EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Annual activity report 2015

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Management Board's assessment report

The Management Board,

- having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004,
- having regard to the Financial Regulation applicable to the budget of the European Medicines Agency ("the Agency") and in particular Article 47 thereof,
- having regard to the 2015 work programme of the Agency adopted by the Management Board at its meeting on 16 December 2014,
- having regard to the annual report 2015 of the Agency adopted by the Management Board at its meeting of 17 March 2016,
- having regard to the annual activity report 2015 of the Agency presented to the Management Board at its meeting of 16 June 2016,

1. Congratulates Professor Guido Rasi for his new appointment as Executive Director in November 2015 ending an unsettled period following the ruling of the EU Civil Service Tribunal and thanks Andreas Pott for the management and operations of the Agency while the post of Executive Director was vacant.
2. Welcomes the results presented in the annual report 2015 as well as the considerable work programme delivered in 2015 and notes that on performance indicators overall the targets were met. The Management Board notes that the expected increase in the scientific advice requests in 2015 has not been reached, as the scientific advice requests appear to have reached a plateau at the level of 2014 results,
3. Is pleased with the fact that the Agency's work is well aligned with the European policy agenda set to ensure that public health is promoted and protected,
4. Acknowledges the efforts of the Agency to ensure co-operation in its work with that of the National Competent Authorities (NCA), ensuring the successful functioning of the EU medicines network,
5. Appreciates the fact that the Agency and the Heads of Medicines Agencies, for the first time, have adopted a common strategy to 2020 for the European medicines regulatory network, and that by following the same strategy, the European regulatory network should be able to tackle current and future challenges more effectively,
6. Welcomes the improved interactions and support to committees and industry that have resulted in continuous and significant decrease in average clock-stop for new active substances and biosimilars. In 2015 the average clock-stop was 138.4 days (from 218 days in 2013 and 166 days in 2014).
7. Supports the Agency on its efforts to improve timely access for patients to new medicines through the adaptive pathways approach, a new concept for medicine development and data generation which allows for early and progressive patient access to a medicine,
8. Welcomes the establishment of the European Network Training Centre whose mission is ensuring that good scientific and regulatory practice is spread across the European medicines regulatory network,

9. Recognizes the growing severity of the antimicrobial resistance and calls on the Agency to intensify its efforts and contribution to combatting the issue,

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

11. Emphasises the importance of timely implementation of the new EU Clinical trial regulation, which is expected to improve significantly the European environment for conduct of clinical trials, including increased transparency regarding clinical trials and the clinical trial data. At the same time the Management Board recognizes the high complexity of this operation that, in order to be successful, requires due respect for feasibility and care in development,

12. Welcomes the revision of the policy on the handling of conflicts of interests of the Management Board members, and looks forward to the revision of the rules concerning the handling of declared interests of staff members,

13. Stresses the overarching importance of implementing the Telematics strategy and using worldwide ISO-IDMP standards in the operations of the EU medicines regulatory network, thus increasing the consistency and inter-usability of information, enabling better connectivity of NCAs and allowing the Agency to fulfil its tasks more efficiently,

14. Supports the changes in the Information Management division which was reorganized with the aim of increasing the Agency's information processing capacity and the implementation of the EU Telematics strategy,

15. Looks forward to the results of the data gathering exercise, which should help the European Commission in its reflection on the future legislative proposal on fees, that bears significant importance in ensuring long-term sustainability of the Agency and the NCAs,

16. Recognizes the progress on the implementation of the Anti-Fraud strategy, and calls on the Agency to report on the results of the assessment of the adequacy and effectiveness of the internal control system in relation to fraud,

17. Notes that the Agency's initial budget for 2015 amounted to EUR 302,117,000 and that after one amending budget and an adjustment in assigned revenue the total budget was EUR 308,097,000, which represents a 9.1% increase over the 2014 final budget (EUR 282,474,000),

18. Notes that at the end of 2015 the Agency achieved an occupancy rate for temporary agents of 98% with 587 staff against 599 posts available, and that in regard to gender distribution women accounted for 45% of heads of Service, 46% of heads of Department and have reached 33% of the senior management team,

19. Is satisfied that the audit carried out by the Internal Audit Service of the European Commission on Paediatric Regulation procedures confirmed that the Agency deploys and uses adequate systems for the management and control of these procedures and notes with satisfaction that neither critical nor very important recommendations were open as at 31 December 2015,

20. Notes the results of the audit of the European Court of Auditors, confirming the reliability of the 2014 accounts and the legality and regularity of the transactions underlying the accounts of the Agency and calls on the Agency to implement in 2016 the remaining actions to address the comments made by the Court,

21. Is pleased that the European Parliament granted the discharge in respect of the implementation of the budget of the Agency for the financial year 2014,

22. Acknowledges the well-functioning internal control system, as demonstrated by the review of the Internal Control Standards and notes the improvements for the standards concerning ethical and organisational values, staff evaluation and development, risk management as well as is calling on the Agency to implement the planned actions to further improve efficiency to the standards concerning objectives and performance indicators, operational structure, document management and information and communication,
23. Acknowledges that in regard to ex-ante verifications, all transactions without exception were checked by applying appropriate checklists, in line with the financial regulations and the charter of the Verifying Officer, and that the 2015 ex-post controls programme showed no significant weaknesses in the Agency's internal controls,
24. Notes that the systems to support the Executive Director's declaration of assurance were in place,
25. Notes that the main risks to threaten the achievement of key objectives were identified and mitigating measures were in place,
26. Takes note of the declaration of assurance of the Executive Director and acknowledges that no reservations were made,
27. Thanks scientific committees' members, experts and patient representatives, as well as all NCAs and EMA staff for their exceptional commitment.

London, 16 June 2015

[signature on file]

Christa Wirthumer-Hoche
Management Board Chair

Executive Summary

The consolidated annual activity report provides an overview of the activities and achievements of the European Medicines Agency (EMA). It follows closely the guidelines developed by the EU Agencies Performance Development Network[1].

On the basis of the end-of-year review, the Agency can confirm that the work programme was successfully implemented overall.

Taking into account the conclusions of the review of the elements supporting assurance and the planned corrective actions for the weaknesses identified, the Executive Director can confirm that the management and control systems in place at the Agency provide reasonable assurance that the resources under his responsibility were used for their intended purposes and in accordance with the principles of sound financial management.

Introduction

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 2015, 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

[1] The overall objective of this network, set up by the Heads of Agencies, is to help the agencies to better achieve their objectives, better serve the European stakeholders needs, provide increased added value to European citizens, and to be more cost-effective, with the emphasis on tools and methods performance improvement and accountability.

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.

Governance of the European Medicines Agency

Management Board

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

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

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

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.

Strategy Board

The Strategy Board (ESB) 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 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
- Head of Legal
- Head of International Affairs
- Heads of division
- Deputy heads of division

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 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.

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 and 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.

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.

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
- Head of Programme Design Board
- Head of Corporate Governance.

1. Achievements of the year

1.1. Key achievements

- Celebrating the 20th anniversary of the Agency and in recognition of the 50th anniversary of pharmaceutical legislation in Europe, a 20th anniversary scientific conference was held on 18 March 2015. An EMA 20th anniversary booklet, capturing the important progress in regulatory science and societal changes in the field of medicines regulation, as well as achievements of the EMA in fulfilling its mission over the past two decades, was published and presented at the conference.
- Following the first in-depth meeting with HTAs in December 2014, a report on the initial experience with the adaptive pathways project and the next steps to take was finalised and sent to HTAs in March 2015. The relevant submission guidance and website content were updated in the second half of the year.
- An analysis of experience with conditional marketing authorisations was presented to the EC expert group STAMP in January and May. A CHMP draft guideline on conditional marketing authorisation was released for public consultation in July and is expected to be finalised in Q1 2016.
- Analysis of the accelerated approval concept was completed in Q1 2015 and the revised guidance and templates were presented to the committees in May and June. An updated guideline was introduced to committees in December 2015. Formal adoption and implementation of the guideline is expected in Q1, along with the PRIME framework and the revised guideline on conditional marketing authorisation.
- The ad-hoc expert group on veterinary novel therapies (ADVENT) held its first plenary meeting in January 2015. The CVMP endorsed the ADVENT work plan 2015 and agreed the priority topics for which guidance will be developed by the ADVENT group.
- The EU network strategy was adopted by the HMA in October and the EMA Management Board in December 2015.
- Following consultation with national competent authorities and stakeholders, an EU Telematics strategy and implementation roadmap 2015-2017 was adopted by the EU Telematics Management Board in June 2015. A phased implementation of the EU IDMP/SPOR Roadmap was agreed by the HMA and confirmed by the EC in July.
- The interim platform for the Network Training Centre was launched in January and the first comprehensive training catalogue with over 100 training events for the whole network was advertised. Seven training events and 22 webinars were supported by the EU NTC in 2015.
- The extension of the multinational team concept in relation to veterinary medicines assessment was presented to the HMA at the beginning of the year. The concept was extended to scientific advice procedures for human and veterinary products. Guidance to rapporteurs and coordinators was finalised in June and the human medicines rapporteur outcome template letters were revised to outline involvement of a multinational team in the rapporteur or co-rapporteur team.
- The pilot project gathering data on scientific advice/protocol assistance started in January and was completed in Q3, with a high rate of reporting from both the network and the EMA secretariat. The Management Board extended the scope of the initiative to include veterinary procedures in March 2015, and work to gather data on fee-generating procedures started over summer. A high-level plan to extend data-gathering to a number of fee-generating and non-fee generating procedures in

human and veterinary areas of activity was presented and agreed by the Management Board in December and the final report of the exercise is targeted for December 2016.

- The medical literature monitoring (MLM) service was launched in July for the 50 most common active chemical substances. On 1 September, the MLM service entered into full production, screening for 300 active chemical substances and 100 herbal substances.
- A draft strategy on the methods and approach for measuring pharmacovigilance impact was presented to the PRAC in June and finalised with PRAC feedback in December, including a detailed work plan for 2016. It is expected to be adopted by the PRAC in January 2016.
- The strategy for developing an EU collaborative framework for patient registries was published in October 2015. The cross-committee task force endorsed four candidate products for the pilot phase in December 2015.
- The finalised code of conduct for vaccine benefit-risk studies was published on the ADVANCE project website in May 2015.
- The Agency provided its contribution to the European Commission's report on three years of pharmacovigilance tasks undertaken by EU Member States and the EMA. Publication of the Commission's report is expected in 2016.
- The first annual pharmacovigilance-fee invoices were issued in July 2015 to approximately 4,200 marketing-authorisation holders.
- The PSUR repository went live on 26 January 2015, and the audit started as originally planned. The audit was concluded successfully and, following the PRAC's positive endorsement, the Management Board confirmed full functionality of the repository in June. A pilot on centrally and nationally authorised products is underway.
- As part of the clinical-trials programme delivery, business analysis and business requirements-gathering for the EU portal and database and safety-reporting projects were carried out over the first half of 2015. The EMA Management Board endorsed the appendix on transparency rules to the functional specifications of the EU clinical trials portal and database in October and the timeframe for implementation of the EU portal and database in December 2015.
- A workshop on good clinical practice for bioequivalence trials/generics took place in October 2015. This was a first step to establish a platform for direct interaction between regulatory authorities and concerned stakeholders with regards to GCP aspects of bioequivalence studies included in generic marketing-authorisation applications. Industry associations were invited to consider preparation of guidance to reflect best practices in line with the topics discussed.
- A stakeholder meeting on product shortages due to manufacturing and quality issues was held in October 2015 to review solutions proposed by industry associations. During this meeting the need for further measures and proposed next steps were discussed. Next steps include work on ways to evaluate the impact of measures taken to prevent shortages and on communication issues, including communication between industry and regulators, across the supply chain and to the public.
- Work aiming at establishing a mutual reliance framework with the FDA has progressed, with finalisation of the EMA response to FDA questions and the completion of the EC and member states' audit of the FDA supervisory system.
- A new report using Article 57 data (Article 57 publication dashboard) was made available to NCAs in October 2015. Based on the release of this tool, in December, the EMA Management Board

decided that the Article 57 database was functional for the purpose of notifying changes in OPPV and location of PSMF. As a result, type IA variations shall no longer be submitted from 1 February 2016.

- The EU veterinary medicinal product database to replace Eudrapharm (Vet) was delivered in Q1 2015.
- The previous pandemic preparedness plan was reviewed and transformed into a wider-ranging preparedness plan for emerging health threats. Implementation work continued in the second half of the year, with a few outstanding aspects still to be finalised in 2016.
- The procedural/regulatory guidance for pandemic vaccines was adopted by the CHMP/CMDh in May 2015.
- As part of an initiative to improve collaboration and communication between committees, common templates and streamlined processes for delivering committee work plans were implemented in Q1, further strengthening interactions between the committees.
- As part of the work to continuously improve the way scientific opinions are delivered, an effects table has been included in the assessment reports of all applications for marketing authorisation and extension of indication since February 2015.
- Improved interactions and support to committees and industry have resulted in a continuous and significant decrease in average clock-stop for new active substances and biosimilars. In 2015, the average clock-stop was 138.4 days (from 218 days in 2013 and 166 days in 2014).
- The revised policy on handling of declarations of interests of scientific-committee members and experts entered into force on 30 January 2015. A revised EMA breach-of-trust procedure on conflicts of interests for scientific-committee members was also adopted and published in May 2015.
- A revised conflict-of-interests policy for Management Board members was adopted by the Management Board in December, and will be implemented in May 2016.
- Working to increase patient involvement and obtain real-life data, a focus group was convened in Q2 2015, in collaboration with the Melanoma Patient Network Europe and Myeloma Patients Europe, and discussed patient preferences based on a fictitious case study. Additional focus groups were held in the second half of the year and the results of the focus groups were presented at the annual meetings of European Society of Haematology (EHS) and European cancer organisation (ECCA), and also published in Clin Pharmacol Ther.
- In the area of transparency and in preparation for the publication of clinical-data reports, draft guidance on anonymisation of individuals in clinical reports was prepared in the first half of the year, and revised following a targeted consultation with academics, pharmaceutical industry, NGOs and patients' organisations. An opinion from the EDPS is awaited.
- As part of the activities to increase the quality and consistency of the product information provided to stakeholders, a new labelling process was introduced in the middle of the year. Preliminary monitoring conducted in September showed overall positive trends regarding adherence to the new process.
- An EC/EMA–Swissmedic confidentiality arrangement on exchange of non-public information relating to medicines for human and veterinary use was signed and came into force in July 2015.
- An EC/EMA–WHO confidentiality arrangement on exchange of non-public information relating to medicines for human use was signed and came into force in September 2015.

- The IGDRP pilot for sharing generic medicines' assessment reports was extended to centralised products in January 2015. A call for expressions of interest for applicants was launched in January. Three companies have expressed their interest to participate in the pilot.
- WHO-nominated experts/observers from Ghana and Tanzania participated in the Article 58 procedure for the malaria vaccine Mosquirix. In addition, the EMA, together with the EC and Bill & Melinda Gates Foundation, with the support of external consultants, carried out a strategic review of the use, role and vision of its Article 58 scientific opinion.
- In October 2015, a web-based tool was introduced for online reporting on sales of veterinary antimicrobials as part of the European Surveillance of Veterinary Antimicrobials (ESVAC) activity.

1.2. Work programme implementation

The work programme consists of four parts: evaluation activities for human medicines; evaluation activities for veterinary medicines; horizontal activities and other areas; and support and governance activities. Each of these is further broken down into chapters covering the Agency's activities in specific areas or stages in the medicines lifecycle.

Each of the chapters outlines the achievement of workload and performance indicators included in each chapter of the work programme, as well as covering a set of objectives, with the relevant activities and results outlined.

