategic initiatives. The lack of leadership to help shape the future in medicine regulation was felt by partners and stakeholders, both inside and outside the European Union. Preparations for the launch of a new recruitment procedure were initiated by the end of 2014 and are expected to result in an appointment of the new Executive Director in the second half of 2015.

2.2.2. Move to 30 Churchill Place

In August 2014, the Agency moved to its new offices at 30 Churchill Place in Canary Wharf, London.

The new premises occupy a total surface area of approximately 23,500 square metres and include six floors of offices, as well as two floors of conference rooms to host the over 1,000 meetings organised each year with thousands of scientific experts from across the EU, as well as other Agency stakeholders. It also includes a dedicated working area for industry representatives.

The building includes many environmentally friendly features, such as photovoltaic (or solar) cells and a 'green' roof to enhance biodiversity. It achieves a new standard for environmental performance and energy efficiency in London, and the design was awarded an 'excellent' rating according to the Building Research Establishment Environmental Assessment Methodology (BREEAM).

2.2.3. Creation of the Stakeholders and Communication Division

In August 2014, the Agency created a new Stakeholders and Communication Division. The new division is responsible for ensuring that the Agency has a coherent, coordinated and consistent approach to stakeholder and partner relations management and communication. The new division reflects the increasing demand for transparency and information, knowledge and data about medicines, as well as an expectation from stakeholders that information is tailored to their needs.

The division manages relations with and provides information to patients and healthcare professionals, coordinates medicines information in the European medicines regulatory network and manages the Agency's online presence, external communication and press relations, as well as the EMA Information Centre. The division also manages relations with the pharmaceutical industry, and provides support to micro, small and medium-sized enterprises (SMEs) through its SME Office.

2.2.4. Updates on the IT Division

At the request of the Agency, in 2013 the IAS conducted a consultancy engagement to review the management and control systems related to IT project management.

The consultancy report, received by the Agency on 27 March 2014, showed weaknesses in several areas of IT project management, governance, and design of the IT project management framework and internal control.

The Agency implemented several changes, including the establishment of a new structure for programme and project management, the reassignment of accountability for programmes to business, and the transfer of budget accountability in order to increase business involvement in ownership of projects.

Independently from the IT consultancy engagement, the Executive Director had informed OLAF about certain alleged conflicts of interests concerning three contractors providing services to the IT Division. The OLAF investigation on this matter is ongoing. To the best of our knowledge, no individuals other than the above-mentioned three contractors are affected by the OLAF investigation.

Additionally, in order to increase efficiency, management changes in the IT Division were implemented.

2.2.5. Data-gathering initiative

At its March 2014 meeting, the Management Board established a steering group for the data-gathering initiative. The objective is to gather the evidence needed by the European Commission in drafting the future legislative proposal on fees.

The steering group is composed of representatives of the European Commission, Member States, the EMA and civil-society representatives at the Management Board. It was decided that the methodology should capture time spent on activities, rather than their financial cost. At first the initiative will be started around human data only, and then extended to veterinary data, once the methodology is proven to be stable.

The approach to data gathering is based on an initial, exhaustive mapping of all EMA 'non fee' and 'fee' generating activity areas. In the absence of robust and auditable historic data, the steering group considered a prospective data-collection approach, where time spent on each product/procedure by NCA experts and EMA staff will be collected and analysed. Where needed, this approach could be supplemented with retrospective data.

At its December 2014 meeting, the Board agreed to the start of a pilot to validate the time-collection methodology agreed by the steering group, and collect feedback on operational feasibility. The pilot is due to start in February 2015 on scientific advice procedures.

2.2.6. EMA anti-fraud strategy

In December 2014, the Management Board adopted the EMA anti-fraud strategy. The strategy is developed within the framework of the European Commission's Common Approach on EU decentralised agencies, which requires a set of anti-fraud measures to be put in place, with the aim to improve the efficiency, transparency and accountability of the agencies. This is an additional building block against fraud and illegal activities, complementing the several existing policies, such as the code of conduct, breach-of-trust policies, and transparency on declarations of interests. With the adoption of this strategy, the Agency aims to develop further the anti-fraud culture, deterring and preventing fraud.

The scope of the anti-fraud strategy does not encompass 'regulatory fraud' (e.g. the intentional submission to the Agency of manipulated or false data for regulatory purposes), which is dealt with through other mechanisms (e.g. inspections). However, a possible widening of the scope so as to include this type of fraud will be reconsidered in the future.

2.2.7. EU Telematics Programme

A revised governance structure for EU Telematics approved by the Heads of Medicines Agencies and the EMA Management Board in spring 2013 was fully implemented in 2014. The new governance structure provides a framework to foster collaboration across the European medicines network and to maximise efficiency of communication around the development and operation of IT for the network. The new governance body is the EU Telematics Management Board, which provides the vision and strategic oversight of the EU Telematics Programme and its implementation, together with the IT Directors Group, Telematics Enterprise Architecture Board and EU Network Data Board.

A decision was taken to involve industry stakeholders in EU Telematics by inviting them to an annual meeting of the EU Telematics Management Board to consult on the strategy and plans. Industry will not be involved in decision-making, but will participate in the consultative groups as appropriate for each programme/project or maintenance group.

A new strategy for the future of EU Telematics was agreed by the EU Telematics Management Board and endorsed by both the EMA Management Board and Heads of Medicines Agencies. This strategy is a result of joint work between the members of the network and describes how the vision for EU Telematics will be delivered through a set of projects and programmes that address the IT needs of the network.

In addition, more detailed strategies, such as the IT and Data Strategy for Veterinary Medicines and HMA eSubmission Roadmap, have been developed within the overall framework of the Telematics strategy and adopted by the EU Telematics Management Board.

The EU Telematics strategy is intended to be delivered by cooperation between the partners of the network and in consultation with stakeholders. It includes the objective of providing a structured approach for partner and stakeholder interaction and offering greater certainty on the timelines for developing new telematics systems.

A number of benefits were realised with a delivery of EudraCT (Clinical Trials) v9.1 and v10, eSubmission Gateway v3 go-live, Common Repository go-live, Substance Management Service v1, eAF (electronic application forms) releases and ADR (adverse drug reaction) reporting, including for nationally authorised products.

2.2.8. Benchmarking of European Medicines Agencies (BEMA) visit

An exercise on best-practice benchmarking within the European medicines regulatory network (BEMA III) was carried out in 2014. The Agency completed the self-assessment in the first half of the year, sending the self-assessment report to the BEMA assessors in June.

The BEMA assessors' team, composed of representatives of national competent authorities (PEI of Germany, MHRA of the UK and FIMEA of Finland), visited the Agency in September to assess the Agency's activities against the BEMA criteria. The EMA received a high range of best rankings, identifying it as an effective driving agency in its coordinating role in the EU network.

2.3. Financial reporting

2.3.1. Initial budget and amending budgets

The European Medicines Agency's revenue consists of contributions from the general budget of the European Union (general EU contribution and special EU contribution for orphan medicinal products), fees for applications, and other revenue (administrative charges etc.).

Authorised appropriations in the Agency's initial budget for 2014 totalled EUR 297,169,000. Two amending budgets were introduced in 2014 to account mainly for a decrease in revenue from services rendered and a decrease in the EU contribution requested, the final revenue (as per the provisional accounts) was EUR 271,785,929.76, which represent a 13.1% increase over the 2013 final revenue of EUR 240,387,264.66.

2.3.2. Revenue

Revenue entered in the accounts as at 31 December 2014 amounted to a total of EUR 271,785,929.76.

Of total revenue, 80.09% was derived from the evaluation of medicines and other business-related activities, 12.53% from the European Union budget to fund various public-health and harmonisation activities, and 6.96% from externally assigned revenue as described in the work programme (2013: 82.97%/17.03%/0.00%).

2.3.3. Expenditure (commitments and payments)

Commitments totalled EUR 266,419,810.75, or 94.32% of final appropriations (2013: 96.76%). Payments totalled EUR 219,262,042.99, or 82.30% of commitments entered into (2013: 86.28%).

2.3.4. Carry-over from 2014 to 2015

Automatic carry-over to financial year 2015 totalled EUR 47,157,767.76, or 17.70% of appropriations committed (to 2014: 13.72%). There was no non-automatic carry-over to financial year 2015.

2.3.5. Carry-overs from 2013 to 2014

Automatic carry-overs to financial year 2014 totalled EUR 33,398,987.91. Payments against the carry-overs equalled EUR 32,063,693.85, or 96.00% (2013: 96.04%). The value of appropriations cancelled was thus EUR 1,335,294.06.

2.3.6. Appropriation from assigned revenue

The Agency introduced assigned revenue in 2014 in order to manage the inducements received in the context of the project to construct, fit out and occupy its new headquarters. For consistency, grants received from external sources to fund various scientific and regulatory projects were also managed as assigned revenue.

In 2014, an amount of EUR 18,758,206.72 was recognised as assigned revenue related to the project for the new headquarters. This amount was partly consumed by outstanding fit-out costs in 2014 as well as carry-forward to 2015 to cover the remaining fit-out cost. Additional assigned revenue will cover part of the fit-out costs for the 10th floor of the new headquarters and the rent for the premises in 2015, 2016 and part of 2017.

Grant-related assigned revenue recognised in 2014 amounted to EUR 145,992.11. This covered a varying part of the expenditure related to the Agency's activities on certain projects. The Agency's input to these projects is mainly human resources, with some duty travel and meeting activity also taking place.