Explanation of symbols used

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

	Results more than 10% above the forecast/target
	Results within +/-10% of the forecast/target
	Results 10%~25% below the forecast/target
	Results more than 25% below the forecast/target
	No activity/result to report

The traffic light system in general reflects the direction and magnitude of change as described above. However, for some performance indicators, such as average assessment or clock-stop days, or calls reopened due to incorrect handling, the traffic light system is reversed to better reflect the essence of these indicators: results below the target are marked green or blue, while results above the target will appear amber or red.

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

For indicators that have been included in the work programme 2015 for the first time, data on previous years' results are not provided.

1.2.1. Evaluation activities for human medicines

1.2.1.1. Pre-authorisation activities

Workload indicators

	Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
	Scientific advice and protocol assistance requests, of which:	357*	429*	493*	421*	In 2015 EMA received fewer SA and PA requests than forecasted; however, the volume has remained at similar level as in 2014, possibly signalling a plateau in the scientific advice and protocol assistance requests
	Parallel scientific advice with international regulators	8	2	4	3	The result is in line with regular variations and as such is regarded as falling within acceptable range of the forecast
	Joint scientific advice with HTA bodies	7	11	30	30	
	Protocol assistance requests	108	113	129	137	
	Novel technologies qualification advice/opinions	15	22	17	20	
	Scientific advice/protocol assistance pre-submission meetings	116	137	165	89	Increasing familiarity of medicines' developers and applicants with the regulatory processes reduces the need for formal pre-submission meetings, with questions and issues being solved through informal contact
	Scientific advice finalised	363	432	431	386	
	Protocol assistance finalised	111	101	162	139	
	Orphan medicines application pre-submission meetings	-	-**	200	163	

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Orphan medicines applications, of which:	201	329	240	258	
Parallel orphan applications with international regulators	82	109	96	86	
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	471	485	480	515	
Finalised procedures for compliance check on PIPs	58	85	72	67	
Requests for classification of ATMPs	20	28	28	61	Significant increase is due to the requirement of Polish NCA for all applicants of clinical trials with cell-based products (borderline with transplants) to request an ATMP classification for all these products. This trend is expected to continue in 2016
Innovation Task Force briefing-meeting requests	28	28	42	34	
Innovation Task Force Art 57 CHMP opinion requests	10	5	2	0	

* Scientific advice and protocol assistance are split in pre-authorisation and post-authorisation. Total number of SA and PA requests was 473 in 2013, 551 in 2014, and 510 in 2015.
** New indicator introduced in 2015.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Scientific procedures completed within regulatory timeframes*	99.5%	99%	100%	100%	
Increase in scientific-advice requests	12.6%	17%	10%	-8%	In 2015 the volume of scientific advice requests has remained at the level of 2014, approximately 8% lower than forecasted for 2015. This could be a

Procedure		2013 result	2014 result	2015 target	2015 result	Notes
						random undulation or, if the trend continues in future years, would signify reaching a plateau for scientific advice requests
	SME requests for scientific advice (percentage of total SA requests)	24%		20%	32%	Previously observed trend in the SME requests for scientific advice continued in 2015
	Percentage of initial evaluation applications (for new active substances and biosimilars) that have received scientific advice	72%		76%	82%	
	Percentage of applications designated as orphan medicines	69%		75%	67%	
	Number of confirmation of applicability of paediatric class waivers	78	41	45	57	The publication of revised list of class waivers could be one of the reasons contributing to higher than expected year-end results in 2015

* Includes scientific advice, protocol assistance, orphan designation and paediatric procedures.

Achievements

Objective	Activity	Achievements/results
Promote more active use of scientific advice and other pre-application support, including early and iterative dialogue with pharmaceutical sponsors	Launch a scheme to facilitate interaction and early dialogue with sponsors throughout the medicines lifecycle	Development of the single interface for sponsors and developers to improve access to scientific and regulatory guidance has been delayed and will progress further in line with the corporate website project implementation.
	Organise a workshop on significant benefit	The workshop was successfully held on 7 December 2015.
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product life-cycle	Finalise guidance to applicants to facilitate access to parallel scientific advice HTA procedure	Following the further analysis of the comments received earlier on the draft guideline, it was finalised in the second half of 2015. An interim revision of the HTA-EMA parallel advice best practice guide, responses to the comments and a report on the pilot were delivered in the second half of 2015.
	Review existing guidance on parallel scientific advice with the FDA	The guidance was reviewed, finding that no changes need to be introduced.

Objective	Activity	Achievements/results
	Develop guidance for the qualification of novel methodologies, in collaboration with IMI, EFPIA and FDA	Common letter of intent with IMI, EFPIA and FDA was finalised and published on EMA website in January.
Facilitate research and development of new medicinal products	Complete the adaptive pathways pilot project and review outcomes of the pilot	Following the first in-depth meeting with HTAs in December 2014, a report on the initial experience with the adaptive pathways project and the next steps was finalised and sent to HTAs in March 2015. Submission guidance and webpage were updated in the second half of the year.
	Provide scientific and regulatory input to the European Commission on specific borderline products	Presentation on the EMA scientific and regulatory issues/experience with borderline products was given at the DG Research workshop on Key Enabling Technologies in May. Input to the follow up meeting on Key Enabling Technologies and the Medical device expert group (MDEG) was provided in the second half of the year.
	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	Work on new process and criteria for proposing research topics, as well as criteria to define level of EMA involvement in various research projects, started in Q1 2015. A suite of documents has been created to support more streamlined and targeted, strategic EMA involvement in IMI. Following a request from DG Sante, an overview of all EMA involvement in research was prepared for presentation at the Management Board in early 2016. No research topics were submitted in 2015. All IMI–related activities were put on hold in the second half of the year.
Support development and availability of medicines for specific target groups	Develop and implement EMA Gender strategy	Presentation on the EMA actions regarding Gender strategy was given at EUGenMed conference in Q2 2015. Activity was suspended and not progressed in the 2nd half of the year.
	Implement EMA Geriatric medicines strategy	Following discussions at CHMP Organisational Matters Group, concerned working parties and the Guideline Coordination Group the draft frailty guideline released for public consultation in October. The first draft of the geriatric GVP was finalised in Q2 2015. Additional pilot was requested by CHMP on assessment reports for 10 products.

1.2.1.2. Initial evaluation activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Initial evaluation applications, of which:	80	100	112	111	
New non-orphan medicinal products	48	38	40	36	
New orphan medicinal products	18	21	24	25	
Similar biological products	1	3	9	12	The result is in line with regular variations and as such is regarded as falling within acceptable range of the forecast
Generic products	12*	25	26	28	
Hybrid and abridged applications	-*	12	12	9	
Scientific opinions for non-EU markets (Art 58)	1	1	1	1	
Paediatric-use marketing authorisations	1	0	0	1	

* Hybrid and abridged applications included in the number of generic products in 2013.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of applications evaluated within legal timeframes*	99%	100%	100%	100%	
Average assessment time for new active substances and biosimilars (days)	207	197	205	200.7	

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Average clock-stop for new active substances and biosimilars (days)	218	166	180	138.4	Improved interactions and support to committees and industry have resulted in continuous and significant decrease in average clock-stop for new active substances and biosimilars

* Includes marketing authorisation and plasma master file applications.

Achievements

Objective	Activity	Achievements / results
Provide high quality, robust, scientifically sound and consistent scientific opinions to the EC	Embed the use of Effects table in all assessment reports	Effects table has been included in the assessment reports of all applications for marketing authorisation and extension of indication since February 2015.
	Implement guidance to support a consistent approach for imposed PASS/PAES	The initial list of items for monitoring as part of the pharmacovigilance indicators was developed at the beginning of 2015. Additional items for monitoring will be developed in 2016, once the oversight group is operational. A new cross-functional oversight group on the post-authorisation studies, providing guidance to committees and product teams on the imposition of PASS and PAES was established in Q4 2015.
Provide high quality, evidence-based and consistent product information that meets stakeholders' needs	Implement an improved process for the review of the product information	New labelling process was introduced in the middle of 2015. Complete performance report will be prepared in Q2 2016, however, preliminary monitoring conducted in September showed overall positive trends regarding adherence to the new process.
	Initiate discussions with HTA bodies on labelling usability	Development of the principles for indication wording started in March and discussions were initiated at EMA/EUnetHTA meeting in May. The principles were introduced at the CHMP at the December plenary. Finalisation of the principles is expected in early 2016, with the aim to use the relevant elements at the EMA/EUnetHTA plenary in Q2 2016.

Objective	Activity	Achievements/results
	Strengthen existing guidance on labelling and promote the use of the guidance and advisory groups to support labelling discussions during product evaluation	Guidance on labelling was updated and presented in a dedicated training in March 2015. Q&As providing additional guidance and interpretation on specific SmPC topics were published. Six webinars to provide training for the assessors on SmPC-related matters were held in 2015.
Increase patient involvement in benefit/risk evaluation of medicines	Prepare 1-year analysis report on patient involvement in benefit/risk evaluation in CHMP	Due to insufficient number of cases of patient involvement in benefit/risk evaluation at CHMP since September 2014, the pilot phase has been extended and the analysis and the report have been postponed to 2016. Interim report was presented to CHMP in December.
	Develop recommendations on the feasibility of convening focus groups in specific disease areas to obtain real-life data	The first focus group was held in Q2 2015 in collaboration with Melanoma Patient Network Europe and Myeloma Patients Europe, and discussed patient preferences based on a fictitious case study. Additional focus groups were held in the second half of the year and the results of the focus groups were presented at the annual meetings of European Society of Haematology (EHS) and European cancer organisation (ECCA). Article reflecting the results and recommendations was also published in Clin Pharmacol Ther in 2015 (Postmus, D., et al. "Incorporating patient preferences into drug development and regulatory decision making: results from a quantitative pilot study with cancer patients, carers and regulators").
	Analyse the applicability of methods, including visualisation and patient values, for benefit risk assessment (2015) and publish an interim report (2016)	Survey on the necessary guidance and systems to support efficient and effective conduct of pharmacovigilance was launched in June 2015 among the participants of a PROTECT symposium held in February with the results expected in July. Work on the report started in Q3 2015 and it is expected to be completed in Q2 2016.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within the existing legal frameworks, including through collaboration with international partners	Deliver analysis of the use of conditional marketing authorisation concept and review changes needed regarding tools or training	Analysis of experience with the conditional marketing authorisation was presented to the EC expert group STAMP in January and, following its update, in May. Discussions with CHMP sponsors took place throughout the first half of the year, and the analysis was presented in the committee meetings in Q2 2015. Updated CHMP guideline on conditional marketing authorisation was released for public consultation in July 2015. The comments are being discussed at CHMP and finalisation of the guideline is expected in Q1 2016.

Objective	Activity	Achievements/results
	Deliver analysis of accelerated approval concept and review changes needed regarding tools and training	Analysis of the accelerated approval concept was completed in Q1 2015 and the revised guidance and templates were presented to the committees in May and June. Following the public consultation in Q3 2015, the updated guideline was introduced to committees in December 2015. Formal adoption and implementation of the guideline is expected in Q1, along with PRIME framework and the revised guideline on conditional marketing authorisation.
	Provide guidance on optimal use of the full range of available regulatory tools to address emerging public health threats	The previous pandemic preparedness plan was reviewed and transformed into a wider-ranging preparedness plan for emerging health threats. The new plan was completed towards the end of Q2, and the composition of the internal task force was revisited and key documents updated. Implementation work continued in the second half of the year, with few outstanding aspects still to be finalised in 2016.
	Explore with HTA bodies the opportunity for information exchange on assessments around time of licensing to support rapid relative effectiveness assessments	Following the discussions at the EMA/EUnetHTA meeting in May, the draft agreements for information exchange on assessments were sent to the EC for comments. Discussions with the EC and EUnetHTA on the new arrangements continued in the 2nd half of 2015; the legal position of the EC is awaited before developing the proposal further.
Enrich the tools available to the European regulatory network to support a robust benefit-risk evaluation of human medicines throughout their lifecycle	Explore approaches and scenarios for use of individual patient data (IPD) to enhance committees' scientific assessment	The activity was put on hold until further decision.

1.2.1.3. Post-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Variations applications, of which:	5,841	6,006	5,602	5,999	
Type IA variations	2,922	2,969	2,750	2,864	
Type IB variations	1,958	1,886	1,820	1,980	
Type II variations	961	1,151	1,032	1,155	
Line extensions of marketing authorisations	16	16	19	14	
Post-authorisation scientific advice requests	116	122	105	89	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of post-authorisation applications evaluated within legal timeframes	99%	100%	100%	99%	
Percentage of risk management plans peer-reviewed within the assessment process of variations and line extensions	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements / results
Provide high quality, efficient and consistent scientific assessment of post-authorisation changes to marketing authorisations	Develop agreed high quality standards to support review PASS protocols	New process for review of non-imposed PASS protocols through the Scientific Advice Working Party was developed in the first half of the year, including aspects of risk management in the scientific advice process. More refined indicators were developed for the non-imposed PASS process through scientific advice, including data collection. The indicators will be rolled out to a wider group of PASS protocol reviews in 2016.
Further promote use of scientific advice throughout the lifecycle of the product, including further development of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)	Implement a pilot process for review of non-imposed PASS protocols through scientific advice procedures	Joint Scientific Advice Working Party members were nominated in June and SAWP membership was enhanced with PRAC members in August. The process for review of non-imposed PASS protocols has been developed and the pilot PASS procedure through scientific advice was initiated in September 2015.
Improve the knowledge of the impact of medicines' use on environment	Update review of environmental risk assessment in submitted dossiers	The updated risk-based approach in relation to environmental risk assessment was implemented in the first half of 2015 and is now in operation as a routine approach. Training on identifying environmental risk assessment issues and application of the risk-based approach in the process of assessment work was given to the EPLs in May.

1.2.1.4. Referrals

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Pharmacovigilance referrals started	18	7*	8	5	
Non-pharmacovigilance referrals started	25	11*	8	16	Following the low activity and a downward revised forecast in the middle of 2015, large number of non-pharmacovigilance referrals were received in the second half of the year

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

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements/results
n/a		

1.2.1.5. Pharmacovigilance activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Total adverse drug reaction reports, of which:	1,063,456	1,132,363	1,215,893	1,228,342	
Adverse drug reaction (ADR) reports for CAPs	679,413	691,897	763,534	855,631	
Adverse drug reaction (ADR) reports for NAPs	384,043	440,466	452,359	372,711	
Number of signals peer-reviewed signals by EMA	2,449	2,030	2,000	2,372	
Number of signals validated by EMA	43	34	40	61	
PSURs received	518	520	566	512	
PSUSAs received	-	-	210	268	Additional PSUSAs that started as a result of phasing out of the voluntary CMDh work-sharing scheme
Number of imposed PASS/PAES	-*	32	51	40	
Number of emerging safety issues received	24	19	35	34	
Notifications of withdrawn products received	18**	132	160	160	

* New procedures established in 2014.
** Notifications only received starting November 2013.