2.3.7. Transfers

In line with Article 27(1) of the Financial Regulation, the Executive Director may make transfers within a title and up to 10% of appropriations from one title to another. Transfers *per se* are not an indicator for deficiencies in financial management but a necessary tool to adjust the budget in a changing environment, e.g. 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 2014, nine transfers were made. All were adjustments within the limits of Article 27(1) of the Financial Regulation and approved by the Executive Director. They totalled EUR 19,755,000, or 6.99% of final appropriations (2013: nine transfers totalling EUR 29,811,800.00, or 11.85% of final appropriations).

The transferred appropriations were primarily used for expenditure on business IT development, rapporteur payments and other adjustments to administrative budget items.

2.3.8. Cancellations

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

For budget 2014, expenditure appropriations totalling EUR 16,054,189.25 remained unused (cancelled), corresponding to 5.68% of final appropriations (2013: EUR 8,140,571.11; 3.24%).

These cancellations have to be seen in correlation with the EUR 10,688,070.24 revenue appropriations remaining uncollected at year-end, thus creating a positive overall outturn balance (before adjustments for exchange rate, cancellations of carry-over, etc.) of EUR 5,366,119.01, or 1.90% of final appropriations (2013: -3,032,164.23; -0.01%).

2.3.9. Payment of interest on late payments

In accordance with the Agency's standard contract, Article 77 of the Financial Regulation, 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%[1]. The default interest accrued is paid automatically if it amounts to more than EUR 200.

In 2014, 718 payments out of a total of 47,663, i.e. 1.51% of all payments, were made later than 30 days after receipt of a valid invoice (2013: 1.77% of all payments). This resulted in default interest of EUR 21,726 being paid to suppliers and contractors and EUR 1,225 to national competent authorities (NCAs).

2.4. Human resources needs

In January 2014, the EMA had initially requested a total of 636 posts to phase in the posts agreed for the implementation of the pharmacovigilance fee regulation. This request was reduced to 599 posts for the March 2014 Management Board upon the instruction of the European Commission and in line with

[1] 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.

DG Budget's long-term financial perspective. In the submission for the general budget applicable to the Union for the EMA's EU contribution and posts 2015, the European Parliament provided for the EMA request of 636 posts, while the Commission supported maintaining 599 posts.

In mid-2014 the legal service of the European Parliament clarified that the approach taken by the European Commission in reducing the posts for all EU agencies by 10% over 5 years was not in line with the budgetary authorities' request, and each Agency's staffing needs shall be evaluated separately. In the EU budget negotiations for 2015, the European Parliament supported an increased establishment plan for EMA to 636 posts; however, the version adopted maintains the number of posts at 599 (Annex 4).

2.5. The Agency's internal controls

Internal controls are broadly defined as processes intended to provide reasonable assurance to the management on the achievement of the Agency's objectives. More specifically, internal controls are all the measures that the management takes to ensure that:

- operational activities are effective and efficient;
- legal and regulatory requirements are met;
- financial and other management reporting is reliable;
- assets and information are safeguarded.

To assist the Executive Director in implementing internal controls, the Agency has adopted a set of internal-control standards (ICS). These standards are intended to guarantee a consistent level of internal control of all business activities throughout the Agency, and define the management rules that all services must follow in their management of resources.

Compliance with internal-control standards

The Agency has assessed the effectiveness of its key internal-control systems during the reporting year. Findings of the review demonstrated that the Agency's internal controls have performed well during the year, and there has been no control failure exposing the Agency to the identified risks.

The management has reasonable assurance that appropriate controls are in place and are working as intended, risks are mitigated and monitored, and improvements are being implemented.

Tangible improvement was made in 2014 in the following areas:

- ethical and organisational values;
- staff allocation and mobility;
- staff evaluation and development;
- document management.

The standards that will require particular attention were also highlighted by the analysis. These will be prioritised in 2015, and include:

- objectives and performance indicators;
- operational structure;
- information and communication.

The state of implementation of all standards in 2014 and the actions planned for 2015 can be found in Annex 7.

2.6. Management of conflicts of interests

2.6.1. Procedures for the handling of declared interests of scientific-committee members and experts

In November 2014, the Agency published its revised policy on handling of declarations of interests of scientific committees' members and experts. The revisions reflect a more balanced approach to handling conflicts of interests and aim to effectively restrict the involvement of experts with possible conflicts of interests in the Agency's work, while maintaining the EMA's ability to access the best-available expertise. The revisions took into account the experience gained with the policy since its last revision, in 2012, and the outcome of the EMA public workshop on conflicts of interests, held on 6 September 2013.

The revised policy was endorsed by the Management Board in March 2014, and includes a number of measures that better 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 medicinal product during previous employment with a pharmaceutical company now results in a lifetime non-involvement with the concerned company or product.
- 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, restrictions remain as before, with no cooling-off period required when the interest is no longer present.

The revised policy entered into force on 30 January 2015.

All EMA scientific-committee members and experts were required to submit their updated declarations of interests by the end of January 2015.

The declarations of interests, their assigned interest level and the curriculum vitae of all experts are published on the Agency's website for transparency purposes. The outcome of the evaluation of declarations of interests and restrictions applicable to meeting participation are included in the meeting minutes.

A breach-of-trust procedure for scientific-committee members and experts is in place. No breach-of-trust procedure for scientific-committee members or experts was launched in 2014.

2.6.2. Systematic ex ante – ex post controls on electronic declarations of interests

A systematic ex ante control on electronic declarations of interests (e-DoI) has been performed for all newly appointed experts since June 2013. The control verifies whether information in the e-DoI submitted by the expert was entered in the correct sections of the form and hence if the interest level that was automatically assigned to the e-DoI was correct. In 2014, 640 e-DoIs have been checked. For three experts (0.5%), a minor error was noticed in the e-DoI, i.e. an interest was declared

unnecessarily. Updated e-DoIs were submitted with a lower interest level than the original e-DoI. For 13 experts (2.0%), a clarification on interests declared in the e-DoI was requested. In four cases, the expert submitted an updated e-DoI with the same or a lower interest level.

The Agency has performed ex post controls on handling of conflicts of interests since 2012.

The 2013 ex post control focused on the key aspects of the process of handling the conflicts of interests of experts: correct completion of the e-DoI by the expert, correctness of the information included in the e-DoI by the expert versus the previous e-DoI, correct evaluation of the declared CoIs by the Agency, and correct implementation of restrictions applicable to the expert for scientific meetings by the Agency. A sample of 305 experts was checked. The report was finalised in January 2014 and included the following findings: 0.7% of the experts (2 out of 305) did not declare an interest in the appropriate section of the e-DoI; 0.4% of the experts (1 out of 305) did not declare all interests from their previous e-DoI in the e-DoI applicable to the meeting; 13.8% of the evaluations (8 out of 58) were not recorded in the DoI evaluation form, but in another document; 20.0% of the evaluation forms (10 out of 50) contained minor errors with no impact on the evaluation; 6.0% of the evaluation forms (3 out of 50) contained errors with impact on the evaluation. For none of these findings was there an impact on the Agency's activities in which these experts participated. Conflicts of interests were a standard topic on the agenda and the minutes of all checked meetings, but were not recorded as such for three meetings. For meetings where restrictions were applicable to experts, the reporting regarding conflicts of interests was either minimal or more elaborate.

In 2014, the ex post control focused on two key aspects of the process: the correct evaluation of e-DoIs of experts as performed by the meeting secretariats and the correct implementation or restrictions applicable to experts in meetings by the secretariats. A sample of 75 committee members and experts participating in a scientific meeting between 1 January 2014 and 30 June 2014 were checked. No major findings were found on the e-DoI evaluation and application of restrictions. As a minor finding, it was noted that not all secretariats use the DoI evaluation form as foreseen in SOP/EMA/0126. However, in all cases, the outcome of the DoI evaluation was recorded in detail in a tracking tool.

2.6.3. Procedures for the handling of declared interests of Management Board members

The EMA policy on the handling of conflicts of interests of the Management Board members came into effect on 3 April 2012. The policy will be revised in 2015 after the ongoing revision of the policy for scientific-committee members and experts.

No breach-of-trust procedure for members of the Management Board was launched in 2014.

2.6.4. Procedures for the handling of declared interests of EMA staff

The EMA has in place implementing rules to reinforce a systematic approach to assessing declared interests of staff, and to provide the required assurance to stakeholders and the public. These rules were amended following the reform of the Staff Regulations in January 2014, whereby, prior to recruiting temporary and contract agent staff, and for staff returning from unpaid leave, the Agency must examine any personal interest which may impair the independence of the staff member. The rules apply in general to all temporary and contract agents, national experts on secondment, trainees and interims.

The declarations of interests and curricula vitae of all EMA management staff are also published on the Agency's website.

2.7. Engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

On leaving the Agency, staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Trainees and national experts are also required to seek permission, although the period is restricted to the equivalent duration of the traineeship or, in the case of national experts, the period of secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

For the period from 1 January 2014 to 31 December 2014, a total of 55 applications were made, resulting in 49 authorisations without restrictions and 6 applications with restrictions. Examples of restrictions imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff or attend meetings at the EMA 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 2014 is given in Annex 6.

3. Building blocks towards the declaration of assurance

The aim of this section is to provide information on the current set of 'building blocks' that enable the Executive Director to obtain a full picture of the state of play of the Agency and give adequate assurance to the Management Board.

3.1. Management review

Assessment by management is based on the results of controls and control procedures performed by the staff of the Agency.

The Agency regularly conducts management reviews, during which the key areas and reports are discussed, conclusions on progress are drawn, and further actions and improvements agreed upon. The following areas were subject to the 2014 management review:

- Periodic review of deviations in the implementation of the work programme.
- Review and prioritisation of projects.
- Review of factors in the Agency's business environment affecting its priorities for coming years.
- Review of ex ante, ex post control reports and the register of exceptions.
- Annual review of internal control standards.
- Risk-management review.
- Review of audit reports.

The majority of issues identified during the management review were addressed in the course of the year. The Agency's management continues to monitor the effectiveness and efficiency of the Agency's management systems, with the aim of finding opportunities for further integration of the processes and increasing their effectiveness.

3.1.1. Ex ante control system and register of exceptions

The day-to-day ex ante verification is a financial activity based on the subjective evaluation of risks where sound judgment applies. The Agency has decentralised the verification for low-risk or standard transactions requiring either operational expertise or specific controls. The aim of the financial ex ante verification is to assure that the budget implementation respects budgetary principles, of which sound financial management and transparency principles are the two main principles on which attention is focused.

Since 2012, 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 accounting operations.

In 2014, the Verifying Office performed its duties and achieved its objectives. No delays had to be reported, and all transactions, without exception, were checked by applying appropriate checklists in line with the Financial Regulation, its Implementing Rules and the Charter of the Verifying Officer.

During the year, 992 rejections were recorded, of which 789 (79.5%) related to manual adjustments, technical rejections or interface issues in a decentralised entity. The balance of 203 (20.5%) – a 30% decrease from the previous year's 292 – reflects the effective rate of rejections of less than 1% of total

transactions. 50% of the rejections required a file revision, whereas the other 50% were payments or commitments showing either low-risk errors or mistakes, or procedural issues. The total rejected payments represented 0.5% of the total payments made. Most of the rejections were later corrected, amended and validated with due respect to budgetary principles and procedures in force.

Seven rejections deemed to be recorded in the register of exceptions. All of them were financial commitments scoring a low or medium risk level. One record showed an oversight and the last record initiated an HR procedural review. None of the 7 rejections revealed a breach of rules or contract provisions.

3.1.2. Ex post control system

In 2014, the Agency completed ex post controls in the following areas:

- Unemployment insurance contribution deducted from EMA staff salaries, calculated according to the formula provided by the Staff Regulation.
- Mission-expenses declarations made by staff members against the information provided by the event organisers.
- Annual-fee revenue and payments made to NCAs, taking into account any fee reductions applied and fee receptions.
- Procedures for medicinal products for human use, such as initial MA, line extensions, renewals, type II variations.
- Payments made to NCAs for inspections performed and invoiced.
- Fees due to the Agency and payments made to NCAs prior the identification of the correct scope of applications for marketing authorisations and extensions.
- Evaluation of conflicts of interests of experts involved in the Agency's activities between 1 January and 30 June 2014.
- Hotel and travel arrangements for delegates attending scientific meetings.
- Reimbursement of NCAs and delegates attending scientific meetings.
- Recording and maintenance of staff members' job descriptions in the SAP HR database.
- Expatriation allowance and foreign-residence allowance payments available in SAP HR and the EC payroll system.
- On-site tracking procedure for archive boxes recalled from EMA's off-site facility.

Overall, the 2014 ex post controls programme showed no significant weaknesses in the Agency's internal controls. Among the financial controls carried out, the main findings related to procedures for medicinal products for human use, such as initial MAAs and line extensions, renewal and type II variations, and fee payments made to NCAs for inspections (including GMP, GCP and pharmacovigilance inspections).

Although the mentioned findings constituted errors with direct financial impact, they did not show major weaknesses of the systems as they represent, after extrapolation, less than 2% of the respective budget lines.

3.1.3. 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 the EMA and, ultimately, serve as the key elements to underpin the Director's annual declaration of assurance.

A longer-term (5-year) strategy sets out the strategic objectives of the EMA. These are translated into more specific objectives and implementation activities within the multi-annual work programme. The annual work plans are derived from the multi-annual work programme and reflect specific objectives and activities set in attaining the Agency's strategic objectives in the current year.

Environmental analysis is performed annually, to confirm the strategy or identify necessary adjustments. These are implemented through 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.

Quarter 1 reports, mid-year reports and annual activity reports are employed as means of tracking implementation of the strategy and work programme objectives and activities. Quarter 1 and mid-year reports are also used to identify and address any significant deviations from the work programme plans.

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

Starting with the planning cycle for 2017, the new Financial Regulation requires the Agency to prepare a programming document, which combines the annual and multi-annual work programme, multi-annual budgets and staff plans into a single document. Furthermore, Article 33 of the regulation requires the programming document to be sent to the budgetary authorities by 31 January each year. In order to comply with these requirements, the format of planning documents and timelines of the process are gradually being changed. As a first step, the final work programme 2015 and preliminary work programme 2016 were combined into a single document and presented to the Management Board in December 2014. The 2016 planning cycle will see further changes to the planning documents, to align them with the requirements of the regulation and proposed common template for the programming document of European agencies.

As the current EMA strategy expires at the end of 2015, work on the new strategy started in the second half of 2014. In order to better reflect the close collaboration of the EMA and the national competent authorities in medicines regulation in Europe, and the need for a coordinated approach to address the multiple challenges and opportunities that face the network, a common network strategy is being developed, and will replace previous individual EMA and HMA strategies. This network strategy will highlight the key strategic priorities and areas where collaboration within the network can make a real difference to human and animal health in the European Union over the next five years. A separate multi-annual EMA work programme will give more detailed information on the work of the Agency and how it will take forward the common strategy.

3.1.4. Project management and controls

Overall responsibility for project approval and monitoring is delegated to the Agency's Executive Board (EEB), thus ensuring senior management involvement and control over project developments and key decisions. The EEB is supported by a Programme Design Board (PDB) and a Programme Implementation Board (PIB), which have delegated roles and authority for project approvals.

The Agency operates a gated approval process whereby the idea or concept for a project has to be approved firstly by the PDB ('Gate 1'), which verifies that the idea is in line with the Agency's strategic objectives, priorities and current work programme before any resources are assigned to deliver the project business case. The preliminary business case with identified benefits and costs is subject to the PDB's assessment before a project is approved by the EEB ('Gate 2'). On approval, the project starts and is overseen by the PIB and the EEB. Once the analysis and design are complete, a final business case is presented for assessment and approval to the PIB ('Gate 3'). If the agreed cost threshold is exceeded, approval at this stage is escalated to the EEB. Project progress past Gate 3 is overseen by the PIB and EEB. Changes to a project between gates are subject to assessment and approval of the relevant boards. At the end of the project, a closure report is presented to the PIB for assessment. The EEB is responsible for final approval at closure.

In order to increase the efficiency of project management, control and delivery in the Agency, a new programme governance structure was out in place and a Programme Management Office was established in 2014. The project portfolio was reviewed and streamlined, and programme and project maturity assessments were conducted. A new definition and criteria for projects was agreed, project-related guidelines were developed and regular programme and project reporting to the EEB and PIB was introduced. A procedure for ex ante and ex post evaluation of projects as required by the EMA Financial Regulation and Implementing Rules was agreed for implementation in 2015.

3.1.5. Advisory Committee on Procurement and Contracts (ACPC) and procurement management

The Advisory Committee on Procurements and Contracts was set up in 2012, to examine procurement contracts prior to signature on behalf of the Agency.

The ACPC gives its opinion, in an advisory capacity:

- for all proposals for a negotiated procedure over EUR 60,000 prior to the procedure being launched by the responsible delegated authorising officer;
- for 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 (currently EUR 134,000) over the contract duration;
- for 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;
- for 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, change the deliverables, value or duration of the contract;
- prior to the start of the tendering procedure, for 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.

In 2014, the Advisory Committee on Procurement and Contracts reviewed 73 dossiers.

During 2014, 28 new procurement contracts exceeding EUR 25,000 in value were concluded by the Agency following procurement procedures, compared to 30 in 2013 and 43 in 2012. The total value of

all such new contracts was EUR 39,944,023. In addition, the Agency signed up to 8 inter-institutional framework contracts run by the Commission.

There were 227 specific contracts concluded from framework contracts, making an overall total of 255 new contracts concluded in 2014. There were also 124 contract amendments/renewals.

This year, many of the procedures had several lots and/or contracts in cascade. There were fewer Infrastructure Services Department (ISERV) tenders than in previous years, due to ISERV minimising tender activity around the time of the office move in July 2014.

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.

Central Sourcing Office was created in December 2014, to improve efficiency and effectiveness of Agency's procurement and contract management, whilst ensuring compliance with the relevant regulations.

3.1.6. Risk management

The Agency's strategic risk-management processes have been operating over a number of years. A key objective is the identification and management of all strategic and significant risks. The identification and management of significant risks is the responsibility of the Executive Director, heads of division and their management teams. Strategic risks are reviewed by the EMA Executive Board. To manage risks, and escalate them as necessary, the Agency has in place a network of risk coordinators across the divisions.

The highest risks of the Agency were considered to be ones relating to: stakeholder and reputation management; threats to ethical values, including managing conflicts of interests; experts' competencies and expertise; and IT system security.

Mitigating actions were developed for these risks, to reduce them to an acceptable level.

3.1.7. Continuous improvement

Throughout 2014, the Agency continued the work started in 2013 to reorganise its processes and structures in order to better support the work of its scientific committees, share knowledge throughout the European medicines regulatory network and meet the needs of its various stakeholders. The ultimate aim of this exercise is to improve the efficiency and effectiveness of the Agency's operations so that it can continuously conduct its core business activities to the highest level of quality and consistency in a rapidly changing environment.