Performance indicators

Procedure		2013 result	2014 result	2015 target	2015 result	Notes
	Percentage of reaction monitoring reports supplied to the lead Member State monthly	100%	100%	100%	100%	
	Percentage of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	98.4%	
	Cumulative number of products on the list of products subject to additional monitoring	152	203	270	261	

Achievements

Objective	Activity	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	Publish the report on the impact of the EU PROTECT project on medicines development, regulation and pharmacovigilance	Survey on the necessary guidance and systems to support efficient and effective conduct of pharmacovigilance was launched in June 2015 among the participants of a PROTECT symposium held in February with the results expected in July. Work on the report started in Q3 2015 and it is expected to be completed in Q1 2016. A new annex of the GVP Module IX is being drafted to integrate the recommendation from PROTECT regarding signal detection published in peer-reviewed journals and is foreseen for public consultation in 2016. Rev 5 of the ENCePP Guide on Methodology standards will integrate the recommendations on pharmacoepidemiology. The results will also be published in full as a supplement of the Pharmacoepidemiology and Drug Safety journal (January/February 2016).
	Launch literature monitoring service	Contract with the service provider was signed in May and the service was launched for the most common 50 active chemical substances in July. On 1 September the MLM service entered in full production, screening for 300 active chemical substances

Objective	Activity	Achievements/results
		and 100 herbal substances.
	Publish Good practice guide on coding & reporting and on risk minimisation & prevention of medication errors	Following the 2-month consultation held in April-May 2015, the draft guidance was revised and the revision consulted with EU regulatory network. The final Good practice guide on medication errors (part I and II, including addendum on insulins) was adopted by HMA in October and published on EMA website in November.
	Develop, test and validate a Standardised MedDRA Query (SMQ) on medication errors to facilitate ICSR data retrieval as a first step in investigating drug safety issues	Council for International Organisations of Medical Sciences (CIOMS) working group developed and tested the draft SMQ in May 2015. SMQ terms for a narrow and broad list were agreed at CIOMS meeting in September 2015. Support documentation was provided to MedDRA Maintenance and Support Services Organisation for compilation, and SMQ is planned to be released in production with MedDRA version 19.0 in March 2016.
	Prepare (2015) and publish (2016) a report on methods and approach for measuring pharmacovigilance impact	Draft strategy on the methods and approach for measuring pharmacovigilance impact was presented to the PRAC in June and finalised with PRAC feedback in December, including a detailed work plan for 2016. It is expected to be adopted by PRAC in January 2016.
	Finalise remaining GVP modules	The set of GVP modules is completed. The development of further considerations chapters is ongoing.
	Publish draft code of conduct (2015) and governance proposals (2016) for vaccine benefit risk studies from the ADVANCE project	The finalised code of conduct for vaccine benefit risk studies was published on the ADVANCE project website in May 2015. A lighter version of the document was published for 2 month consultation in September, and the comments received were discussed at the ADVANCE WP1 workshop on 11 December 2015.
	Conduct pilot studies, based on common protocols, with a small number of Member States in the context of PRAC safety assessments (2015). Develop recommendations for a sustainable process, based on the experience gained (2016)	The overall approach to conducting pilot studies related to clinical use of medicines in Member States was agreed at PRAC in Q1 2015, and common study protocol was developed and agreed by the UK, Spain and EMA in December 2015. Pilot studies are ongoing with the final results and conclusions expected in Q2 2016.
Maximise benefits to public health	Deliver a PCWP/HCPWP workshop on risk	The workshop was held on 16 September.

Objective	Activity	Achievements/results
promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through use of high quality data, information and knowledge	minimisation tools	
	Define the scope and process of best evidence generation in the context of PRAC	The overarching approach on best-evidence generation for pharmacovigilance issues (Real World Evidence approach) was agreed with PRAC in Q2 2015. Long term strategy outlining scope and process for best evidence generation was presented to senior management in December 2015.
	Establish a new framework procedure for the external procurement of effectiveness and pharmacoepidemiology studies on medicines	The framework contract tender for effectiveness and pharmacoepidemiology studies was finalised in April, and the contracts with the external centres were signed. Tenders for two studies were sent to four centres in November 2015.
	Amend eRMR to include products that are subject to additional monitoring	Amendments to eRMR to include products subject to additional monitoring have been fully implemented since June 2014.
	Initiate a pilot on EU collaborative framework for Patient registries	The EU Joint Action methodological guideline was presented to the cross-committee task force in January 2015, and was being improved in the first half of 2015 to consider the comments received. The strategy for developing an EU collaborative framework for patient registries was published in October 2015. Manuscripts for publication in peer-reviewed journals are in preparation. The Cross-committee task force endorsed four candidate products for the pilot phase in December 2015.
	Analyse in collaboration with the Member States the need to update relevant guidance for the industry to reflect the use of social media and other tools in ADR reporting, considering output from the WebRADR project	Analysis of the need to update relevant guidance continued in the first half of the year, including discussion of the legal aspects relating to the use of social media and other tools in ADR reporting. The report of the first WebRADR workshop to identify stakeholder's needs and potential challenges was published in September 2015. Initial assessment of the personal data protection requirements in line with EU data protection legislation was completed in December 2015, with the ethical considerations under further development. A second survey on the regulatory requirements in relation to digital media monitoring in pharmacovigilance was performed in Q3 2015 with a draft report summarising the results circulated for review in November 2015.
	Investigate compatibility of Applications for patient reporting developed at national level	The data analysis was completed and the report (Patient reporting in the EU – analysis of EudraVigilance data) is being prepared.

Objective	Activity	Achievements/results
	(WebRADR project) with subsequent reporting from Member States to EudraVigilance	
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish report on EMA pharmacovigilance activities	The Agency provided its contribution to the European Commission's report on 3 years of pharmacovigilance tasks undertaken by EU member states and EMA. Publication of the Commission's report is expected in 2016.
	Publish final report on the IMI PROTECT study of consumer reporting during pregnancy, including recommendations for action	The final report was published in peer-reviewed journal in December 2015 (N. Dreyer et al. JMIR Public health Surv 2015; 1(2), e22, 1-11).
	Deliver analysis from the pilot-phase conducted in 2014 on publication of Risk Management Plan summaries for newly centrally-authorised products	The pilot phase was completed in March 2015, and the results were analysed in Q2. The report was presented at HMLT and CHMP in Q4 2015, and will be presented at PRAC in January 2016. Updating the risk management plan summary template and procedure started at the end of 2015, according to the results of the pilot phase.

In addition to the activities outlined in the Agency's work programme, the new business and financial processes and IT systems to ensure accurate invoicing of the annual pharmacovigilance fees were implemented in the first half of 2015. The first annual pharmacovigilance fee invoices were issued in July 2015 to approximately 4,200 marketing authorisation holders.

1.2.1.6. Other specialised areas and activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Herbal monographs, new*	9	11	15	14	
Herbal monographs, revised	7	5	5	3	
List entries	0	1	1	0	

* Where assessment does not lead to the establishment of a monograph, a public statement is prepared. 2 public statements were prepared in 2015.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
n/a					

Achievements

Objective	Activity	Achievements/results
Implement the new Clinical Trials Regulation (EU) No 536/2014	Deliver Clinical Trials programme	Business analysis and business requirement gathering for both, EU portal and database, and safety reporting projects were carried out over the first half of 2015. The appendix on transparency rules to the functional specifications of the EU clinical trials portal and database was endorsed by the EMA Management Board in October, and the timeline for implementation of the EU portal and database was endorsed by the Management Board in December 2015.

Objective	Activity	Achievements/results
		Further work on the EU portal and database will be done after the decision on the workflow/case management tool is made.
Assure quality of data and appropriate protection of participants of clinical trials through risk proportionate approaches to the design and management of clinical trials, especially those conducted outside EU/EEA	Implement a standardised set of information on clinical trials to be included in applications, CHMP assessment reports and EPARs	Day 210 assessment report template was amended in the first half of 2015, to refer to GCP/GLP inspections information to be included in the report. The amended template was adopted at the June CHMP meeting. Additional templates for industry for the provision of information in relation to GCP and GLP status as part of the marketing authorisation application were developed and published on the Agency's website in the second half of the year. MAA pre-submission meeting request form amended in July to include guidance on the pivotal clinical study(-ies) information required for applications proposed for accelerated assessment to facilitate early identification of a need for pre-authorisation inspections. The Q&A - Good clinical practice (GCP) was updated to provide guidance on the presentation of clinical study data prior to GCP inspections and on the report format of the patient data listings.
	Implement framework for ethics experts to advise CHMP	The draft mandate of the Ethics advisory group was amended in May 2015, addressing the comments received earlier from the CHMP.
Facilitate development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	Deliver workshops on pharmacokinetics / pharmacodynamics of antibacterial agents and bacteriophages	The workshop on the therapeutic use of bacteriophages was held in June 2015 and the workshop on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products was held in November 2015.
	Review the guideline for development of new tuberculosis medicines	Public consultation on the concept paper for the guideline ended in February 2015. The comments received are being reviewed and considered for the drafting of the guideline, which is expected to begin in 2016.
Support high level of coordinated cross-European preparedness to act upon public health threats	Finalise guideline on clinical/non-clinical development of influenza vaccines	Consultation on the guideline finished on 31 January. The guideline was revised, considering the comments received during the public consultation, and the final version of the guideline will be submitted to the Guideline consistency group for review and subsequent finalisation by Q2 2016.
	Finalise procedural/regulatory guidance for	The guidance was adopted by CHMP/CMDh in May 2015.

Objective	Activity	Achievements / results
	pandemic vaccines	
Facilitate availability of herbal medicines in the European Union	Identify remaining herbal substances requiring EU harmonisation and develop strategies/guidance to maintain up-to-date consistent standards (monograph/ guideline revisions)	Four new substances identified by the NCAs were added to the priority list for assessment in 2015. Based on a survey conducted at the beginning of the year on registered/authorised herbal medicinal products in the Member States, marketed substances not yet considered for HMPC assessment were extracted. No urgent assessments were identified but agreed to define future criteria for assessment of less common substances in the EU in 2016. The public statement prioritisation for assessment of herbal substances associated with safety concerns was revised and published. Transitory measures on prioritisation for systematic review were agreed and announced in the September public meeting report and reflected in HMPC priority list and 2016 Monograph and list working party (MLWP) work plan. Revision of guideline on the reasons and timelines for revision of final Community herbal monographs and Community list entries, and of the procedure for the systematic review of Community herbal monographs and supporting documents, was postponed to 2016.
	Assess combination products and herbal substances originating from non-European traditional systems	Working party discussions on setting European standards for herbal combination products, including solutions for tea combinations, took place throughout 2015. Representatives from the Taiwanese government (Nat. Res. Inst. of Chinese Medicine, Ministry of Health) and Indian government (Ministry of AYUSH) attended HMPC/MLWP in July and November 2015, respectively, to foster understanding of data requirements for non-European substances. Work on six Indian plants has so far led to public statement. One major traditional Chinese medicinal plant was discussed twice in the first half of 2015 and draft public statements on two major traditional Chinese medicinal substances (Paeoniae radix rubrae and albae) were adopted by MLWP in November 2015.

1.2.2. Evaluation activities for veterinary medicines

1.2.2.1. Pre-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Innovation Task Force briefing requests	-*	2	4	2	Uptake of ITF slower than expected. However, the result is in line with regular variations and as such is regarded as falling within acceptable range of the forecast
Scientific advice requests received	40	31	28	27	
Requests for classification as MUMS/limited market	23	29	23	28	Unexpected increase in MUMS requests in the second half of the year

* ITF procedure made available to veterinary products in 2013.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of scientific advice procedures completed within set timeframes	97%	100%	100%	100%	

Achievements

Objective	Activity	Achievements / results
Provide support and incentives to development of new medicines for MUMS/limited markets	Inform companies of expiry of MUMS status of their products and possibilities for requesting extension, and review products currently classified as MUMS/limited markets whose status expires in 2015	The MUMS status of 12 products was identified to expire in 2015. Five reminder letters of the approaching expiry of MUMS status were sent to the relevant companies in February, six months before status expiry (remaining seven letters were already sent in 2014). One applicant requested reclassification in the second half of 2015.
	Publish annual report on MUMS/limited market activities	Annual report on MUMS/limited market activities was adopted at CVMP in February and published, following its adoption at the EMA Management Board in March.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	Review the procedures for scientific advice to identify areas for improvement, considering the views of recipients regarding the usefulness and quality of the advice received	It was decided at the end of 2015 to include the review of scientific advice processes as part of the overall review of the procedures carried out in the veterinary division. The user evaluation (to inform process evaluation) will be carried out in 2016.
	Inform applicants of the possibility to apply for parallel scientific advice with the FDA, as part of pre-submission advice	As part of the regular process of providing scientific advice, the applicants are continuously informed on a bilateral basis of the possibility to receive parallel scientific advice with FDA Center for Veterinary Medicine. Parallel advice was also promoted at the IFAH-Europe Day 2015 and the SME workshop 2015.
Promote innovation and use of new approaches in development of veterinary medicines	Establish and start operation of the ADVENT group	Following the establishment of the ADVENT group, it held its first plenary meeting in January 2015 and prepared problem statements for two areas as a basis for guidance development. At its March meeting, CVMP adopted ADVENT work plan 2015 and agreed the priority topics for which guidance will be developed by ADVENT group. The working methodology for ADVENT including interaction with the public is expected to be finalised in early 2016.
	Inform industry through presentations and as part of existing pre-authorisation procedures of the possibility to access the Agency's Innovation Task Force	Innovation Task Force was presented as part of the presentation on support to novel therapies, at the CVMP interested parties meeting in March and SME meeting in April 2015. ITF was also continuously promoted on a bilateral basis in the pre-submission meetings and in response to individual queries. ITF was included on website landing pages in the second half of the year, as part of

Objective	Activity	Achievements / results
		information highlighting the range of advisory services to companies in research and development of medicines, including novel therapies.

1.2.2.2. Initial evaluation activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Initial evaluation applications	23	12	14	10	Several expected applications were deferred to 2016 late in the year
New MRL applications	6	4	2	4	
MRL extension and modification applications	6	2	2	3	
MRL extrapolations	1	2	1	1	
Art 10, Biocides	0	0	2	0	
Review of draft Codex MRLs	0	5	0	0	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of procedures completed within legal timeframes	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements / results
Provide high quality and consistent scientific opinions to EC	Put in place the arrangements necessary to facilitate multinational national assessment teams and update the register of expertise of CVMP members and experts	The multinational team concept was presented to HMA in Q1. The EMA MB amended fee-related documents to allow remuneration of multinational teams at its March meeting. Four requests to set up multinational assessment teams were received in 2015.
	Update assessment report templates to provide new guidance on the principles for preparing veterinary medicines' assessment reports and further embed benefit-risk methodology in the veterinary medicines assessment process	The guideline and scientific overview template for pharmaceuticals were discussed and revised in working parties in the first half of the year. CVMP adopted the final guidance in December and the template for pharmaceutical products will be implemented during early 2016. The template for immunologicals will also be updated in 2016.
	Provide assessor training to ensure consistent use of the above-mentioned assessment methodology	Following the adoption of the guidance by CVMP, assessor training will be provided in the first half of 2016.
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	Provide technical support to the European Commission in drafting the implementing acts specified in Regulation (EC) No 470/2009	A request from the EC on one implementing measure was received in Q2. The recommendation adopted by CVMP in September was further revised in October concerning requirements on analytical methods, further to the discussion with EU reference laboratories. The recommendation was sent to the Commission in October.
	Provide technical support to the European Commission as part of the development of a Commission strategy for managing risks to the environment related to the use of medicines (both human and veterinary)	No requests for support were received in 2015.

1.2.2.3. Post-authorisation activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Variation applications, of which:	315	340	343	373	
Type IA variations	175	175	175	196	
Type IB variations	108	118	120	116	
Type II variations	32	47	45	61	Two workshare applications containing a number of variations were received in the second half of 2015, resulting in higher number of type II variations
Line extensions of marketing authorisations	5	6	3	3	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements / results
Ensure efficient delivery of post-authorisation procedures	Review the procedures for variations and introduce necessary improvements	The actions to improve Type II procedure management were agreed in April. The implementation of the improvements started in Q3 2015 and is expected to be completed n Q1 2016.
	Develop revised templates and guidance for the assessment of Type II variations	Review of Type II variation assessment template with integrated guidance started was completed in Q3 2015 and the improvements will be finalised in Q1 2016.

1.2.2.4. Referrals

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Arbitrations and Community referral procedures initiated*	10	7	10	7	A number of anticipated referrals were deferred to 2016

* It is expected that a substantial proportion of referrals will each relate to a large number of products, sometimes even hundreds of products.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements / results
n/a		

1.2.2.5. Pharmacovigilance activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Periodic safety-update reports (PSURs)	149	158	150	159	
Total adverse-event reports, of which:	22,326	28,404	22,500	31,467	Measures to promote averse event reporting have proved more successful than anticipated, resulting in higher number of reports
Adverse-event reports (AERs) for CAPs	8,166	11,878	8,000	14,387	Measures to promote averse event reporting have proved more successful than anticipated, resulting in higher number of reports
Adverse-event reports (AERs) for NAPs	14,160	16,526	14,500	17,080	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of PSURs evaluated within the established timeline	97%	97%	90%	99%	
Percentage of AERs for CAPs monitored within the established timelines	100%	95%	95%	98%	

Achievements

Objective	Activity	Achievements / results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	Publish reflection papers on integration of signal detection and PSUR assessments, and promotion of pharmacovigilance reporting	A reflection paper on promotion of pharmacovigilance reporting was adopted by CVMP and published on the EMA website in March. The concept paper for the revision of recommendation for the basic surveillance of EudraVigilance veterinary data was adopted for 3 month public consultation in November 2015. The recommendation will cover topics of integration of signal detection and PSUR assessments.
	Develop a scheme for categorising products in the product database to further facilitate cross-EU pharmacovigilance	Documentation including use cases describing a phased development and implementation of fields and standard lists required was developed in the second half of 2015. Ad hoc requirements to categorise antiparasitic products were discussed at the efficacy working party and pharmacovigilance working party.
	Revise the process for CAPs and develop a new one for NAPs for surveillance of EVVet data	Draft recommendation on pharmacovigilance surveillance and signal detection of veterinary products (both, CAPs and NAPs) was adopted by CVMP and HMA in Q2 2015. The concept paper for the revision of recommendation for the basic surveillance of EudraVigilance veterinary data was adopted for 3 month public consultation in November 2015.
	Implement parts of the veterinary EU Telematics strategy covering pharmacovigilance elements not dependent on the new legislative proposal, including product data, data warehouse and others	The EU veterinary medicinal product database replacing Eudrapharm (Vet) was delivered in Q1 2015. In the 2nd half of the year attention shifted to planning for the future inclusion of veterinary products within the SPOR database.
	Publish reflection paper on causality assessment	Drafting of the reflection paper continued throughout the first half of the year. In the 2nd half of the year the activity was deprioritised and not progressed further.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish the veterinary pharmacovigilance annual bulletin	The veterinary pharmacovigilance bulletin was published, following its adoption by CVMP in March.

1.2.2.6. Other specialised areas and activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
n/a					

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
n/a					

Achievements

Objective	Activity	Achievements/results
Support increased availability of veterinary medicines	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation	Throughout 2015, EMA provided technical advice to the EC during the Council Working Party discussions on a new veterinary regulation.
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Clarify the regulatory requirement for the development of new veterinary antimicrobials by providing further guidance/advice to applicants	In February, CVMP adopted for consultation a revised guidance for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and a new draft guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals.

Objective	Activity	Achievements / results
		The comments received to both, the revised guidance and the new draft guideline, were incorporated in the second half of 2015 and both guidelines are expected to be published in 2016.
	Prepare with the Commission workshop for stakeholders on advice provided by the EMA on assessment and control of the risks to man that may arise from the use of antimicrobials in animals	EMA supported preparation of and in November attended the Commission workshop on the impact of the use of antibiotics in animals on public and animal health. Over 70 participants from the Commission, EU agencies, Member States' authorities, industry and non-governmental organisation took part in the workshop.
	Complete a pilot survey of antimicrobial consumption in pigs	Pilot survey was completed in January and work on the report on the pilot started in Q2. At the end of October, the draft report was sent for consultation to the participants of the trial (10 EU countries). Comments were received by the end of 2015 and the final report will be published in Q1 2016. The methodology to measure use of antimicrobials was updated and finalised in June, based on the experience gained. In order to establish technical units of measurement (DDDA and DCDA) for veterinary antimicrobials, the working group calculated preliminary technical units of measurement in the first half of 2015.
	Contribute to TATFAR recommendations related to veterinary medicines	In 2015, EMA contributed to producing the inventory of knowledge gaps in the transfer of resistance from animals to man and coordinated the work on TATFAR recommendation 18, including organising six teleconferences for the implementers. The draft report on recommendation 18 was finalised and the final version is expected in Q1 2016, after endorsement by TATFAR members.
	Produce first drafts of reflection papers on extended-spectrum penicillins and on benefit risk assessment in the case of veterinary antimicrobials	A guideline on benefit-risk assessment in the case of veterinary antimicrobials was published in Q1 2015 for six-month consultation, ending in August. Draft concept paper on extended-spectrum penicillins was prepared and was published for consultation until October 2016. Both documents will be finalised in 2016.
Promote uptake of harmonised standards at international level	Contribute to development of the VICH Strategy (phase IV)	Drafting of the VICH Strategy (Phase IV) that establishes VICH priorities 2016-2020 continued in the first half of the year. The finalised strategy was adopted at the

Objective	Activity	Achievements/results
		VICH Steering Committee meeting in Japan in Q4 2015.
	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	EMA provided training at a VICH Outreach forum Training session in Tanzania in June.
Contribute to minimising the need for testing of veterinary medicinal products in animals	Contribute to development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch testing of veterinary vaccines	Draft guideline on criteria to waive target animal batch safety testing for live vaccines was agreed at VICH meeting in Q4 2015 and will be published for six month consultation in Q1 2016. At the same meeting it was decided to develop a new guidance on criteria to waive laboratory animal batch safety testing for veterinary vaccines. EMA is leading the development of this guideline and it is hoped that a first draft of the guideline will be circulated to the VICH expert working group by the end of 2016.

In addition to the activities outlined in the Agency's work programme, in Q1 2015 the EC requested a joint EFSA-EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU and the resulting impacts on food safety. A draft work plan was prepared with EFSA in the first half of the year and work on drafting the opinion started in the second half of the year. The recommendations and conclusions arising from the report are expected to be agreed Q3 2016.

In October 2015, a web-based tool was introduced for online reporting on sales of veterinary antimicrobials as part of the European Surveillance of Veterinary Antimicrobials (ESVAC) activity.

1.2.3. Horizontal activities and other areas

1.2.3.1. Committees and working parties

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Number of meetings	354	397	437	437	
Number of teleconference meetings*	2,737	3,215	4,300	4,273	
Number of delegates	6,869	7,488	8,300	8,105	

* Total audio, video and web-conference meetings.

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of delegate satisfaction with the service level provided by the secretariat	-	87%	80%	93%	
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%	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%	100%	

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
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	-*	94%	80%	90%	

* New performance indicators introduced in 2014.

Achievements

Objective	Activity	Achievements/results
Improve collaboration and communication between committees to increase quality, efficiency and consistency of opinions	Implement harmonised product evaluation and post-authorisation processes for human medicines committees	Implementation of harmonised processes for product evaluation and post-authorisation processes continued throughout 2015 as a follow-up from the cross-Agency efficiency improvement programme that was concluded in 2014. Common templates and streamlined process for delivering committee work plans was implemented in Q1, further strengthening interactions between the committees. 86% of activities identified as strategic cross-committee activities were completed in 2015 or are on track to be delivered in 2016, as planned.
Provide up-to-date, timely state-of-art guidance documents on relevant topics of medicines' development	Improve planning and delivery of working parties guidance documents	Work to review the functioning and outputs of the Agency's working parties and scientific advisory groups, including guidance documents, started in Q1 2015 with the review of the WPs/SAGs' architecture, governance and operations. Extensive data-gathering exercise on products, guidelines and operational aspects was performed, including interviews with selected working parties' chairs in the 2nd half of 2015. The analysis of findings was started in the second part of the year and will continue into 2016 towards the preparation of recommendations.

1.2.3.2. Inspections and compliance

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
GMP inspections	397	420	425	567	The increase is due to an unforeseen increase in pre-approval inspections as well as higher than expected number of re-inspections of the same site during 2015
GLP inspections	0	0	1	1	
GCP inspections	70	66	70	86	Following the revision of the implementing rules to the Fee Regulation, one site can now have more than one distinct GCP inspection, resulting in higher total number of inspections in 2015
Pharmacovigilance inspections	13	20	15	14	
Notifications of suspected quality defects	178	147	180	164	
Other GMP inspections related notifications	-*	-*	20	18	
Number of medicinal products included in the sampling and testing programme	45	46	52	48	
Standard certificate requests	3,137	3,338	3,000	3,221	
Urgent certificate requests	297	535	700	785	
Parallel distribution initial notifications received	2,532	2,492	2,600	2,838	
Parallel distribution notifications of change received	2,563	1,295**	1,500	2,096	The increase is almost exclusively the result of significant increase in safety updates to the centrally

Procedure		2013 result	2014 result	2015 revised forecast	2015 result	Notes
						authorised products
	Parallel distribution notifications of bulk change received	1	9	10	13	
	Parallel distribution annual updates received***	1,279	2,339	3,000	4,550	Significant increase in annual updates reflects - increasing popularity and compliance with the annual update procedure; - cumulative effect of additional notices issued per year; - the backlog of 560 annual updates received in 2014 but only processed in 2015

* Previously included under suspected quality defects.
** Sharp decrease due to introduction of annual updates.
*** Parallel distribution annual updates introduced in May 2013.

Performance indicators

Procedure		2013 result	2014 result	2015 target	2015 result	Notes
	Percentage of inspections conducted within established regulatory timeframes	100%	100%	100%	100%	
	Percentage of standard certificates issued within the established timelines	51%	30.4%	90%	91%	
	Average days to issue standard certificate	11	13.7	10	7	
	Percentage of urgent certificates issued within the established timelines	100%	100%	100%	100%	
	Percentage of parallel distribution notifications checked for compliance within the established timeline	90%	97%	90%	99%	

Procedure		2013 result	2014 result	2015 target	2015 result	Notes
	Number of training activities organised in the area of inspections	-	7	4	10	Training for QWP assessors, Pharmacovigilance inspectors (human and veterinary), as well as GCP training and bioequivalence forum were held in 2015. In addition, 5 webinars were organised
	Additional GCP inspections addressed through information exchange on inspections carried out by international partners	-	29%	25%	46%	Increasing number of applications EMA received in parallel with the FDA in 2015 (38 vs 24 applications in 2014), allowing to increase inspection coverage by using FDA inspection information
	Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	-	8%	10%	14%	
	Percentage of outcome reports of the sampling and testing programme for centrally authorised products followed up with the MAH within one month of receipt	100%	100%	100%	100%	

Achievements

Objective	Activity	Achievements/results
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	Launch implementation of the risk-based inspections programme for 3rd country manufacturing plants of centrally authorised products, focusing EU inspectional resources to sites of highest risk	Risk-based approach to inspections has been fully implemented since Q3 2014, with the inspections programmes for each year prepared, considering the risk-based aspects.
	Identify and develop compliance and inspections activities in areas of particular interest, based on mutual reliance with trusted international partners, in particular those with confidentiality	During 2015 a number of teleconferences with FDA and WHO on the bio-equivalence initiative were held and regular teleconferences with FDA on GCP initiatives took place. Other compliance and inspections activities are being discussed via regular and ad

Objective	Activity	Achievements/results
	agreements in place (e.g. FDA and Japan)	hoc teleconferences and documents are being exchanged.
	Deliver training and capacity-building activities for inspectors and clinical assessors	In 2015, four online training courses were delivered: a basic training course for GCP inspectors; an online course on the use of EudraGMDP for international partners, including FDA, TGA and EDQM, and two training courses on the use of EudraGMDP for all EU supervisory authorities. Quality Working Party (QWP) assessors training was held in June 2015. GCP IWG workshop and bioequivalence inspection forum were delivered in October 2015 and pharmacovigilance IWG training courses (human and veterinary) were held in November. Webinar-based information sessions on European Pharmacopoeia for CHMP/CVMP QWP members and certification procedure for the members of joint CHMP/CVMP QWP, GMDP IWG and BWP were delivered in September and November respectively.
	Identify, develop (2015) and implement (2016) tools for GCP related information exchange within international GCP network	In 2015, information exchanges continued through regular communication channels and meetings. Preliminary contacts on expanding the collaborative framework on GCP information exchange with PMDA were established in May and a meeting in September was held, to explore the possibility to expand the collaboration framework.
	Prepare (2015) and set up (2016) a pilot phase with FDA on sharing information on pharmacovigilance inspections	In Q4 an EMA representative participated at an FDA fellowship on pharmacovigilance inspections with the aim of increasing mutual understanding of each other's processes and to facilitate further discussion in 2016.
	Develop (2015) and implement (2016) tools to support pre-clinical assessors in identification of triggers for GLP inspections	The checklist of triggers for GLP inspections was adopted in February 2015. The pre-submission guidance was also amended in February to reflect the new requirements regarding GLP to be provided by marketing authorisation applicants.
	Identify, develop (2015) and implement (2016) a plan for further co-operating with Member States in co-ordinating 3rd country inspections	The GMP re-inspection programme for CAPs was re-framed in Q2 2015, to encompass inspection plans from EDQM and third-country inspection planning module from NCAs. Draft paper proposing for EDQM to have access to EudraGMDP for direct input of data on inspection plans was agreed with EDQM and is expected to be adopted at GMDP IWG meeting in February 2016.
	Establish a mutual reliance framework with US	US FDA reaffirmed their support to the initiative in the first half of 2015.

Objective	Activity	Achievements/results
	FDA based on the existing mutual recognition agreements to increase the scope of EU international inspections activities	EMA response to FDA queries was finalised in Q1, and the EC and Member States' audit of the FDA supervisory system was completed in July 2015.
	Establish a mutual reliance framework with international partners performing inspections of manufacturers of active pharmaceutical ingredients and human and veterinary medicines	-
Maintain quality and continuity of medicines' supply chain and prevent circulation of falsified medicines	Develop procedures to link parallel distribution process with GMP procedures and allow use of parallel distribution information in the detection of falsified medicines in the supply chain	Internal discussions took place during the first half of 2015 to discuss the linkage between parallel distribution and market surveillance activities. Parallel distribution statistics were used to identify products of interest in developing the sampling and testing programme for 2016. This will allow sampling and testing of a selected parallel distribution product for the first time in 2016.
	Conduct lessons learnt exercise from the 2014 stolen medicines problem to further reflect on how the Network can address similar future threats to the supply chain	Report 'Operation Volcano' on stolen medicines was adopted by HMA in May 2015. The lessons learnt exercise will build on the in the report and the learnings identified in the report. A workshop on preventing shortages due to manufacturing and quality problems was held in October, to capture the progress and status since the last workshop held in 2012 and identify actions to take. In December a workshop on quality defect management was held with Member States, resulting in an agreement to establish a best practice group that would focus on checking and communicating on supply chains when suspected falsified or stolen medicines are implicated.
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects	Identify (2015) and implement (2016) process improvements on the handling of quality defects and non-compliance issues	The recording steps and tracking tool for quality defects were redesigned in Q2 2015. The redesigned reporting form on quality defects was agreed with the Member States at a workshop in December 2015. The review of the related SOP was started and will be finalised in 2016.
	Research the root causes of quality defects and GMP non-compliance leading to shortages of human medicinal products	The spreadsheet template was redesigned in Q2 to facilitate reporting and analysis of root causes of quality defects. The use of an adapted MedDRA catalogue for quality defects and root cause terms was agreed in principle with Member States in December 2015.