The reorganisation introduced a new operating model for how medicines are managed throughout their lifecycle at the Agency, as it separates scientific and procedure management.

The main change for applicants relates to their focal point, as the old product team lead (PTL) concept has been replaced with two new roles:

- a procedure manager, or PM, to oversee all aspects of the management of specific procedures. Procedure managers ensure regulatory consistency at the EMA and are responsible for managing the regulatory process for each application. Procedure managers provide guidance on regulatory procedural matters and serve as the primary contact point for applicants and experts from the national competent authorities in respect of their specific procedure.

- an EMA product lead, or EPL, to maintain oversight of a medicine as it moves through the different stages of its lifecycle. EPLs are responsible for the overall knowledge about a medicine and the wider context of a therapeutic area. They provide regulatory science input and facilitate discussions within and between the EMA's scientific committees when needed.

As part of its reorganisation, the Agency also revised its process for handling access-to-documents requests, to provide a tailored service for requesters. Each request is now assigned to an EMA coordinator who liaises with the individuals to understand their needs. The Agency also released a practical guide, detailing the process for requesting access to unpublished documents held by the Agency.

3.1.8. Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2014, 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.

3.1.9. Staff-engagement survey 2014

In October 2013, the Agency launched a new staff-engagement survey, which was developed jointly with 20 other EU agencies. The results of the first survey were presented to both Agency management and all staff in January 2014, and an inter-agency benchmarking report was presented to senior management in October 2014. To address the identified issues, a series of action plans were implemented in the second half of 2014, such as the launch of an all-Agency team briefing process, and implementation of others is ongoing. In addition, the Agency will run a set of focus groups to further analyse specific engagement areas in 2015.

3.1.10. Data protection

The 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 70 processing operations in the data-protection register maintained by the EMA DPO. Positive feedback on the EMA's compliance with data-protection notifications was received from the EDPS in the last Measuring Compliance in the EU institutions' General Report.

In terms of activities related to data protection at the Agency, no new processing operations were filed in the Data Protection Register in 2014. The EDPS communicated the finalisation of two prior check procedures concerning leave and administrative inquiry, following the measures adopted by the EMA. Draft notifications concerning future processing operations were reviewed by the DPO.

In February 2014, the EMA received the EDPS Inspection Report on CCTV and EudraVigilance, which was held in 2013. Measures to address the recommendations received have already been adopted or are being implemented.

The DPO has been providing advice to data controllers on a regular basis, in particular with regard to the revision of the EudraVigilance Access Policy, the technical specifications of the Clinical Trial Database, the processing of health data under the policy on access to clinical data, and the WP1 of the WEBRADR IMI-funded project concerning new digital tools for pharmacovigilance.

Quarterly bilateral meetings took place between the DPO and the Executive Director/Deputy Executive Director in 2014. One complaint made by a former member of staff was lodged to the EDPS. The EDPS informed the EMA that it would investigate the complaint, but it has subsequently suspended the procedure in light of court proceedings on the same subject matter that are currently pending.

3.2. Results from audits and evaluations during the reporting year

3.2.1. Audits of the European Court of Auditors (ECA)

The European Court of Auditors conducted its annual audit of the Agency's 2013 accounts, and adopted its report on 1 July 2013.

The report contains the following statement of assurance:

- **On the reliability of the accounts:** In the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2013 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.
- **On the legality and the regularity of the transactions underlying the accounts:** In the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2013 are legal and regular in all material respects.

No observations were made by the Court.

3.2.2. Audits of the Internal Audit Service (IAS)

In 2014, the European Commission's Internal Audit Service carried out an audit on stakeholder management and communication at the EMA, and submitted its report on IT consultancy engagement, carried out at the end of 2013.

- **Consultancy engagement on IT project management at the European Medicines Agency**

The fieldwork of this engagement was carried out in December 2013 and the final report was received on 23 March 2014. Therefore, the results of this engagement have been included in this year's report.

The objective of this consultancy engagement was to review the management and control systems related to IT project management at the Agency. The engagement examined and assessed whether the management and control system as implemented at the time of the fieldwork provided reasonable assurance regarding successful and timely execution of IT projects within the planned budget and quality tolerances.

To be noted that, in a consultancy engagement, the IAS does not issue an audit opinion providing assurance on the adequate design and effective and efficient implementation of the internal control system reviewed.

The scope of the consultancy engagement covered the project management practices on IT projects, and more specifically:

- the governance of project management;
- the design of the project management methodology;
- the implementation of the controls described in the project management methodology.

The consultancy report showed weaknesses in several areas of IT project management, governance, and the design of the IT project management framework and internal control.

The Agency immediately set out to implement several changes, including the establishment of a new structure for programme and project management, and the reassignment of accountability for

programmes and transfer of budget accountability to business, in order to increase business involvement in ownership of projects.

- **Audit report on stakeholder management and communication at the European Medicines Agency**

The audit assessed whether the stakeholder management and communication processes as implemented at the time of the fieldwork provide reasonable assurance regarding:

- compliance with the Agency's mandate and the applicable legal basis;
- adequacy and effectiveness of the processes mentioned in the scope below; and
- reliability of information.

The audit showed that stakeholder management and communication at the EMA are conducted effectively. This is evidenced by several factors, such as the organisation of the two functions subject to this audit in one division, and the cooperation frameworks for two important groups of stakeholders (patients and consumer organisations, and healthcare professionals).

At the same time, the audit also identified a number of areas with room for improvement and two very important recommendations were recorded:

- strengthen communication objective setting, planning and implementation monitoring;
- reinforce the governance of the communication and stakeholders' management process.

Following the audits, the Agency prepared an action plan and the IAS considered that it adequately addressed the risks and would mitigate them if implemented as planned.

No critical recommendations were open as of 31 December 2014, and all very important recommendations were well within the agreed timeline, as specified in the action plans submitted to the IAS after the audits.

3.2.3. Audits of the internal audit capability

In 2014, the Agency's audit function carried out audits in the following areas:

- **Pharmacovigilance**

The objective of the audit was to review compliance of the Agency's quality system of the pharmacovigilance system in place with the requirements of the legislation.

Based on the results of the audit, the auditors are of the opinion that the system in place complies with the legal requirements. No critical findings were identified, but suggestions for strengthening certain areas were made and an action plan is being implemented for these.

- **SAP security**

The scope of this audit focused on key control areas within SAP Basis and security (including access controls), which, if configured inappropriately, could expose the Agency's financial and HR data to unacceptable levels of risk and/or fraud. In addition to 'standard' IT general control areas, like change management and joiners/leavers processes, the audit included an assessment of important technical configuration settings in the SAP HR production environment (excluding development and testing environments).

Based on the work undertaken during the audit, the auditors were of the opinion that, while business controls within SAP are satisfactory, certain technical controls require improvement both in terms of control design and operation.

- **Records management**

The objectives of the audit were to review the compliance of the EMA records-management policies, systems and procedures with both the relevant European legal framework and best practice in records management, as well as assess their effectiveness for business purposes.

The audit also looked at lessons learnt from the archiving campaign launched in 2013 in preparation for the move to new premises.

The audit focused on records management for centralised procedures for human and veterinary products, covering both electronic and paper records, and provided reasonable assurance regarding the achievement of the EMA's business objectives. Improvements were identified for certain areas, for which an action plan has been drafted and is currently being implemented according to an agreed timeline.

- **Maximum residue limits (MRLs)**

The objective of the audit was to provide reasonable assurance that the procedures leading to the adoption of an opinion by the CVMP on maximum residue limits were in compliance with the current regulatory framework, and that they were being effectively implemented.

Based on the work done and the results of the samples taken, the auditors were of the opinion that the procedures in place had an adequate design and that these procedures were generally adhered to, with few exceptions that, nevertheless, did not have a significant effect on the overall opinion.

- **Follow-up to previous audit engagements**

In 2014, the internal auditors also followed up on open recommendations stemming from audits carried out in previous years (2010–2013). In total, 55 recommendations out of 87 were considered implemented by the auditors in 2014. Of the remaining 32 recommendations, 29 are from audits conducted in 2014, two recommendations from 2013 and one from 2012.

No critical recommendations were open as at 31 December 2014.

3.3. Previous year's reservation

There were no reservations in the Agency's previous annual activity report.

3.4. Latest discharge and follow-up of observations from the discharge authority

3.4.1. Discharge 2013

The European Parliament voted on 29 April 2014 in favour of the discharge of the Agency's budget from 2013.

3.5. Reservations

Based on the assurance provided by the control system results and without prejudice to the information reported by the Agency in Section 2.2.4 of this report, the Deputy 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 is 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.

3.6. Conclusions

Taking into account the management and control system — which is implemented within the framework of the Agency's integrated management system, the Financial Regulation, its implementing rules and internal control standards, and which is composed of a set of planning, monitoring, control, supervision, self-assessment and risk-management activities — 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.

3.7. Declaration of assurance

I, the undersigned, Andreas Pott, Deputy 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 learnt from the reports of the Court of Auditors for years prior to the year of this declaration.
- Confirm that I am not aware of anything not reported here which could harm the interests of the institution.

London, 23 April 2014

[signature on file]

Andreas Pott

(Deputy Executive Director)

4. Annexes

Annex 1: Workload and performance indicators

Traffic light system is used to describe performance against objectives and targets:

Workload indicators	
	Results more than 10% above 2014 forecast
	Results within +/-10% of the 2014 forecast
	Results 10%~25% below the 2014 forecast
	Results more than 25% below the 2014 forecast
	New indicator/previous information not available/no activity

Performance indicators	
	Results more than 10% above the target
	Results within +/-10% of the target
	Results 10%~25% below the target
	Results more than 25% below the target
	New indicator/annual target

Please note that for the workload indicators the traffic light system only reflects the *direction* and *magnitude* of change; it does not always reflect the *nature* of the change: this is a matter of interpretation. For example, decrease in received and validated signals will be marked amber or red, yet this should be regarded as positive trend.