1.2.3.3. Partners and stakeholders

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Requests for SME qualification	401	499	800	798	
SME status renewal requests	808	813	1,200	995	
Requests for access to documents	293	416	550	701	
Documents released following requests for access to documents		1,771	2,500	2,972	
Requests for information	5,840	4,625	4,500	4,573	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Satisfaction level of SMEs		80%	80%	92%	
Percentage of responses to ATD requests provided within set timelines			99%	94%	
Percentage of responses to RFI requests provided within set timelines			98%	97%	

Achievements

Objective	Activity	Achievements / results
Enhance cooperation within European medicines regulatory network	Develop common vision and strategy 2016-2020 for the EMA and Member States	The EU network strategy was adopted by HMA in October and EMA Management Board in December 2015.
	Publish report on experience so-far on coordination of safety announcements, including outcomes of the survey on the use of 'Early Notification System' by NCAs	Surveys to provide information for the report (audit of communication practices by NCAs as part of SCOPE project and EMA communication perception survey) were concluded in Q2 2015. Drafting the report started in Q4 2015, following the revision of GVP module XV, which sets the principles and guidance on EU coordination of safety announcements. The report is expected to be finalised in Q3 2016.
	Establish an EU Network Training Centre	Following the HMA and EMA endorsement of the EU Network training centre training strategy, the EU NTC was established in 2015. The interim platform for the Network Training Centre (NTC) was launched in January. Training activities for 2015 were mapped and the communication strategy and stakeholder engagement plan were developed. Monthly newsletter was launched in March 2015. First comprehensive training catalogue with over 100 training events for the whole Network was advertised. Seven training events and 22 webinars were supported by the EU NTC in 2015. Processes for daily operation of the NTC were also designed, and a guideline for reimbursement of the training events by the EU NTC was prepared.
	Complete initiative to collect procedure-related time data	The pilot project gathering data on scientific advice/protocol assistance started in January and was completed in Q3, with a high rate of reporting from both the network and EMA secretariat. The Management Board extended the scope of the initiative to include veterinary procedures in March 2015 and work to gather data on fee generating procedures started over summer, using similar methodology piloted with human medicines scientific advice/protocol assistance. A high level plan to extend data gathering to a number of fee generating and non-fee generating procedures in human and veterinary areas of activities was presented

Objective	Activity	Achievements/results
		and agreed by the Management Board in December. A final report of the exercise is targeted for December 2016.
	Expand implementation of multinational teams concept	Pilot scheme covering co-rapporteur team for initial marketing authorisation applications for human medicines has been formalised. Following an earlier extension of the scheme in 2014 to rapporteur teams for initial MA applications for human and veterinary medicines, co-rapporteur teams for initial MA applications for veterinary medicines, it was also extended to scientific advice procedures for human and veterinary products in Q2 2015. Guidance to rapporteurs and coordinators was finalised in June 2015. Human medicines rapporteur outcome template letters were revised to outline involvement of a multinational team in the rapporteur or co-rapporteur team. SOP on rapporteurs has been revised to include the multinational assessment teams' concept, and will be finalised once the new PRIME rapporteur appointment is included.
Further strengthen Agency's transparency and open data commitments	Develop an EMA Transparency policy	Preparatory work for developing an overarching EMA Transparency policy was undertaken in 2015, considering transparency measures already in place/being implemented and the need for introducing further transparency measures.
	Develop (2015) and implement (2016) necessary processes for clinical data publication, including processes for document receipt, redaction consultation and decision, public access process and others	Business processes were developed and approved in June and work on IT solution started in the second half of 2015. Drafting guidance documents for the pharmaceutical industry began in March and are expected to be finalised in 2016.
	Initiate stakeholder consultation (2015) and develop methodology (2016) for preventing identification of individuals in clinical reports	Draft guidance on anonymization of individuals in clinical reports was prepared in the first half of the year, and revised, following the targeted consultation with academics, pharmaceutical industry, NGOs and patients' organisations. Opinion from the EDPS is awaited.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency work, outputs and	Publish EMA guidance on product-related communication, indicating to partners and stakeholders 'when' and 'what information' the EMA publishes on medicines	Draft guidance was prepared in the second half of the year and is under internal consultation. It is expected to be finalised and published in Q1 2016.

Objective	Activity	Achievements/results
medicinal products	Review communication products to streamline Agency information outputs	Review of the Agency's communication products was completed in the second half of the year and the outcome will feed into EMA communication strategy to 2020 and 2016 annual communication plan.
	Develop and agree with HMA a strategy paper on European Web Portal	The results of the Member States' survey (conducted in October 2014) were discussed at the HMA meetings in February and May and in the Telematics Management Board in June. The reflection paper was updated in the second half of the year to account for the results of the survey with Member States and HMA discussions earlier in the year.
	Deliver analysis on information needs of different stakeholders regarding the Agency's scientific output (2015). Review Agency's communication tools as per the results of the analysis (2016)	EMA communication perception survey was carried out in February 2015. The analysis of the results was presented to the Agency's management and the follow-up activities were agreed.
Strengthen stakeholder relation focusing on patients and consumers, healthcare professionals, industry associations and academia	Implement the stakeholders' relations management framework	Draft principles for EMA stakeholder relation management were finalised and are being incorporated into an overall stakeholder management framework.
	Implement the revised EMA framework of interaction with patients and consumers' organisations	Pilot phase on involvement of patients in benefit-risk evaluation continued in 2015. A training day for patients on the patient involvement in EMA activities was organised in November. The interim report on the pilot was presented to CHMP in December, and the pilot was extended into 2016, in order to gain more experience.
	Conduct satisfaction survey on healthcare professionals' involvement in EMA activities	The survey was completed in Q1 2015, and the results were presented to the Management Board in October.
	Survey the SME stakeholders and prepare 10 year report	SME survey was updated in Q2 and finalised in the second half of the year. 10 year report will be finalised and published in Q1 2016.
	Develop (2015) and implement (2016) framework for collaboration with academia	Internal survey on the current EMA collaboration with academia – needs, expectations and development of the framework – was completed in the first half of the year. A brainstorming discussion on the collaboration with academia was also held during the HCPWP meeting in June. A survey for the academia was prepared in the second half of the year and sent to

Objective	Activity	Achievements/results
		HMA for comments in December. The survey will be finalised and launched in early 2016. Drafting of the framework started in 2015 and it is expected to be finalised and presented to the Management Board by the end of 2016.
	Implement (2015) framework for interacting with industry stakeholders and conduct survey to monitor the progress (2016)	The framework for interactions with industry stakeholders was finalised in October. Eligibility criteria for industry stakeholders have been drafted and will be finalised in 2016.
	Publish annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations	The report was presented to the EMA Management Board in October 2015.

1.2.3.4. International activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
n/a					

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
n/a					

Achievements

Objective	Activity	Achievements/results
Enhance international cooperation activities to increase efficiencies and synergies through greater work-sharing	Implement strategy to enhance cooperation between regulators in the field of paediatric medicines	SOP for common commentaries was agreed between FDA Office of Pediatric Therapeutics and the EMA paediatric office, and was published on the FDA website in June and on EMA website in August. TIGRE initiative (Team of International Global Rare Disease Experts Working Group (TIGRE Working Group)) was started in the first half of the year, and support to develop it within the paediatric cluster was expressed by both sides at the June FDA/EMA/EC bilateral. The start of the initiative awaits final FDA internal agreement. Following a teleconference in 2014 on increasing collaboration, FDA has been actively participating in the internal EMA Extrapolation Working Group during 2015,

Objective	Activity	Achievements/results
		and took part in the EMA extrapolation workshops in September 2015 (and will participate also in May 2016).
	Implement pilot information sharing on generic medicines	The IGDRP pilot for sharing generic medicines' assessment reports was extended to centralised products in January 2015. A call for expression of interest for the applicants was launched in January. Three companies have expressed their interest in participating in the pilot in 2015. No generic submissions in the CP by companies participating in the pilot have been received so far.
	Increase involvement of non-EU regulators in assessment activities as observers to further develop Article 58 as a capacity building opportunity	WHO-nominated experts/observers from Ghana and Tanzania participated in the Article 58 procedure for malaria vaccine Mosquirix. In addition, EMA, together with the EC and Bill & Melinda Gates Foundation, with the support of external consultants, carried out a strategic review of the use, role and vision of its Article 58 scientific opinion. Possibility to observe Article 58 procedure has been promoted to additional stakeholders, including NGOs and African regulators, and all new applications and scientific advice applications now involve both experts and observers from non-EU regulators.
	Finalise confidentiality arrangements with WHO and other international partners	EC/EMA–Swissmedic confidentiality arrangement on exchange of non-public information relating to medicines for human and veterinary use was signed and came into force in July 2015. EC/EMA–WHO confidentiality arrangement on exchange of non-public information relating to medicines for human use was signed and came into force in September 2015.
Support the development of a strategic global vision and oversight of international activities	Map the progress of international initiatives to identify gaps and duplications	Analysis of the various incentive packages offered by different international regulators to encourage pharmaceutical R&D innovation was completed in February 2015. Mapping of the interactions with FDA and PMDA within the new organisational structure of EMA was completed in March-April this year. Mapping and analysis papers for pharmacovigilance, crisis management and supply chain international activities were also finalised within the ICMRA framework.

1.2.3.5. Data management support

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
n/a					

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of substance data registered in 4 working days		-*	75%	95%	
Percentage of substance data registered in 8 working days		-*	90%	98%	
Percentage of calls reopened due to incorrect handling		0%**	<3%	1.3%	
Percentage of stakeholders satisfied with service level of data management services			80%	n/a	Stakeholder survey was not conducted in 2015

* 2014 results incomparable due to change in indicator in 2015.
** Data only available June-December 2014.

Achievements

Objective	Activity	Achievements/results
Engage the Agency's stakeholders in the governance of data and promote a wider and deeper understanding of	Consolidate the EU Network Data Board (EU NDB)	Additional four NCAs joined the group in the first half of 2015, bringing additional relevant experience and actively contributing to the group. The EU NDB has been consolidated as a key group for the implementation of the ISO

Objective	Activity	Achievements/results
the value of data assets		IDMP in 2015 and its members participate in multiple forums, representing not only their NCA but also the network. In December it was decided to extend the participation to veterinary NCAs in 2016.
	Establish the IDMP Implementation Working Group with EMA and NCAs	ISO IDMP Implementation Working Group (task force) was established in March and the terms of reference were agreed by the task force in June 2015. In order to increase efficiency, subgroups to discuss the four individual SPOR domains were created and started working in April. Consolidation of the ISO IDMP task force and the subgroups took place in the second half of the year. The task force agreed a phased approach to implementation of ISO IDMP, which has been confirmed and approved by the EC and the Telematics governance. In December it was decided to extend the participation to veterinary NCAs in 2016.
	Develop and implement common policies, procedures and standards to maximise the sharing and optimise investment in data	ISO/DTS 19844 (substances) reached first publication in mid-December. New annexes for herbals, homeopathic, plasma-derived substances and polymers, as well as revised versions of annexes A (substance ID), B (chemical), C (protein) and D (nucleic acid) were submitted to ISO at the end of 2015, aiming for second publication in May 2016. The next version of HL7 SPL message, which will carry all the EU requirements in line with ISO IDMP DTSs, was sent out for ballot in June. Following the comments, both the HL7 SPL v7 and HL7 CPM v3 successfully passed the last recirculation of the ballot in mid-December and will be published in Q1 2016. Discussions with CDISC and FDA started in June on the way to integrate ISO IDMP in the clinical trial data model and to assess feasibility of ad-hoc, CDISC or HL7 based message for exchanging clinical trial data. In the second half of the year the consultations with CDISC continued, to ensure compliance of PRIME and CTR2 with regulatory requirements through inclusion of ISO IDMP and other controlled vocabularies in these standards.
	Develop and implement appropriate security and privacy policies to protect data assets	Identity and access management (IAM) project started in January 2015. During the first half of the year the Agency's IAM strategy and roadmap were defined, IAM solution was selected and IAM processes were analysed and designed.

Objective	Activity	Achievements/results
		Implementation phase of the project will start in January 2016. Review of the Agency's security policy for internal and external users started at the beginning of 2015 and the new Agency security policy was adopted in September.
Increase consistency of information shared across the EU Network	Develop an end-to-end process map to integrate data flow across all systems (PhV, regulatory submissions, xEVMDP, etc.)	The EU implementation strategy for the MDM solution, including the target operating model, was drafted in Q2 2015 and agreed at HMA in July. Draft end-to-end process maps for data flow integration across systems were prepared in 2015 but will be further discussed with NCAs, MAHs and internally during 2016. Periodic workshops and meetings at EU NDB and EU ISO IDMP taskforce were organised throughout 2015, to ensure dialogue with MAHs, NCAs and other interested parties. Software required to manage SPOR data in their lifecycle was installed in Q3, and article 57 data has been integrated in pharmacovigilance (pharmacovigilance fees, EudraVigilance), eAF, PSUR and referral activities.
	Analyse (2015) and implement (2015-2016) ISO IDMP roadmap with EU NCAs and industry	Work on EU IDMP Roadmap started in May 2015, building on the EMA roadmap that was adopted in March. The high level EU IDMP Roadmap with a phased implementation approach was agreed at the ISO IDMP task force and presented to the IT directors and EU Telematics Management Board at the end of June. The phased implementation of the EU IDMP/SPOR Roadmap was agreed by the HMA and confirmed by the EC in July. Webinars for all NCAs, including veterinary agencies, took place in September and October, to inform on the agreed phased approach, and extensive communication and change management plan was drafted for 2016.
Ensure effective decision making in the EU regulatory network by providing access to more analytical data	Develop and provide metrics and dashboards to EU NCAs on the state of the EU data management performance	NCA dashboard was updated in June to include data on human medicinal products as per NCA requirements. Report with type II procedures was added as the first one enabling 'self-service' of regular dispatched reports. Various improvements to the standard reports and several specific new reports were introduced during 2015, as well as increased automation of SIAMED templates (183 human SIAMED templates were available in November 2015). At the end of 2015 over 80% of NCAs had requested access to the NCA dashboards and only five national authorities (Bulgaria, Cyprus, Liechtenstein, Luxembourg and

Objective	Activity	Achievements/results
		Romania) did not have access to NCA SIAMED dashboard. eRMR pilot phase to test methodological updates proposed by SMART WS 2-3 started in April for 8 EMA validators and 9 NCAs. After the end of the pilot in September, 6 EMA validators and 7 NCAs opted to continue receiving eRMR in the pilot format, supporting the encouraging results of the pilot. Implementation of a new report using Article 57 data started in May. Following the testing and internal pilot of the Article 57 publication dashboard, it was made available to NCAs in October 2015. Based on the release of this tool, in December the EMA Management Board decided that Article 57 database was functional for the purpose of notifying changes in OPPV and location of PSMF. As a result, type IA variations shall no longer be submitted from 1 February 2016.

1.2.4. Support and governance activities

Workload indicators

Procedure	2013 result	2014 result	2015 revised forecast	2015 result	Notes
Requests for interviews and comments by media representatives	1,987	2,384	2,000	2,268	
Number of press releases and news items published	271	24	180	190	
Number of reports, brochures, leaflets produced			8	7	

Performance indicators

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
Percentage of posts on the Agency establishment plan filled	95.4%	97%	97%	98%	
Percentage of revenue appropriations implemented	95.6%	96%	97%	98.7%	
Percentage of expenditure appropriations implemented	96.8%	94%	97%	95.8%	
Percentage of payments against appropriations carried over from year N-1	96%	97%	97%	94%	
Maximum rate of carry-over to year N+1, of total commitments within the title:					
Title 1	0.6%	1%	1%	0.9%	
Title 2	11.6%	23%	15%	7.6%	Substantial reduction in appropriations carried over due to full implementation of article 17 (advance

Procedure	2013 result	2014 result	2015 target	2015 result	Notes
					commitments) and article 69(4) (annual instalments) of Financial regulation
Title 3	24.6%	28%	25%	26.9%	Slight excess of appropriations carried over against target is due to alignment of committee timelines and year-end closure deadlines allowing for processing of NCA budget commitments until year-end closure
Percentage of payments made within 30 days' time	-*	98%	97%	99.7%	
Satisfaction level of partners / stakeholders with EMA communications	-	-	80%	84%/87%	
Media articles covering key messages of EMA press releases:					
At least one key message	-	-	95%	100%	
At least two key messages	-	-	70%	100%	
Quote included	-	-	60%	100%	100% of quotes included in 7 EMA press releases were picked up by at least one key media outlet
Telematics and corporate IT systems availability against Agency working hours		99%	98%	97.6%	
ICT Service Desk: meeting of service-level agreements (SLAs) per system/priority level:					
Critical (resolution time: 4 hours)	31.8%	46%	80%	100%	
Severe (resolution time 1 business day)	31.3%	50%	80%	100%	
Important (resolution time 10 business days)	89.1%	91%	80%	92%	
Minor (resolution time 120 business days)	99.4%	99%	80%	100%	

* 2013 results not comparable due to change in indicator (30 days vs 45 days timeline in 2013).

Achievements

Objective	Activity	Achievements / results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Review IT operating model	A new IT operating model was developed as part of the information management strategy and the Target Operating Model for the information services. The strategy was adopted by senior management in October and presented to the Management Board in December. Implementation of the new operating model will begin in early 2016.
	Develop a corporate communications strategy 2015-2020	Internal discussions on the concept, scope and approach for the corporate communication strategy started in June. Future communication needs across the Agency were collected and compiled, and the structure and focus of the communication strategy was decided. The strategy is expected to be finalised by Q2 2016.
	Select a new media monitoring and press office software management tool	Business requirements for a new media monitoring tool were gathered during 2015 and drafting of the tender documentation started.
	Develop (2015) and implement (2016) electronic documents / records management strategy	Work on the first draft of an information management strategy, which includes electronic documents/records management strategy, started at the beginning of 2015. The strategy was finalised and adopted by the senior management team in October and presented to the EMA Management Board in December 2015.
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	Implement the policy on handling of conflicts of interest of scientific committees' members and experts	The revised policy on handling of declarations of interests of scientific committees' members and experts entered into force on 30 January 2015. All experts in the EMA Experts database were reminded to submit an up-to-date declaration of interests in the revised format before the implementation date. The DoIs of experts involved in EMA activities after the implementation date were evaluated against the revised policy. An impact assessment of the revised policy on the scientific committees was prepared for internal use. Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company was published in May. A revised EMA breach

Objective	Activity	Achievements/results
		of trust procedure on conflicts of interests for scientific committee members was also adopted and published in May 2015. Systematic ex ante controls on the declarations of interest of new experts were performed as well as annual ex post control on the handling of declarations of interests of committee members and experts participating in meetings.
	Implement antifraud strategy, including internal processes on reporting alleged fraud instances and anti-fraud office	As part of the activities to implement the Agency's anti-fraud strategy, an Antifraud Office was established in February 2015. Internal survey of senior management was conducted in February-April, benchmarking the antifraud awareness, and mandatory antifraud e-learning course for all staff was developed and launched at the end of 2015. Standard procurement contracts were also amended in Q1, to include antifraud clauses. Internal processes and templates for reporting fraud instances were prepared and accepted by EDPS.
	Develop and implement whistle-blower policy	A draft whistle-blower policy was prepared during the first half of 2015 and discussed with the Commission. Finalisation of the policy was deferred to 2016, following further responses from the Commission in late 2015. The policy is expected to be finalised by June 2016.
	Revise (2015) and implement (2016) the conflicts of interest policy for Management Board members and EMA employees	Guiding principles for a revised conflicts of interest policy for Management Board members were discussed at the EMA Management Board June meeting. The revised policy was adopted by the Management Board in December and will be implemented in May 2016.
	Develop (2015) and implement (2016) a policy on public consultations	Guiding principles for the policy on public consultations were established and incorporated into the stakeholders' relations management framework. The framework will be finalised in 2016 and the necessary toolkit is expected to be finalised in 2017.
Highlight the public and animal health contribution of the Agency and the whole European medicines network in recognition of 50th anniversary of	Launch campaign on the 20th anniversary of the inauguration of the Agency	20th anniversary scientific conference was held on 18 March 2015. EMA 20th anniversary booklet, capturing the important progress in regulatory science and societal changes in the field of medicines regulation, as well as achievements of EMA in fulfilling its mission over the past two decades, was published and presented at

Objective	Activity	Achievements / results
pharmaceutical legislation in Europe and 20th anniversary of the Agency		the conference. Celebration of the 20th anniversary of the Agency with partners, stakeholders and staff was organised on 26 January 2015. Series of monthly events, including panel discussions and lectures on topical issues related to the work of EMA were organised throughout the year.

2. Management

2.1. Management Board

This section details significant items adopted or endorsed by the European Medicines Agency's Management Board in 2015.

Handling competing interests: revised rules for Management Board members

The Agency revised its policy on handling competing interests for members of its Management Board, which was adopted in December 2015 and entered into force on 1 May 2016. The revised breach of trust procedure on conflicts of interest for Management Board members was adopted as well and was applied as of 1 January 2016.

The revision aligns EMA's Management Board policy with the Agency's policy on handling declarations of interests for scientific committee members and experts, which underwent a major overhaul and became effective in January 2015.

Adoption of programming document and 2016 budget

At its December meeting, the Management Board adopted the Agency's programming document, which includes a multi-annual programme, the EMA's work programme and budget for 2016, and a preliminary draft programme and budget for 2017. The single programming document is required by the new EU Financial Regulation and was developed for the first time.

Endorsement of timeframe for the development of the EU clinical trial portal and database

The Board endorsed the timeframe for the implementation of the EU clinical trial portal and database at its December meeting. This ambitious project will provide a single portal for submission and maintenance of clinical trial applications and authorisations, and support their coordinated assessment and supervision. The portal and database will also serve as the source of public information on the full lifecycle of all clinical trials conducted in the EU, from their initial review up to publication of their results. The timeframe endorsed by the Board enables the robust development and testing of the system, and allows for resolving unforeseen difficulties and potential issues.

Review of the Agency's 2014 activities

The Board adopted the Agency's 2014 annual report and the document was published in April 2015.

Adoption of formal framework for interaction with industry stakeholders

The Board adopted a framework for interaction between EMA and industry associations. The aim of the framework is to formalise and structure EMA's interaction with industry stakeholder groups to: facilitate exchange of views and promote dialogue; improve delivery of efficient, targeted and timely communication; enhance understanding of the EU medicines regulatory framework by pharmaceutical companies; increase transparency of EMA's engagement with stakeholders from pharmaceutical industry; and report on these interactions annually. The framework covers a broad range of industry association types, including industry trade associations, organisations engaged early on in the innovation lifecycle, associations of service providers or professionals supporting the industry, and associations with multi-stakeholder membership, including industry. An action plan is included in the framework.

Adoption of the European medicines regulatory network common strategy to 2020

In December 2015, the Management Board and the Heads of Medicines Agencies adopted a common strategy to 2020 for the European medicines regulatory network. This was the first time that a single strategy for the whole network has been developed. It outlines common challenges and opportunities, and sets out joint key priorities and a high-level roadmap to achieve these over the next five years. The strategy also supports the strategic priorities of the European Commission and the EU agenda on human and animal health. By joining forces and following the same strategy, the network will be able to tackle current and future challenges more effectively, and better advance and protect public and animal health in the EU. The agreement of the strategy follows a public consultation, during which stakeholders had the opportunity to send their comments and feedback to the EMA and HMA.

The strategy focuses on areas where collaboration within the network can make a real difference to human and animal health in the EU over the next five years, and is built around four key themes:

- Contribution to human health
- Contribution to animal health and human health in relation to veterinary medicines
- Optimising the operation of the network
- Contributing to the global regulatory environment.

The strategy progresses a strong international role for the network in enhancing oversight of global supply chains, contributing to global convergence of regulatory standards, promoting reliance and work-sharing with other regulators and strengthening capacity building.

The strategy builds on the EMA roadmap to 2015 and the HMA strategy for 2011-2015, and will form the basis for separate multi-annual work programmes/implementation plans for EMA, HMA, and the coordination groups for mutual recognition and decentralised procedures, human and veterinary (CMDh and CMDv). These will give detailed information on the work of each component of the network, and will also describe how the joint network strategy will be taken forward in terms of detailed activities.

Management Board's chairmanship

At the end of 2015, Sir Kent Woods stepped down as Chair of the Board, a position that he had held since 2011. Sir Kent, who had led the UK's Medicines & Healthcare products Regulatory Agency (MHRA) as Chief Executive from 2004 to 2013, had been recently appointed as the senior medical trustee and chairman of the Advisory Council of the British Heart Foundation. In taking leave from the Board, he remarked that a lot had been achieved jointly by the EMA and the NCA network during his tenure; the development of a shared strategic plan for the next five years was a major landmark. The Management Board Vice-chair, Christa Wirthumer-Hoche, Head of the Austrian Medicines and Medical Devices Agency (AGES), was elected as new Chair in March 2016.

Anti-fraud strategy

A progress report on the implementation of the EMA anti-fraud strategy was presented in December 2015 at the Management Board, who adopted the strategy together with its action plan in December 2014. The anti-fraud strategy was set up following a call by the European Commission and OLAF to all EU agencies. All nine actions scheduled in the action plan to be implemented during 2015 have been completed. A tenth action is ongoing, as it relates to the yearly assessment of the adequacy and effectiveness of the system of internal controls. The focus of action for 2015 was on fraud prevention, pursued through raising anti-fraud awareness among staff. This was achieved also by means of a

compulsory e-learning training course for all staff of the Agency, whose material was developed entirely in-house. Some efforts were also devoted in 2015 to the enhancement of fraud detection, for example through the elaboration of internal reporting procedures. EMA works closely through its Anti-fraud office with other EU agencies and OLAF, taking into account new developments and exchanging best practices. For 2016, efforts will continue to be devoted to prevention, but will mainly focus on fraud detection.

Member State access to Art. 57 data on medicinal products: functionality for qualified persons responsible for pharmacovigilance and location of pharmacovigilance system master file

At its December meeting, the EMA Management Board confirmed that the Article 57 database of medicines authorised in the European Union can now be relied upon to provide the name and contact details of the qualified person responsible for pharmacovigilance (QPPV) for each authorised medicine in the EU and the location where the pharmacovigilance system master file (PSMF) of the marketing-authorisation holder of a given medicine is held.

This endorsement by the Board allows EMA and the national competent authorities in the EU to fully rely on the Article 57 database for this information. This allows all EU regulators to access this information at a single point, facilitating their work and helping to coordinate enquiries from regulators to companies and the conduct of pharmacovigilance inspections.

As a result of reliance on the Article 57 database, for medicines for human use, companies will no longer be required to submit type IA variations to notify regulators of changes in relation to the contact details of their QPPV or the location of their PSMF, simplifying processes for the notification of these changes for both companies and regulators.

The Article 57 database is a repository of structured and quality-assured information on all medicines for human use that are authorised in the European Economic Area, whether they are centrally or nationally authorised. EMA established the database in 2012 and it currently contains approximately 500,000 medicines.

The information contained in the database is provided by marketing-authorisation holders, based on the legal obligation set out in Article 57 of Regulation 726/2004/EU. The quality of the data is continuously verified by EMA according to a robust quality-assurance and control process, established together with the industry.

PSUR repository

In June 2015, the Management Board gave its green light for the central repository for periodic safety update reports (PSURs) for medicines authorised in the EU. On 13 June 2016, the central repository will become the single, central platform for these reports to be used by all regulatory authorities and pharmaceutical companies in the EU to exchange information on the safety of medicines. This decision by the Board follows an independent audit of the repository that evaluated whether it meets the agreed functional specifications.

Additional MB adoptions/endorsements

In addition, the MB in 2015 also adopted or endorsed the following items:

- Appointment of the Executive Director (October 2015).
- Annual report 2014.

- Budget and establishment plan 2016.
- Amending budget 01-2015.
- Revised European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts.
- EMA Framework for interaction with industry stakeholders.
- Review of Internal Control Standards and underlying framework.
- Assessment of the Executive Director's Annual Activity Report (AAR) 2014.
- Revised EudraVigilance Access Policy.
- Transparency rules for Clinical Trial Regulation.
- Joint annual report on the interaction with patients', consumers' and healthcare professionals' organisations (2014).
- Annual report on the performance of the Agency's scientific procedures.
- Revised implementing rules to the Fee Regulation as of 1 April 2015.
- Management Board liaison process for PRAC composition.
- Revision of Section 6 of the 'Functional specifications for the EU portal and EU database to be audited', setting out features to support making information public.
- 5th Annual Report Veterinary MUMS/limited market.

2.2. Major developments

The year 2015 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.

Ruling of the EU Civil Service Tribunal

One unprecedented event that overshadowed the Agency's work in 2015 was the ruling of the EU Civil Service Tribunal, announced in November 2014, to annul the Commission's decision shortlisting the candidates and, consequently, the Board's appointment of the Executive Director three years earlier. The Executive Director post was immediately re-advertised. At the end of a fully competitive process, the Board appointed Professor Guido Rasi for a five-year mandate in November 2015. During this unsettled period, the Deputy Executive Director, Andreas Pott, had taken over responsibility for the management and operations of the Agency, supported by Guido Rasi as Principal Advisor in charge of Strategy. Despite the difficult situation, the Agency delivered its work programme.

Clinical trial portal and database

The Agency advanced the development of the clinical trial portal and database, and worked closely with national competent authorities to ensure that the new IT systems will benefit researchers, patients and the public as a whole from day one, as foreseen by the Clinical Trial Regulation.

EMA 20th anniversary

To mark its 20th anniversary, the Agency held a conference on 18 March 2015 entitled 'Science, Medicines, Health: Patients at the heart of future innovation'. At the conference, representatives from academia, the pharmaceutical industry, patient organisations, health-technology-assessment bodies, international regulators, the European Commission, national competent authorities and EMA discussed how best to support and shape innovation to improve the health of people in the European Union.

Data gathering

In 2015, the Steering Group on the Management Board data-gathering initiative focused on the mapping of all activities of the Agency and NCAs, with the purpose of designing data collection to support the European Commission in drafting the future legislative proposal on fees.

A pilot exercise was carried out on scientific advice and protocol assistance to validate the time-collection methodology agreed by the Steering Group at the end of 2014. A total of 124 procedures were included in the collection over three cycle-starts (Feb/March/Apr). The exercise was deemed a success, with high compliance rates (approx. 82%), providing a solid sample for analysis. Reproducible estimates across the three cycles and strong association between time spent and complexity of procedures were observed. Based on the results of the pilot, in October the Management Board gave the green light to extend the exercise to all major fee-generating and non-fee generating procedures.

Updates on Information Management Division

Following the changes in ICT management, the division was reorganised and renamed 'Information Management'. A strategy to reshape the Agency's information technology into information management, and support the implementation of the EU Telematics strategy, was adopted by senior management and presented to the Management Board.

Information management activities aim to establish and manage information as a key asset to support sound decisions and provide reliable information on medicines for the promotion and protection of human and animal health in compliance with the European pharmaceutical legislation. This involves the delivery and operation of efficient and effective data and information management services, and increasing the Agency's information processing capacity. It covers internal and external data and financial workflows for applications submitted to the Agency. To meet business needs, the division relies on good information technology governance, agreed IT principles and the orchestration of solutions by the EMA data board and the EMA IT architecture board.