In cases where absolute numerical change results in disproportionate variation, discretion might be used to reflect more accurately the significance of the change. For example, number of applications falling from 1 to 0 (or vice versa) can be marked green rather than red (blue), if this is in line with regular variations.

Evaluation activities for human medicines

Pre-authorisation activities

Workload indicators	Forecast	Actual result	Notes
Scientific-advice and protocol-assistance requests, of which:	357	429*	
Joint scientific advice with HTA bodies	10	11	
Parallel scientific advice with international regulators	4	2	Low interest in the parallel procedure from the applicants
Designation of orphan-medicine applications, of which:	213	329	Unexpected increase (also experienced in USA) could be caused by - increasing interest of the industry to develop orphan medicines - new requirement to be designated as orphan medicinal product to be eligible for Horizon 2020 funding
Parallel orphan designations with international regulators (applications)	120	109	
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	485	485	
Requests for classification of ATMPs	20	28	The increase in requests for ATMP classification and the stable number of requests in Q3-Q4 (traditionally a low activity period) could be reflecting the increase in the pipeline for advanced therapy products
Innovation Task Force briefing-meeting requests	30	28	
Innovation Task Force Art 57 CHMP opinion requests	10	5	Results depend on EC activity and decisions to request CHMP opinion on specific topics

* In 2014 scientific advice and protocol assistance are split in pre-authorisation and post-authorisation scientific advice. Total number of SA and PA requests in 2014 was 551, with 429 of requests received in pre-authorisation phase

Performance indicators	Target	Actual result	Notes
Percentage of scientific procedures completed within regulatory timeframes*	100%	99%	
Percentage increase in scientific-advice requests	9%	17%	

* This includes scientific advice and protocol assistance, orphan designation and paediatric procedures, as well as recommendations on ATMP classification

Initial evaluation activities

Workload indicators	Forecast	Actual result	Notes
Initial evaluation applications, of which:	118	100	
New non-orphan medicinal products	48	38	Slightly lower results could be attributed to shift in the industry submission plans, with lower activity towards year-end. 2015 should see positive trends
New orphan medicinal products	23	21	
Similar biological products	5	3	
Generic products	30	25	Unexpected industry activity has resulted in high number of generic applications in 2014. This is expected to gradually return to usual low levels in the coming years
Hybrid and abridged applications	10	12	The increase in applications is most likely attributed to change in market environment that also led to sharp increase in generics
Scientific opinions for non-EU markets (Art 58)	1	1	
Paediatric-use marketing authorisations	1	0	

Performance indicators	Target	Actual result	Notes
Percentage of applications evaluated within regulatory timeframes	100%	100%	

Post-authorisation activities

Workload indicators	Forecast	Actual result	Notes
Extensions and variations applications, of which:	5,104	6,022	
Type-IA variations	2,506	2,969	
Type-IB variations	1,610	1,886	
Type-II variations	970	1,151	
Line-extensions of marketing authorisations	18	16	
Post-authorisation scientific-advice requests*	125	122	

* Separation between pre- and post-authorisation scientific advice only introduced in 2014

Performance indicators	Target	Actual result	Notes
Percentage of post-authorisation applications evaluated within legal timeframes	100%	100%	
Percentage of risk-management plans peer reviewed within the assessment process of variations and line-	100%	100%	

Performance indicators	Target	Actual result	Notes
extensions			

Arbitration and referrals

Workload indicators	Forecast	Actual result	Notes
Arbitrations and Community referral procedures initiated	28	18	Decrease in number of pharmacovigilance referral procedures, in particular towards year-end, could in part be due to ongoing complex reviews and introduction of pharmacovigilance fees. A trend for decreasing number of Article 30s referrals contributed to lower overall number of non-pharmacovigilance referrals started

* Lower numbers than before due to change in legislation and accounting/grouping of products in the procedures

Performance indicators	Target	Actual result	Notes
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	

Pharmacovigilance activities

Workload indicators	Forecast	Actual result	Notes
Reviewed signals (for CAPs)	2,100	2,030	

Workload indicators	Forecast	Actual result	Notes
Validated signals	35	34	
PSURs received	530	520	
PASS/PAES	41	32	

Performance indicators	Target	Actual result	Notes
Percentage of reaction-monitoring reports supplied to the lead Member State monthly	100%	100%	
Percentage of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	

Other specialised areas and activities

Workload indicators	Forecast	Actual result	Notes
Herbal monographs, new*	13	11	
Herbal monographs, revised	5	5	
List entries	1	1	

* Where assessment does not lead to the establishment of a monograph, a public statement will be prepared. 1 public statement was finalised in 2014

Performance indicators	Target	Actual result	Notes
Number of workshop/training sessions on clinical-trial supervision held with international partners	At least 1	2	
Number of workshops held in the area of GMP inspections and quality defects	At least 1	1	

Evaluation activities of veterinary medicines

Pre-authorisation activities

Workload indicators	Forecast	Actual result	Notes
Innovation Task Force briefing requests	2	2	
Scientific-advice requests	28	31	
Requests for MUMS classification	18	29	Higher number of requests for MUMS classification could signal increasing industry interest in developing MUMS products

Performance indicators	Target	Actual result	Notes
Percentage of scientific advice procedures completed within set timeframes	100%	97%	1 scientific advice request was finalised beyond original timetable as additional time was requested at the end of the procedure

Initial evaluation activities

Workload indicators	Forecast	Actual result	Notes
Initial evaluation applications	18	12	Following an exceptional year in 2013, industry activity in 2014 has returned to regular, slightly lower level of applications
New MRL applications	5	4	
MRL extension and modification applications	2	2	
MRL extrapolations	2	2	
Art. 9, Biocides	2	0	
Review of draft Codex MRLs	5	5	

Performance indicators	Target	Actual result	Notes
Percentage of procedures completed within legal timeframes	100%	100%	

Post-authorisation activities

Workload indicators	Forecast	Actual result	Notes
Extensions and variations applications, of which:	245	346	
Type-I variations	200	293	
Type-II variations	40	47	
Line-extensions of marketing authorisations	5	6	

Performance indicators	Target	Actual result	Notes
Percentage of post-authorisation applications evaluated within legal timeframes	100%	100%	

Arbitration and referrals

Workload indicators	Forecast	Actual result	Notes
Arbitrations and Community referral procedures initiated*	10	7	Arbitration and referral procedures are triggered by the EC or Member States

* It is expected that substantial proportion of referrals will each relate to a large number of products, sometimes even hundreds of products. This is especially valid for referrals relating to antibiotics

Performance indicators	Target	Actual result	Notes
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	

Pharmacovigilance activities

Workload indicators	Forecast	Actual result	Notes
Periodic safety-update reports (PSURs)	150	158	
Total adverse-event reports, of which:	22,500	28,404	

Workload indicators	Forecast	Actual result	Notes
Adverse-event reports (AERs) for CAPs	7,200	11,878	Increased awareness of the value of pharmacovigilance reporting by veterinarians and the increased control of the implementation of pharmacovigilance legislative requirements by the industry

Performance indicators	Target	Actual result	Notes
Percentage of PSURs evaluated within the established timeline	90%	97%	
Percentage of AERs for CAPs monitored within the established timelines	95%	95%	

Horizontal activities and other areas

Committees and working parties

Workload indicators	Forecast	Actual result	Notes
Number of meetings	355	397	
Number of teleconference meetings*	3,050	3,215	
Number of delegates	7,000	7,488	

* Total audio, video and web-conference meetings

Performance indicators		Target	Actual result	Notes
	Percentage of delegate satisfaction with the service level provided by the secretariat	80%	87%	
	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	100%	100%	
	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.	100%	100%	
	Percentage of ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	80%	94%	

Inspections and compliance

Workload indicators		Forecast	Actual result	Notes
	GMP inspections	360	420	Higher than forecasted number of inspections was carried out in sites classified as higher risk
	GLP inspections	1	0	
	GCP inspections	71	66	
	Pharmacovigilance inspections	14	20	Higher number of pharmacovigilance inspections is triggered by CHMP and CVMP requesting additional inspections to investigate particular situations, as well as increasing requirements for inspections from continued implementation of the legislation

Workload indicators	Forecast	Actual result	Notes
Quality-defect reports	180	147	
Number of medicinal products sampled*	48	46	
Standard certificate requests	3,500	3,338	
Urgent certificate requests	450	535	Growing popularity of the new service results in very high number of requests received; further increase can be expected in 2015
Parallel distribution initial notifications	2,700	2,492	
Parallel distribution notifications of change	1,600	1,295	Decrease in notifications of change largely due to companies shifting to annual updates, a procedure introduced mid-2014 to simplify and converge high number of change notifications
Parallel distribution annual updates**	2,500	2,339	

* Including all testing completed
** Parallel-distribution annual updates only introduced since May 2014

Performance indicators	Target	Actual result	Notes
Percentage of inspections conducted within established regulatory timeframes	100%	100%	
Percentage of standard certificates issued within the legal timelines	90%	30.4%*	Major changes to the team and consequent loss of capacity resulted in lower performance. Training and utilising additional team members will help improve results in 2015
Percentage of urgent certificates issued within the legal timelines	100%	100%	
Percentage of parallel-distribution notifications checked for compliance within the standard timeline	90%	97%	

Performance indicators	Target	Actual result	Notes
Number of training/workshop activities organised in the area of inspections	At least 4	7	
GCP inspections addressed through information exchange on inspections carried out by international partners	Additional 10%	Additional 29%	
Routine re-inspections of manufacturing sites addressed through exchange of information with international partners	Additional 10%	Additional 8%	Formal framework to assess inspections from third country authorities and decide on deferral of an inspection adopted internally in June 2014
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%	

* Average issuing time in 2014 – 13.7 days (instead of 10).