EU Telematics

An important responsibility of the division is in EU Telematics, which aims to put in place and maintain effective common information-technology services that add value and optimise support to the EU medicines regulatory network in the evaluation and supervision of medicines. It is a joint endeavour of the European Commission, the EMA and medicines regulatory authorities in the Member States. This activity covers the support and coordination of the Telematics governance and the delivery and maintenance of shared data, IT systems and infrastructure.

EU Network Training Centre

The EU Network Training Centre (EU NTC) continued to build its framework in 2015 with the development of the EU NTC strategy, a plan for stakeholder engagement, a communication strategy and a communication plan.

The major focus was on the development and delivery of services to the EU regulatory network, including the launch of the EU NTC interim platform with the first network-wide catalogue of training events, containing more than 100 entries in 2015. The interim platform was visited by 1,350 unique visitors between February and December 2015. Seven requests for reimbursement of attendance from the EU network to trainings from the allocated EU NTC budget were approved, and, following a successful pilot, a remote webinar hosting service, which allows NCAs and EMA to broadcast their training events to the network, was subsequently rolled out. The EU NTC supported 22 webinars in 2015, organised by EMA and NCAs.

An EU NTC newsletter was created and sent out monthly from March 2015 as a channel to communicate with our stakeholders, with over 200 recipients by the end of 2015. The EU NTC initiative was presented at the different committees, division and department meetings at EMA, and to the HMA with regular updates. A wide range of communication materials were developed, including EU NTC guidelines, a webinar communication pack and an overview of EU NTC services to the network.

The network of EU NTC training champions was further strengthened through a second face-to-face workshop, held in November 2015. The main outcome of this workshop was the agreement on the definition of the training champion role, which was endorsed by the HMA.

An approach for the development of training curricula in the different fields of interest was developed and a successful pilot in the clinical trials area to test the approach was finalised by the end of the year by the Clinical Trials Facilitation Group. The curriculum demonstrates the learning path from beginner level through competent level to expert level within the field of clinical trials.

In parallel, the selection of a learning management system for the EU NTC was undertaken: requirements were gathered, market analyses were conducted and the final learning management system was purchased by the end of 2015.

Network of European medicines regulatory agencies

None of the successes achieved in 2015 would have been possible without the network of European medicines regulatory agencies. The network gives EMA access to a pool of excellent scientists from across Europe, allowing the Agency to source the best-available experts for the regulation of medicines in the EU.

2.3. Budgetary and financial management

Financial highlights for 2015

The Agency started collecting fees related to pharmacovigilance services in late 2014. For the financial year 2015, EUR 21,640,000 were recovered.

In view of the strengthening of the pound sterling over the course of 2015, it was necessary to reinforce the euro appropriations required for the weighting, which is part of salaries, and for rent. This was done through an amending budget and transfers.

The Agency managed to comply fully with the ceilings/KPIs for carry-forwards (automatic and non-automatic), title I (10%), title II (20%) and title III (30%), with the following percentages achieved: title I: 0.9%, title II: 7.6%, title III: 26.9%.

Initial budget and amending budgets

Authorised appropriations in the Agency's initial budget for 2015 totalled EUR 302,117,000, representing a 1.7% increase compared to the 2014 initial budget (EUR 297,169,000).

One amending budget was introduced in 2015 to account mainly for an increase in revenue from cash received for services rendered of +EUR 5,000,000, and an adjustment in assigned revenue of +EUR 980,000, bringing the budget total to EUR 308,097,000 and representing a 9.1% increase over the 2014 final budget (EUR 282,474,000). To balance the budget, expenditure appropriations related to weighting on salaries and rent were increased by the same total amount.

Revenue (income from evaluation activities and EU contribution)

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

Revenue entered in the accounts as at 31 December 2015 amounted to a total of EUR 304,118,788.60.

Of total revenue, 83.1% derived from the evaluation of medicines and other business-related activities, 11.1% from the EU budget to fund various public-health and harmonisation activities, including positive outturn of the previous year, and 5.8% from external assigned revenue as described in the work programme (2014: 80.5%/12.5%/7.0%).

Expenditure (commitments and payments)

Commitments totalled EUR 289,771,808.02, or 94.05% of final appropriations (2014: 94.32%). Payments totalled EUR 252,350,837.88, or 87.09% of commitments entered into (2014: 82.30%).

Appropriations carried forward from 2015 to 2016

Automatic and non-automatic carry-forward to financial year 2016 totalled EUR 42,818,970.14, or 14.78% of appropriations (total carried forward from 2014 to 2015: EUR 47,157,767.76 or 17.70%[2]).

Non-automatic carry-forward to 2016 amounts to EUR 5,398,000.00 and covers various IT developments and related business consultancy for projects, as well as scientific studies which were part of the 2015 work programme and budget. For reasons outside the control of the Agency, this expenditure could not be implemented in 2015 and is not part of the 2016 budget, so, in accordance with the Financial Regulation, the appropriations were carried forward for implementation in 2016.

Appropriations from assigned revenue

The Agency introduced assigned revenue in 2014 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 2015, an amount of EUR 17,303,621.60 was recognised as assigned revenue, from landlord inducements related to the project for the Agency's new headquarters. This amount covered part of the cost of the fit-out of the newly acquired 10th floor and all rent cost. The remainder of the inducements will cover rent cost in 2016 and part of 2017.

Grant-related assigned revenue recognised in 2015 amounted to EUR 255,138.93. This covered a varying part of the expenditure related to the Agency's activities on certain projects, in particular within the Innovative Medicines Initiative (IMI), which receives funding from the EU and the pharmaceutical industry association, EFPIA. The Agency's input to these projects is mainly human resources, with some duty travel and meeting activity also taking place.

Budget 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.

During 2015, 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 22,026,000, or 7.15% of final appropriations. These transfers consist of transfers of revenue appropriations of EUR 8,796,000 and of expenditure appropriation of EUR 13,230,000 (2014: nine transfers of expenditure appropriations only, totalling EUR 19,755,000, or 6.99% of final appropriations).

The transferred expenditure appropriations were primarily needed to cover expenditure on business IT development and adjustments to budget items for administrative expenditure.

Cancellation of appropriations

For budget 2015, expenditure appropriations totalling EUR 12,927,191.98 remained unused, corresponding to 4.20% of final appropriations (2014: EUR 16,054,189.25, 5.68%).

These unused amounts must be seen in conjunction with collected revenue being EUR 3,978,211.40 below budget revenue appropriations, creating a positive overall outturn balance (before adjustments

[2] SAP carry-over to 2015 and subsequently cancelled as compared to that reported in the financial accounts 2014 – difference of EUR 27,141.34. Corrected SAP figures are reported here.

for exchange rate, cancellations of carry-over, etc.) of EUR 8,964,611.10, or 2.9% of final appropriations (2014: 5,366,119.01, 1.9%).

Payment of interest on late payments

In 2015, 151 payments out of a total of 56,335, i.e. 0.27% of all payments, were made later than 30 days after receipt of a valid invoice (2014: 1.51% of all payments). This resulted in default interest of EUR 1,610.00 being paid to suppliers and contractors.

2.4. Human resources management

At the end of 2015, the Agency achieved an occupancy rate of 98% for temporary agents (TA), with 587 staff against 599 posts available in the establishment plan (better than target). In addition there were 153 contract agents (CA) and 35 seconded national experts (SNE). The turnover of TAs remained low (3%).

In 2015, 79.25% of jobs in the Agency were in the operational area; administrative support and coordination absorbed 16.73% of the resources and 4.03% of jobs were considered neutral (finance/control). These results show that the distribution between the three job types set in the Commission screening methodology remained stable when compared to 2014. The main changes can be found within the operational category, where resources related to 'Programme management and implementation' were reinforced (increase from 19.61% to 23.08%), and, in reverse, 'Evaluation and impact assessment' decreased from 45.53% to 41.32%.

In 2015, the Agency advertised 25 vacancies for temporary agent positions externally, and conducted nine internal recruitment procedures. The decrease in recruitment activity compared to previous years can be explained by the fact that the establishment plan saw very little increase in numbers of posts, compared to 2014.

As for gender distribution of staff, women accounted for 45% of heads of service, 46% of heads of department and 33% of the senior management team (i.e. the Executive Director, Deputy Executive Director and heads of division).

The main objectives of the HR department for 2015 were to improve and implement the appraisal and promotion exercise, to support and strengthen the resource planning function, and to implement teleworking. The staff appraisal exercise is now very similar to the Commission's system, and follows the Commission's rules. It evaluates both what has been achieved (the objectives) and also how this has been achieved (e.g. working effectively with colleagues) against specified competencies and Agency values.

The resource planning function was reinforced in 2015 to ensure effective staff planning and resources allocation.

In 2015, the Agency conducted a teleworking pilot, which generated good feedback and results. The pilot was extended until 31 December 2016, in order to review the new implementing rules adopted by the Commission and decide on the best course of action for the Agency.

2.5. Assessment by management

Assessment by management is based on the results of controls and control procedures performed by the staff of the Agency (detailed in Section 4).

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 2015 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 during 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 processes and increasing their effectiveness.

2.6. Budget implementation tasks entrusted to other services and entities

Not applicable.

2.7. Assessment of audit results during the reporting year

2.7.1. Internal Audit Service (IAS)

In 2015, the European Commission's Internal Audit Service carried out an audit on Paediatric Regulation procedures. IAS concluded that the Agency deploys and uses adequate systems for the management and control of Paediatric Regulation procedures. A strong emphasis on internal effectiveness and compliance with legal deadlines contributes to meeting the objectives of timely delivery of high-quality opinions and decisions and in compliance with the Paediatric Regulation. The Agency ensures legal soundness of the final opinions and decisions by involving legal and regulatory experts in the process.

The audit did not result in the identification of any critical or very important issues.

2.7.2. Internal audit capability (IAC)

In 2015, the Agency's Audit function carried out audits in the areas listed below.

Security of product-related information

The objective of the audit was to provide assurance on the confidentiality, integrity and availability of the SIAMED II, EURS and scientific-advice systems.

Based on the results of the audit, the auditors were of the opinion that the current information system management processes provided reasonable assurance regarding the achievement of the EMA's business objectives. A number of findings were raised and an action plan is being implemented to address them.

Building blocks of assurance

The objective of the audit was to provide reasonable assurance that building blocks of assurance are comprehensive enough to enable the Executive Director to obtain full, accurate, reliable and timely information.

Based on the results of the audit, the auditors were of the opinion that the internal control system put in place by the EMA provided reasonable assurance that building blocks of assurance are comprehensive enough to enable the Executive Director to obtain information, especially concerning key items such as implementation of the annual work programme and budget execution, and that the internal control system is effective. Improvements were identified for certain areas, for which an action plan was drafted and is currently being implemented according to an agreed timeline.

Video surveillance

The objective of the audit was to provide assurance that the video surveillance policy and procedures currently in place are in line with the relevant guidance, regulation and best practices.

This audit confirmed and substantiated the weaknesses of the system already known to management. An action plan to address them was drafted and is currently being implemented.

PSUR repository

An audit on the PSUR repository was conducted by an independent external auditor in accordance with Article 25a of Regulation (EC) 726/2004. The objective of the audit was to establish compliance between the IT system developed by the EMA and the 10 functional requirements as defined by the EMA (electronic submission, storage and retrieval, assessment by providing access, query and download functionalities), in collaboration with the NCAs and the Commission. In the course of the audit, several findings and recommendations were made. All of them were addressed by the EMA as concluded by the second run of tests. As stated by the auditors, the PSUR Repository is operational and allows a secure and smooth running of business processes, thereby completely fulfilling the legal requirements as defined in the document 'PSUR repository functionalities to be audited'.

Medical literature monitoring

The scope of the audit was to assess the effectiveness of the services provided by the contractor in charge of monitoring scientific and medical literature and data-entry of relevant information into the supporting system, EudraVigilance. The final audit report is still outstanding.

Innovative Medicines Initiative Joint Undertaking (IMI JU)

An independent external audit on costs claimed/declared under an IMI JU grant agreement was performed to assist the IMI JU evaluate whether the related costs presented on the financial statements of the project PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) have been granted/claimed under the grant agreement. Based on the audit evidence that was obtained, and with respect to the objectives relevant for the engagement, the external auditors were able to conclude that the audited financial statements are prepared, in all material respects, in accordance with the grant agreements.

Assessment of the quality-management system

The internal audit capability, in cooperation with the corporate governance team, conducted an assessment of the quality-management system to identify areas for improvement for the existing

quality programme. On the basis of the analysis performed, several options for further developing the quality system of the Agency were made that would provide both immediate and long-term systematic improvements, and ultimately lead to ISO certification of the Agency.

2.7.3. European Court of Auditors (ECA)

The European Court of Auditors conducted its annual audit of the Agency's 2014 accounts, and adopted its report on 8 September 2015.

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 2014 and the results of its operations and its cash flows for the year in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.

- 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 2014 are legal and regular in all material respects.

The following comments were made by the Court (to be noted that these observation do not put the Court's opinion into question):

Comments on the legality and regularity of transactions

The Agency's fee regulation provides due dates for the collection of fees from applicants and the Agency's related payments to National Competent Authorities. These due dates were not respected for most of the transactions audited by the Court.

Agency's reply: During 2013-2014, the Agency has redesigned and streamlined its main operational processes, including financial authorisations and fee collections. The further planned automation of the latter was delayed because of the Agency's reorganisation in 2014. To ensure compliance with the Agency's fee regulation concerning due dates, this automation is now planned to be implemented by the end of 2015.

Agency's follow up: The majority of the planned actions were implemented in 2015; those remaining will be implemented in the course of 2016.

Comments on internal controls

In 2014, the Agency carried out an administrative procedure against its Information and Communication Technology manager. Significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency. An action plan to address the issue was established and implemented. However, the effectiveness of the measures taken has yet to be evaluated by the Agency.

Agency's reply: Whilst weaknesses in management control were detected, no considerable financial risks were reported in the administrative enquiry report to the Executive Director. The effectiveness of the measures taken by the Agency is to be evaluated through the already planned audits in 2015 by the Internal Audit Service of the EC and the internal audit capability of the Agency.

Agency's follow up: The evaluation of the effectiveness of the measures taken will be conducted after completion of reorganisation.

Other comments

One of the Agency's tasks is to distribute appropriate pharmacovigilance information to Member States and to the general public. This information is collected from individual national authorities and verified with the pharmaceutical companies concerned. However, the Agency is largely dependent on controls and inspections carried out by Member States' authorities. These determine the completeness and accuracy of information disseminated to the public.

Agency's reply: The Agency takes note of the Court's comment. The regulation of medicinal products in the European Union is based on a network model. EMA coordinates the EU pharmacovigilance network system and manages key information systems to support data exchange in pharmacovigilance, in particular EudraVigilance and the Article 57 database of medicinal products. We will continue to work with our stakeholders/partners to ensure adequate protection to the EU citizen in this area.

In 2014, the Agency concluded a 15-million-euro framework contract (covering the years 2014 to 2017) for high-level management consultancy services. The objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract. There is no evidence that the Management Board had been consulted on the procurement decision, which would have been appropriate given the nature and value of the contract, even though the Financial Regulation does not require it.

Agency's reply: An inter-service consultation was conducted prior to the launch of the procurement procedure for a framework contract leading to an estimate of 15,000 person days over four years. The consultation sought to identify for the departments from the perspective of the time certain objectives, estimated profiles, and person days, as well as the assumed nature of services and approximate timing. Given the advance nature of the required estimates, the Agency cannot share the Court's comments. Furthermore, as the Court acknowledges, the Agency was not required to consult the Management Board prior to launch of the tender.

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

Internal Audit Service

Neither critical nor very important recommendations were open as of 31 December 2015.