Partners and stakeholders

Workload indicators	Forecast	Actual result	Notes
Requests for SME qualification	500	499	
SME status renewal requests	1,000	813	Slightly lower results are due partly to companies submitting renewal requests after expiry of their SME status on 31/12/2014, and partly to companies not renewing their SME status altogether
Requests for access to documents	350	416	Includes the number of appeals received
Pages released following requests for access to documents	100,000	167,309	Due to ongoing court cases a cautious forecast was set for 2014. Following the withdrawal of 2 of the court cases in mid-2014, the number of documents (and consequently, pages) released increased significantly

Workload indicators	Forecast	Actual result	Notes
Requests for information	5,000	4,625	
Number of EMA activities involving patients and consumers, of which:	575	633	
Information to the public reviewed by patients	200	185	

Data management support

Performance indicators	Target	Actual result	Notes
Percentage of substance and referentials data registered in 24 hours	90%	15%	Substance data registration is a new service established in 2014. Implementing new software tool and operating model in combination with very high number of substance-related requests towards year-end (due to the deadline to submit Art57 data by end of 2014) contributed to low performance results
Percentage of substance and referentials data registered in 48 hours	99%	18%	
Percentage of calls reopened due to incorrect handling	<3%	0%*	
Percentage of stakeholders satisfied with the responsiveness, cooperation and communication of data-management services	>80%	n/a	Stakeholder survey not carried out in 2014 due to priority focus on processing substance data submitted within timelines

* Data only available for June-December 2014

Process improvements

Performance indicators	Target	Actual result	Notes
Percentage of existing regulatory procedures reviewed and improvement areas identified by the end of 2014	80%	100%	All targeted regulatory procedures were reviewed by the end of 2014, with implementation of improvements continuing in 2015

Support and governance activities

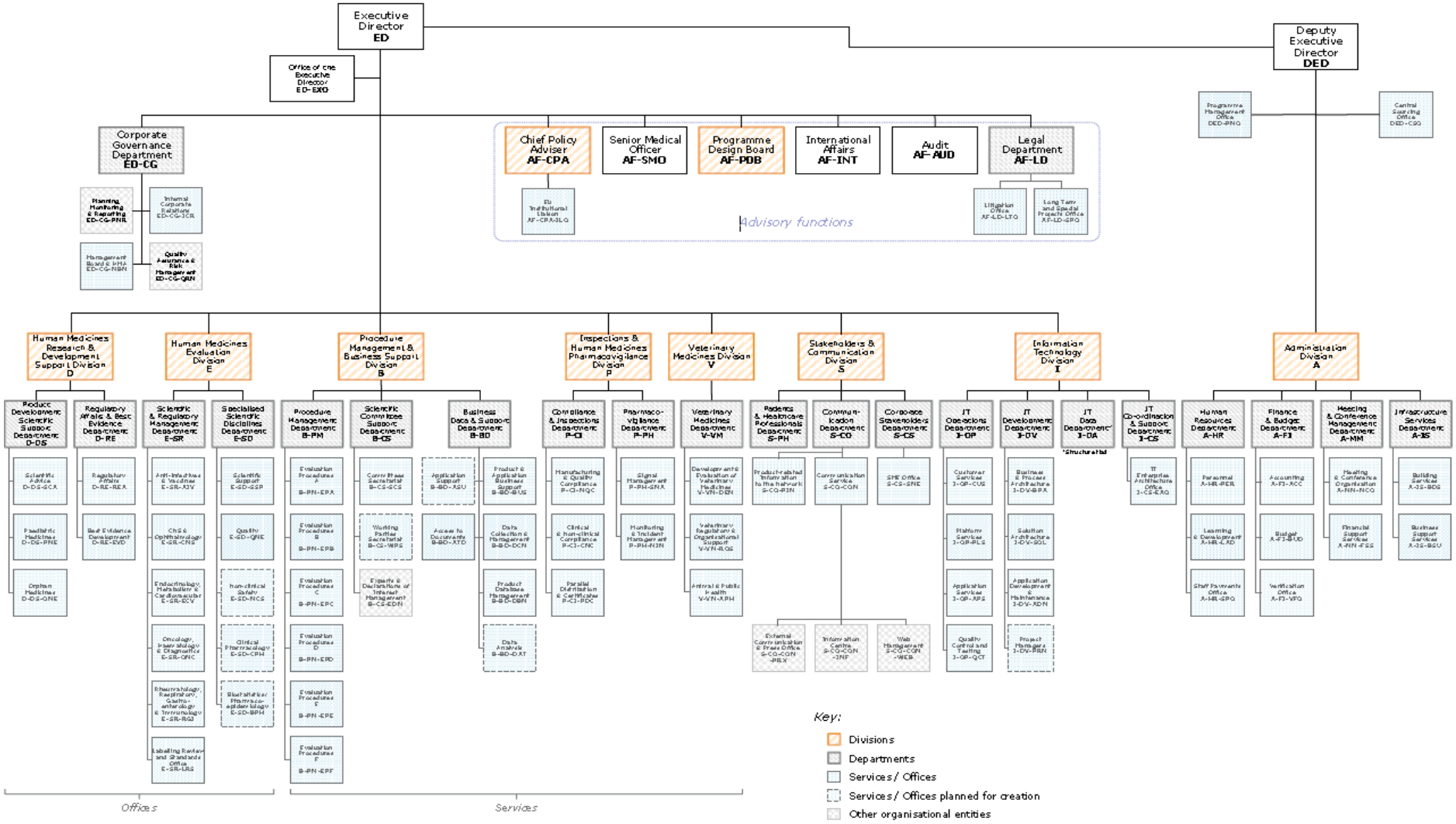
Performance indicators	Target	Actual result	Notes
Percentage of posts on the Agency establishment plan filled	97%	97%	
Percentage of revenue appropriations implemented	99%	96%	
Percentage of expenditure appropriations implemented	99%	94%	
Percentage of payments against appropriations carried over from year N-1	97%	97%	
Maximum rate of carryover to year N+1, of total commitments within the title:			
Title 1	2%	1%	
Title 2	20%	23%	EUR 0.9mln in building-related expenditure not invoiced or operationally validated before year end
Title 3	28%	28%	
Percentage of payments made within 30 days' time	97%	98%	
Telematics and corporate IT systems availability against Agency working hours	98%	99%	
ICT Service Desk: meeting of service-level agreements (SLAs) per system/priority level:			
Critical (resolution time: 4 hours)	80%	46%	Performance results affected in part by delivery of solution by

Performance indicators	Target	Actual result	Notes
Severe (resolution time 1 business day)	80%	50%	third party providers, in part by delays in timely recording the resolution of an issue
Important (resolution time 10 business days)	80%	91%	
Minor (resolution time 120 business days)	80%	99%	
Projects delivered on time	100%	*Project delivery indicators reported separately*	
Projects delivered to original specification	100%		
Projects delivered within budget	100%		

Annex 2: Annual accounts and financial reports

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 2014



Annex 4: Establishment plan

Function Group & Grade	Authorised for 2013		Occupied as at 31.12.2013			Authorised for 2014		Authorised for 2015	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	0	-	0	0	-	0	-	0
AD 15	-	4	-	4	2	-	4	-	4
AD 14	-	6	-	6	1	-	6	-	6
AD 13	-	8	-	7	7	-	8	-	9
AD 12	-	38	-	36	32	-	42	-	42
AD 11	-	38	-	36	20	-	38	-	37
AD 10	-	36	-	33	27	-	36	-	40
AD 9	-	40	-	36	28	-	37	-	36
AD 8	-	47	-	46	48	-	49	-	52
AD 7	-	45	-	44	44	-	51	-	52
AD 6	-	42	-	41	71	-	39	-	36
AD 5	-	42	-	33	37	-	30	-	26
Subtotal AD	***0***	***346***	***0***	***322***	***317***	***0***	***340***	***0***	***340***
Total AD	***346***		***0***	***322***	***317***	***340***		***340***	
AST 11	-	2	-	2	0	-	2	-	2
AST 10	-	5	-	5	1	-	5	-	5
AST 9	-	7	-	7	2	-	7	-	7
AST 8	-	13	-	13	8	-	15	-	16
AST 7	-	20	-	20	12	-	19	-	19
AST 6	-	33	-	31	12	-	36	-	39
AST 5	-	35	-	34	29	-	37	-	42
AST 4	-	51	-	50	36	-	55	-	49
AST 3	-	39	-	39	63	-	39	-	43
AST 2	-	40	-	40	37	-	34	-	37
AST 1	-	20	-	20	66	-	10	-	0
Subtotal AST	***0***	***265***	***0***	***261***	***266***	***0***	***259***	***0***	***259***
Total AST	***265***		***0***	***261***	***266***	***259***		***259***	
SC 6	-	-	-	-	-	-	0	-	0
SC 5	-	-	-	-	-	-	0	-	0
SC 4	-	-	-	-	-	-	0	-	0
SC 3	-	-	-	-	-	-	0	-	0
SC 2	-	-	-	-	-	-	0	-	0
SC 1	-	-	-	-	-	-	0	-	0
Subtotal SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Total SC	***0***		***0***	***0***	***0***	***0***		***0***	
Grand subtotal	***0***	***611***	***0***	***583***	***583***	***0***	***599***	***0***	***599***
Grand total	***611***		***0***	***583***	***583***	***599***		***599***	

Interims: from 1 January 2014 to 31 December 2014, there have been 97 different interims, and on average their interim arrangement was for 5.6 months.

Contractors: from 1 January 2014 to 31 December 2014, there have been 203 different contractors under IT budget, and on average their contract duration was for 7.35 months.

Annex 5: Human and financial resources by activity[2]

Activities	FTEs	Staff Cost (incl. overhead)	Meetings cost (incl. overhead)	Evaluation cost (NCAs)	Miscellaneous expenditure	Total *
Evaluation activities for human medicines	**377**	**54,302**	**12,045**	**82,576**	**11,652**	**160,575**
Pre-authorisation activities	81	12,618	4,224	14,137	276	31,255
Initial evaluation activities	63	9,377	1,682	12,465	996	24,521
Post-authorisation activities	98	12,631	1,531	55,835	6,820	76,817
Arbitrations and referrals	21	2,599	503	139	719	3,960
Pharmacovigilance activities	92	11,669	1,967	0	1,281	14,917
Other specialized areas and activities	23	5,407	2,138	0	1,559	9,104
Evaluation activities for veterinary medicines	**44**	**6,375**	**2,503**	**2,808**	**732**	**12,418**
Pre-authorisation activities	1	231	668	284	0	1,184
Initial evaluation activities	12	2,182	476	948	203	3,809
Post-authorisation activities	13	1,800	244	1,576	133	3,753
Arbitrations and referrals	4	590	219	0	352	1,161
Pharmacovigilance activities	5	756	299	0	0	1,055
Other specialized areas and activities	9	816	599	0	43	1,458
Horizontal activities	**134**	**21,725**	**3,964**	**3,662**	**2,609**	**31,960**
Committees and working parties	20	2,587	1,502	0	0	4,089
Inspection and compliance	33	5,205	1,848	3,662	507	11,222
Partners and stakeholders	32	5,093	404	0	475	5,972
Transparency and access to documents	22	3,534	0	0	0	3,534
Information	27	5,305	209	0	1,628	7,143
Support and governance activities	**183**	**34,281**	**411**	**0**	**1,085**	**35,777**
Governance, quality management and internal audit	32	9,760	411	0	276	10,446
Finance	26	6,427	0	0	435	6,861
Information technology	56	5,713	0	0	0	5,713
Human resources	33	7,269	0	0	375	7,643
Infrastructure services	19	2,588	0	0	0	2,588
Communication (corporate)	17	2,525	0	0	0	2,525
Total	**738**	**116,682**	**18,923**	**89,046**	**16,078**	**240,730**

[2] * The total expenditure excludes exceptional building costs of €10.6 million.

Annex 6: Report for 2014 on staff engaging in an occupational activity within two years of leaving the service (Article 16 of the Staff Regulations)

Case No	Job Title / Function at EMA	Length of service	Date of application	Joint Committee (JC) opinion	Date of JC opinion	Decision of Executive Director (ED)	Date of ED decision
1	Temporary Agent / Paediatrics Medicines	4 years 10 months	27/01/2014	Authorisation with restrictions	30-Jan-14	To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public.	12-Feb-14
2	Contract Agent / Manufacturing and Quality Compliance	2 years 3.5 months	5-Feb-14	Authorisation with restrictions	27-Feb-14	To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public.	17-Mar-14
3	Temporary Agent / Pharmacovigilance department	16 years 10 months	14-Feb-14	Authorisation with restrictions	27-Feb-14	1) To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public. 2) To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on specific	17-Mar-14

Case No	Job Title / Function at EMA	Length of service	Date of application	Joint Committee (JC) opinion	Date of JC opinion	Decision of Executive Director (ED)	Date of ED decision
						products s/he may have worked on in the performance of his/her responsibilities at the Agency during his/her last three years of service for a period of 12 months to be counted as of the date of leaving service. In addition, the former staff member can no longer participate as a co-leader on behalf of EMA in the IMI project and any activity or lecture that former staff member was requested to undertake as an EMA staff member should be taken over by another EMA staff member.	
4	Contract Agent / Signal Management	6 years 9 months	25/03/2014	Authorisation with restrictions	10-Apr-14	1) To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public. 2) To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on specific products s/he may have worked on in the performance of his/her responsibilities at the Agency during his/her last three years of service for a period of 12 months to be counted as of the date of leaving service.	06-May-14

Case No	Job Title / Function at EMA	Length of service	Date of application	Joint Committee (JC) opinion	Date of JC opinion	Decision of Executive Director (ED)	Date of ED decision
5	Contract Agent / Development and Evaluation of Veterinary Medicines	2 years	28/03/2014	Authorisation with restrictions	10-Apr-14	To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he may have dealt with in the performance of his responsibilities at the Agency during his period of service. Since the period of six months has already elapsed, no further distance clause restrictions need to be applied.	06-May-14
6	National Expert on secondment / Legal department	1 year 4.5 months	14/04/2014	Authorisation with restrictions	29-Apr-14	1) To 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 his/her last three years of service. The distance clause is without prejudice to the possibility of the former SNE to liaise or attend meetings through the standards channels available to all members of the public. 2) The former SNE 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 s/he dealt with while in the service of the Agency.	11-Jun-14

Annex 7: Implementation of the internal control standards in 2014 and actions planned for 2015

STANDARD	STATUS	ACTIONS PLANNED FOR 2014: FOLLOW UP	ACTIONS PLANNED FOR 2015/16
Mission	Implemented		
Ethical and Organisational Values	Partially implemented	Define new core values and embed them in the organisation: *Values defined and presented to the General Assembly in May 2014, implementation programme started and will run until mid-2015.*	Complete implementation programme by mid-2015.
Staff Allocation and Mobility	Implemented	Review of timesheet recording system: *System reviewed and modified during 2014 to realign with the revised organisation structure. The updated structure was implemented from July 2014.* Improve monitoring of actual consumption of resources per activity areas: *All divisions completed a detailed analysis of resource allocation in 2014, which was consolidated and presented to senior management.* *In addition, the actual resources utilised against each business activity in 2013, as recorded in the time-recording system, were analysed and used as input into the preparation of the 2014 Annual Work Programme.*	
Staff Evaluation and Development	Partially Implemented	Review performance evaluation framework in line with that used by the European Commission: *Implemented.* Review job descriptions of all staff: *Following the Review and Reconnect exercise, many entirely new job descriptions were written and other substantially modified and*	Introduce the self-development workshops for staff and managers (from 03/2015). Create Divisional Learning and Development plans (Q2 2015)

STANDARD	STATUS	ACTIONS PLANNED FOR 2014: FOLLOW UP	ACTIONS PLANNED FOR 2015/16
		updated, with an Agency-wide exercise to be completed by end of Q3 2015. Design a longer term staff competence development and recruitment plan to reflect scientific and technological development in the Agency's environment: *New technical competences, as well as a managerial competence framework are being defined (target date 05/15).*	
Objectives and Performance Indicators	Partially implemented (due to the need to significantly revise the system to introduce changes brought about by the revised financial regulation)	Develop and agree with senior management a performance indicator list and regularly report on their status: *Further work is needed on KPIs in the context of the implementation of the new financial regulation in the area of planning (as set out in the actions for 2015).* Strengthen the link between the results of the risk management activities and the work programme: *Improvement actions will continue in 2015.*	Develop new format of the work programme integrating operational, financial and staff information. Develop new template for multi annual work programme. Conduct review of KPIs, in the context of the above. Develop a system integrating information on workload, allocated staff resources and KPIs, to better support decision making. Integrate monitoring activities into one system (work programme, risk management, ICS, anti-fraud activities, audit, etc.)
Risk Management Process	Implemented	Reinforce process to ensure that actions to further mitigate risks are implemented according to plan: *Action table to monitor implementation of all actions stemming from the risk review exercise has been implemented.*	
Operational Structure	Partially implemented	Implement an Agency-wide Programme Management Office to oversee all projects across the whole Agency: *implemented*	Develop and implement project management framework (target: end of 2015)

STANDARD	STATUS	ACTIONS PLANNED FOR 2014: FOLLOW UP	ACTIONS PLANNED FOR 2015/16
		Develop/update IT strategy: *to be developed by July 2015*	Complete charter for initiating agents and implement for existing initiating agents as well as any future initiating agent (by 2nd half of 2015)
Processes and Procedures	Implemented	Revise Exceptions procedure: *Revised exceptions procedure effective since 28 July 2014*	
Management Supervision	Implemented		
Business Continuity	Implemented		
Document Management	Implemented	Approve and implement official retention period for business classification scheme (BCS): *Retention list was approved by Data Board in March 2014.* *BCS tool designed, deployed and live since May 2014*.	Develop a strategy and roadmap for unstructured information management as well as the records management operational model.
Information and Communication	Partially implemented	Deliver on-line programme, specifically European Medicines web portal: *A questionnaire on Member States needs and expectations was sent to stakeholders in October and feedback was concluded in December 2014, EMA to present the revised strategy at February HMA meeting (2015)*	Conduct a Full Pen Test exercise, to attest the effectiveness of the security controls.
Accounting and Financial Reporting	Implemented		
Evaluation of Activities	Implemented	Improve ex ante and ex post evaluations related to project and programme delivery:	

STANDARD	STATUS	ACTIONS PLANNED FOR 2014: FOLLOW UP	ACTIONS PLANNED FOR 2015/16
		Process for project ex ante and ex post evaluations implemented.	
Assessment of Internal Control Systems	Implemented		
Internal Audit Capability	Implemented	Review the internal audit charter and other procedures to include references to new Agency's structure and new Financial Regulation: *updated.*	

Annex 8: Statistics on flexi leave according to grade

Grade	Staff members on 31.12.2014	Total flexi leave days taken	Average flexi leave days per staff member
AD15	2	0	0
AD14	1	0	0
AD13	9	9	1
AD12	29	59.5	2
AD11	20	73.5	4
AD10	34	98.5	3
AD09	28	135.5	5
AD08	52	248	5
AD07	45	175.5	4
AD06	70	237.5	3
AD05	27	111	4
AST10	2	4	2
AST09	2	0.5	0
AST08	7	13.5	2
AST07	14	22	2
AST06	16	57.5	4
AST05	33	57	2
AST04	30	39.5	1
AST03	65	125	2
AST02	34	56.5	2
AST01	59	129.47	2
FGIV.16	1	10	10
FGIV.14	25	50.5	2
FGIV.13	27	27.5	1
FGIII.09	12	20.5	2
FGIII.08	9	19.5	2
FGII.06	4	7.5	2
FGII.05	27	36.5	1
FGII.04	39	37.5	1
SNE	28	48.5	2
Grand Total	751	1910.97	3

Annex 9: Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2014 by negotiated procedure

(Contracts signed during the reference period 1/1/2014–31/12/2014.)

Contract no	Type of contract	Date of signature	Subject	Value (or estimated value, where applicable)	Negotiated procedure justification	Organisational entity/authorising officer	Budget line and other details (as applicable)
EMA/2013/35/IS	Service contract	04/03/2014	Provision of fire, health and safety consultancy at the Agency	GBP 49,428	Negotiated under EUR 60,000	A-IS/A Brandt	**BL 2050** 4600001649 - 4600002094
EMA/2014/13/AF	Service contract	11/03/2014	Legal services	GBP 48,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4600001762
EMA/2014/14/AF	Service contract	05/03/2014	Legal services	EUR 17,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4600001622
EMA/2014/15/AF	Service contract	13/03/2014	Legal services	EUR 55,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4600001716
EMA/2014/23/AF	Service contract	14/05/2014	Legal services – staff matters	EUR 20,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4600001713
EMA/2014/26/LD	Framework contract	07/09/2014	Legal services – staff matters	EUR 250,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4500001408 PO4500001456 PO4500001489
EMA/2014/33/AF	Service contract	25/06/2014	Legal services – staff matters	EUR 20,000	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330** PO4500001310
EMA/2014/46/LD	Service contract	05/08/2014	Legal services – staff matters	EUR 16,500	Negotiated tender Art 134 1(i)	AF/T.Jablonski	**BL 2330;** PO4500001835

Annex 10: Annual report 2014

Please see the Agency's 'Annual report 2014', attached as a separate document.

Annex 11: Results of the screening exercise as of December 2014

Article 29(3) of the Framework Financial Regulation sets out 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 which organisational role each job is serving. As its main focus this exercise generates figures on Administrative Support and Coordination (ASC); Operational; and Neutral jobs in all organisational entities, based on the Commission Screening methodology. The table below reflects a snapshot of EMA's annual human resources as of end of December 2014 applying this methodology. As it is the first year that this exercise has been carried out using this methodology there are no comparative figures available for previous years.

Job type (sub) category	2013 (%)	2014 (%)
Administrative support and coordination	**n/a**	**16.36%**
Administrative support		15.45%
Coordination		0.91%
Operational	**n/a**	**79.47%**
Top level operational coordination		1.52%
Programme management & implementation		19.61%
Evaluation & impact assessment		45.53%
General operational		12.80%
Neutral	**n/a**	**4.17%**
Finance / control		4.17%
Linguistics		0.00%
Total		**100.00%**

The jobs include all establishment plan posts (TA) occupied full time, part time, vacant and all other types of contracts occupied by a jobholder (CA, SNE, INT, TR, LT Contractors/Consultants, external service providers) fulfilling all or most of these criteria: min 3 month contract, have a badge, occupy an office space, have a phone (personal number), have a computer (personal ID, e-mail).

Annex 12: Administrative Appropriations – Building Policy (Article 87(3) of the Financial Regulation)

Art. 87(3.a) Current building(s)

30 Churchill Place, London, E14 5EU	Comment
Total area (in square meters): 26,450 • of which office space: 18,448 • of which non-office space and below ground space:8,002	The building is a multi-tenanted office premises and EMA occupies parts of the basement, ground and promenade levels and level 1 through 10.
Annual Rental (in EUR @ GBP 0.81/EUR) EUR 19.4 million	Rent: EUR 14,933,000 Service Charge: EUR 4,500,000
Type and duration of rental contract	Rental lease: 25 years duration Term commencement: 1 July 2014.
Host Country grant or support	None
Present value of building	Not applicable

Art. 87(3.b) Building projects in planning phase

The fitting out of an office floor on Level 10, of 30 Churchill Place, which is ongoing and is part of the overall 'Project 2014' Agency relocation project and which is included in the total area as well as office area above comprising 2,597 square meters. Design and construction is currently ongoing and is planned for completion by September 2015. The layout of the floor will be like the other office floors within EMA premises with 19 singular offices, 171 work-stations in open space, three meeting-rooms, eight pods, eight gas-lifted meeting-tables in open plan layout, two kitchenettes and two breakout areas.

Art. 87(3.c) Building projects submitted to the European Parliament and the Council

The fitting out of Level 10 has been included in the building project 'Project 2014' of floors Basement to Level 9 in 30 Churchill Place and not submitted as a separate project, due to the size and budgeted financial impact, and will be included in the fitting out budget of the original building project. The final terms and costs will to be settled following completion of Level 10.

The financial impact of Project 2014 over the term of the lease, including Basement to Level 10 is estimated to be €565,218,810, compared to the initial €554,600,000 which corresponds to an annual impact of €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 13: Terms and abbreviations

Term	Definition
AAR	annual activity report
ACPC	Advisory Committee on Procurement and Contracts
AD	administrators' function group
ADR	adverse drug reaction
ADVENT	Ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
APEC	Asia-Pacific Economic Cooperation
AR	assessment report
Art.	Article
AST	assistants' function group
ATD	access to documents
ATMP	advanced-therapy medicinal product
BCS	business classification scheme
BE	bioequivalence
BEMA	Benchmarking of European Medicines Agencies
ADREEAM	Building Research Establishment Environmental Assessment Methodology
BSWP	Biostatistics Working Party
BWP	Biologics Working Party
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCTV	closed-circuit television
CETA	comprehensive economic and trade agreement
CHMP	Committee for Medicinal Products for Human Use
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
CoI	conflict of interests
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
CTR	Clinical Trial Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
D(80, 120)	day (80, 120)
DCDA	defined course dose for animals
DDDA	defined daily dose for animals
DoI	declaration of interests
DPO	Data Protection Officer
eAF	electronic application form
EC	European Commission
ED	Executive Director
e-DoI	electronic declaration of interests
EDPS	European Data Protection Supervisor
EEB	Agency's Executive Board
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPL	EMA product lead
EPP	erythropoietic protoporphyria
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU contribution	EU special contribution for orphan medicines

Term	Definition
EU-CTR	EU Clinical Trials Register
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	Interaction and communication with health technology assessment bodies initiated through the European Commission and Member states' joint action
EUR	euro
FDA	United States Food and Drug Administration
FTA	Free Trade Agreement
FG	function group
GCP	good clinical practice
GDP	good distribution practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HR	human resources
HTA	health technology assessment
IAP	improvement action plan
IAS	Internal Audit Service
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICPE	International Conference of Pharmacoepidemiology
ICS	internal control standards
ICT	information and communication technologies
IDVP	Infectious Diseases Working Party
IMI	Innovative Medicines Initiative
IPRF	International Pharmaceutical Regulators Forum
ISERV	Infrastructure Services
ISO IDMP	international standards for the identification of medicinal products
ISPOR	International Society for Pharmacoeconomics and Outcomes research
IT	information technology
ITF	Innovation Task Force
IWG	Inspectors Working Group
JRC	Joint Research Centre
KPI	key performance indicator
LSIF	Life Science and Innovation Forum
MA	marketing authorisation
MAA	marketing-authorisation application
MAH	marketing-authorisation holder
MB	Management Board of the EMA
MDR	multidrug-resistant
Member State	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MHRA	Medicines and Healthcare products Regulatory Agency
MRCT	multi-regional clinical trials
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
NCL	nanotechnology characterisation laboratory
Network	European Medicines Regulatory Network
OLAF	European Anti-Fraud Office
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PCO	patients'/consumers' organisation

Term	Definition
PDB	Programme Design Board
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIB	Programme Implementation Board
PIP	paediatric investigation plan
PM	procedure manager
PRAC	Pharmacovigilance Risk Assessment Committee
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
PTL	product team leader
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
QWP	Quality Working Party
REA	relative effectiveness assessment
RFI	request for information
RMP	risk-management plan
SA	scientific advice
SAG	Scientific Advisory Group
SAP	Systems, Applications & Products (budgetary system)
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SMEs	small and medium-sized enterprises
SNE	seconded national expert
SOP	standard operating procedure
SUSAR	serious unexpected suspected adverse reaction
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TGA	Therapeutic Goods Administration, Australia
TTIP	Transatlantic Trade and Investment Partnership
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WG	working group
WHO	World Health Organization
WP	working party
WPx (x=1,2,3…)	work package