Internal audit capability

Follow-up of earlier internal audit recommendations

At the end of 2015, 11 very important recommendations stemming from audits carried out up to 31 December 2014 were still open, all of which were within the timeline agreed with IAC.

European Court of Auditors

There were no observations from previous reports.

2.9. Follow-up of observations from the discharge authority

Overall, the discharge authority issued seven observations/comments that required the Agency to follow up.

Two comments concerned EMA's recruitment procedures. The European Parliament in its 2014 discharge: "Ascertains that the Agency increased transparency in relation to its recruitment procedures by publishing the status of ongoing external procedures and the status of reserve lists on the Agency's external website, and that it also improved the documentation related to the recruitment procedures".

Five comments concerned the prevention and management of conflicts of interests and transparency. The three observations relating to declarations of interests and scientific advice were implemented. Regarding the two comments on publication of clinical trials, the European Parliament as part of its 2014 discharge procedure "…Stresses that the Agency should ensure maximum transparency in providing access to clinical trials report, [and] welcomes the Agency's decision to proactively publish data on clinical trials".

Regarding the European Parliament resolution of 28 April 2016 on the discharge in respect of the implementation of the budget of the European Union Agencies for the financial year 2014, the observations/comments requiring action from the Agency will be addressed by the Executive Director in his report to the discharge authority (Article 110(2) of the Financial Regulation) in October 2016.

3. Assessment of the effectiveness of the internal control systems

3.1. Risk management

The European Medicines Agency operates in a risk environment of growing uncertainty. To assist the Agency in visualising, assessing and mitigating the risks that threaten delivery of its mission, the Agency has developed a sustainable process to identify, assess, and manage risks across the organisation, to ensure attainment of key organisational objectives and avoid surprises. This process is aligned with the principles of the IRM standard and the Agency-wide risk-management manual, and consists in identifying, assessing and mitigating enterprise risks through the following process:

- Risk identification: this phase consists of facilitated sessions with all middle and senior managers across all areas of the organisation. In these sessions, managers are asked to identify what they view as the key risks to the Agency achieving its strategic objectives. From these sessions, significant risks are selected for further assessment.
- Risk assessment: in this phase, managers identify the likelihood and potential impact of each of the identified risks.
- Risk mitigation: based on the results of the assessment phase, primary risk owners for each key risk and its relevant sub-components are identified, and potential mitigating activities are documented in accordance with the procedures laid out by the Agency-wide risk-management manual.

Significant risks are then reviewed by the EMA Executive Board, which acknowledges the risks and validates the action plans to further mitigate critical risks.

Risks are assessed and reported at a residual level, i.e. taking into account controls and mitigations that are already in place. Risks are reported consistently on a 6x6 matrix (likelihood x consequence), and only the risks with a residual risk rate of 16 or above (critical risk) are discussed by the Executive Board, indicating that the acceptable residual risk rate is 1 to 15.

The significant risks that could potentially impact achievement of the Agency's objectives and the respective mitigating actions and controls are outlined in the tables in Annex IX. None of the risks included were considered critical and none had materialised during the reporting year.

3.2. Compliance and effectiveness of internal control standards

Internal controls are all those 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, and assets and information are safeguarded.

To assist the Executive Director in implementing internal controls, the Agency has adopted a set of internal control standards. 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.

The effectiveness of the internal control standards was assessed via an internal questionnaire addressed to the Agency management at the end of 2015. The main objective of the exercise was to

assess the implementation of the EMA's internal control standards and draw up from the findings a comprehensive action plan for implementation in 2016.

The assessment concluded that EMA implements the internal control standards effectively. The assessment also highlights improvements for the standards concerning ethical and organisational values, staff evaluation and development, and the risk-management process. Measures will be taken to further improve the efficiency and application of the standards concerning objectives and performance indicators, operational structure, document management, and information and communication.

The list of the measures planned for 2016 are detailed in Annex X.

Management of conflicts of interests

Scientific committee members and experts

The policy on the handling of declarations of interests of scientific committee members and experts was last updated in November 2014 and entered into force on 30 January 2015.

The Agency takes a proactive approach to identifying cases where the potential involvement of an expert in the Agency's activities needs to be restricted or excluded due to interests in the pharmaceutical industry, and to searching for alternative experts, where necessary. Experts cannot have any financial or other interests that could affect their impartiality. The Agency screens each expert's declaration of interests to decide whether or not to include him or her as a member of a committee, working party or other group.

To help achieve this, all experts must complete an electronic declaration of interests (e-DoI) form and submit an update at least every year and every time a change in their interests occurs. The submission of an e-DoI requires the submission of an up-to-date electronic curriculum vitae (e-CV) and an electronic signature (validation) of the e-DoI by the expert via single sign-on credentials provided by the Agency. Guidance to experts on inclusion of declared interests in the e-DoI and on how to submit the e-DoI and e-CV is available.

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

Upon receipt of an e-DoI in the Experts database, an interest level is automatically assigned to the e-DoI, depending on whether the expert has any declared interests, and whether these are direct or indirect.

After the system assigns an interest level, the Agency uses the information provided to determine if an expert's involvement should be restricted or excluded in the Agency's specific activities. It bases these decisions on:

- the nature of the declared interests;
- the timeframe during which such interest occurred;
- the type of activity that the expert will be undertaking.

The revised policy reflects a more balanced approach to handling conflicts of interests that aims to effectively restrict the involvement of experts with possible conflicts of interests in the Agency's work, while maintaining EMA's ability to access the best-available expertise. The revision took into account experience obtained since the implementation of the 2012 version, as well as input received from stakeholders at the 2013 EMA public workshop 'Best expertise vs. conflicts of interests: Striking the best balance'.

The revised policy includes a number of measures which 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 medicine during previous employment with a pharmaceutical company, 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, there continues to be no cooling-off period required when the interest is no longer present.

Overall, restrictions for experts who are members of scientific committees remain more pronounced than for those participating in advisory bodies and ad-hoc expert groups. Similarly, requirements for chairs and members in a lead role, e.g. rapporteurs, are more pronounced than those for the other committee members.

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

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

Completed e-DoIs, their interest levels, and the e-CVs of scientific committee members and experts are published on the Agency's external website for transparency purposes. The European experts list on the Agency's website includes only experts who have a valid e-DoI and e-CV.

The 'Breach of trust procedure for scientific committees' members/experts' was last updated in April 2015, to align it with the revised policy. This procedure sets out how the Agency deals with incorrect or incomplete declarations of interests by experts and committee members.

The Agency immediately restricts scientific committee or working party members from any participation in the evaluation of medicines when they inform the Agency that they intend to take up employment in a pharmaceutical company.

Agency staff

The Agency's Code of Conduct extends the requirements for impartiality and the submission of annual declarations of interests to all staff members working at the Agency, including temporary agents, contract agents, seconded national experts, interims, visiting experts and trainees.

The decision on rules relating to Art.11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the EMA and candidates before recruitment is currently under revision as a result of the review of the policy on the handling of declarations of interests of scientific committee members and experts, as well as the review of the policy on competing interests of the MB members.

Staff declarations are available internally in a database and for consultation by external persons at the Agency on request (CVs and DoIs of the Executive Director and managers are published on the Agency's website).

Following completion of a declaration of interests, and depending on the nature of the declared interests, if any, a risk level (1-3) is assigned to the staff member and/or candidate by the reporting officer evaluating the declaration. Staff members and/or candidates at risk level 2 or 3 are subject to a documented risk-based assessment, which includes mitigating actions to reduce the risk.

As regards selection procedures and procurement, any conflict of interests must be declared by selection committee members and procurement evaluation committee members, and action is taken accordingly.

Management Board

In addition to the requirements outlined in the founding legislation and the Code of Conduct, the Management Board adopted the revised policy on handling competing interests for members of its Management Board in December 2015. The new policy will enter into force on 1 May 2016.

The Management Board takes strategic decisions and oversees corporate activities of the Agency, such as setting EMA's budget and approving its annual work programme. The Agency will apply a 'risk-based' approach, to determine the level of involvement in activities of the Management Board for a Board member with a declared interest. This approach is based on four factors:

- the nature of the declared interest;
- the timeframe during which the interest occurred;
- the type of Management Board activity and the likely impact of the Board's decision on the pharmaceutical or other industry; and
- the type of action requested by the Management Board, e.g. whether a decision such as approval or endorsement has to be taken by the Board or not.

The names of members having declared competing interests which could affect their impartiality with regard to specific items on the agenda are identified and communicated to the chair, along with applicable restrictions. In addition, members are informed, in writing, ahead of the meeting of the perceived conflict of interest which has been identified and the applicable restriction to their involvement at the meeting. At the start of each meeting, members are further asked to declare any specific interests which could be prejudicial to their independence with respect to the items on the agenda. Restrictions in the involvement of the chair/vice-chair or the members at the meeting will be noted in the minutes.

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

The 'breach of trust' procedure on declarations of interests for Management Board members was also revised and was adopted by the Board in December 2015. Changes to the breach of trust procedure were introduced to align with those introduced in 2015 for the breach of trust procedure for the scientific committee members and experts. The revised procedure will come into effect on 1 January 2016.

External consultants and contractors

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

- The Contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflicts of interest or professional conflicting interest could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflicts of interest or professional conflicting interest which could arise during performance of the Contract must be notified to the Agency in writing without delay. In the event of any such conflict, the Contractor shall immediately take all necessary steps to resolve it.
- The Agency reserves the right to verify that such measures are reasonable and may require additional measures to be taken, if necessary, within a time limit which it shall set. The Contractor shall ensure that the Contractor's Staff are not placed in a situation which could give rise to conflicts of interest. Without prejudice to Article II.1 the Contractor shall replace, immediately and without compensation from the Agency, any member of the Contractor's Staff exposed to such a situation.
- The Contractor shall abstain from entering into any contract likely to compromise its independence.
- The Contractor declares:
  - that it has not made and will not make any offer or agreement with any third party of any type whatsoever from which an advantage can be derived under the Contract,
  - that it has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any third party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, in as much as it is an incentive or reward relating to performance of the Contract.
- The Contractor shall pass on all the relevant obligations in writing to the Contractor's Staff and to any natural person with the power to represent it or take decisions on its behalf as well as to third parties involved in performance of the Contract including subcontractors. A copy of the instructions given and the undertakings made in this respect shall be sent to the Agency should it so request.

In addition, the Agency requests contractors and consultants to sign a DoI and confidentiality undertaking at the beginning of their assignments. The DoIs submitted are assessed by the responsible EMA manager, who takes appropriate actions in case of potential identified conflict of interests.

The Agency has measures in place to mitigate the risk of project-related commercially confidential information (CCI) being disclosed to non-EMA staff, such as consultants and contractors. CCI includes rates for payment of contracted services, quotations for delivery of contracted goods or services, and services and goods quoted in tender procedures. An internal guidance document was developed by the Programme Management Office that provides information on how project-related CCI should be handled and practical measures that should be taken to avoid disclosure.

[3] Article II.3.

4. Management assurance

4.1. Review of the element supporting assurance

Assurance from the Authorising Officers by delegation

In accordance with the charter of tasks and responsibilities of authorising officer by delegation, and in support of the annual activity report, the Head of Administration and the Head of Information Management Divisions were asked to draft a report and sign a declaration of assurance for their areas of responsibility.

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

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

Ex-ante control system and register of exceptions

The day-to-day ex ante verification is the financial control based on the subjective evaluation of risks where sound judgment applies. The Agency has decentralised the verification for standardised transactions requiring either an operational expertise or specific controls, such as fee revenue and expenditure. The aim of the financial ex ante verification is to assure the authorising officer that the budget implementation does respect the budgetary principles, of which sound financial management and transparency are the two main principles on which attention is focused.

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

In 2015, the Verifying Office performed its duties and achieved all objectives. No delays had to be reported and all transactions, without exception, were checked by applying appropriate checklists in line with the EMA's internal control standards, the Financial Regulation and the Charter of the Verifying Officer.

During the 2015 budget year, 981 (992 in 2014) rejections were recorded, of which 769 (78%) (789 and 80% in 2014) related to manual adjustments, technical rejections or interface issues following the decentralised verification. The balance of 212 (22%) reflects the effective rejection rate for less than 1% of the total transactions being checked.

Among the 144 rejected payments, 67% without materiality required a file revision. 33% did not show a noticeable individual financial risk.

68 commitments were rejected, mainly upon initiating agents' requests. The rest, for a nominal EUR 5,500,000, were rejected for various financial reasons (incorrect currency, calculation errors, wrong allocation, etc.) or procedural issue (missing document, change of requirement, wrong cost centre, etc.), but none of them showed a breach of contract provisions. Most of the rejections were

later corrected, amended and validated with due respect to budgetary principles and procedures in force.

Three rejections deemed to be recorded in the register of exceptions. They were all financial commitments showing either a weakness in the procedure or a follow-up issue; however, their low materiality did not expose the EMA to a financial risk. None of these three rejections revealed any breach of rules or contract provisions.

Ex post control system

In 2015, the Agency completed 14 ex-post controls, of which 4 financial and 10 non-financial.

Financial controls

Inspection and Human Medicines Pharmacovigilance Division:

- Ensuring compliance with procedures in place for processing standard and urgent certificates of medicinal products requests, resulting in correct fee(s) being charged.
- Ensuring compliance with procedures in place for processing parallel distribution notifications, resulting in correct fee(s) being charged.

Administration Division:

- Verifying correctness of the annual fee revenue and payments to NCAs, also taking into account any fee reductions applied.

Information Management Division:

- Establishing compliance with evaluation and pharmacovigilance procedures (medicinal products for human use), such as scientific advice, pharmacovigilance annual fees, pharmacovigilance PSURs, pharmacovigilance PASS, and pharmacovigilance referrals.

Non-financial controls

Human Medicines Research and Development Support Division:

- Ensuring compliance with the orphan designation procedure as set out in SOP 3040.
- Ensuring compliance with the orphan designation review procedure as set out in SOP 3190.

Human Medicines Evaluation Division:

- Verifying the correct application of the procedure for EPL nominations and for checks of conflict of interests for Category B roles in the Scientific and Regulatory Management Department.

Procedure Management and Committees Support Division:

- Determining the correct evaluation of the declarations of interest of experts involved in EMA activities.

Inspection and Human Medicines Pharmacovigilance Division:

- Ensuring that confirmed signals in EPITT are included in PRAC meeting discussions; that recommendations are published for all confirmed signals and that recommendations and meeting minutes published are consistent with each other.

Veterinary Medicines Division:

- Checking the correct creation, content and archiving of core master files of medicinal products for veterinary use relating to marketing authorisation applications, type-II variations as well as MRL applications.
- Verifying the transmission of the correct fee-related information to the financial actors (SIAMED) for type-I and type-II variations for veterinary medicinal products.

Administration Division:

- Determining the correct application of the procedure for the travel allowance payment to delegates and experts attending meetings as set out in the rules for reimbursement of expenses for delegates and experts attending meetings.

Information Management Division:

- Verifying the accuracy of the authorisation process for procuring licences, services and hardware in IT.

Corporate Governance Department:

- Detecting discrepancies between SAP FIN and the Executive Director's decisions on the delegated powers of budget implementation and the appointment of the Verifying Officer respectively.

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

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. The 2016 planning cycle was conducted in line with the requirements of the regulation.

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.

A revised framework for ex ante and ex post evaluation of Agency projects was agreed in December 2014 by the Executive Board. A new internal notice laying down the procedure and requirements for project evaluations became effective on 5 January 2015.

Before 1 February 2015, the Agency conducted evaluations of its programmes and projects through the application of the gated project approval process and the use of project documentation. From 1 February 2015 evaluations started to be conducted in line with the internal notice. Agency activities that qualify as projects on the basis of the definition for a project and are consequently subject to the established project governance and procedure are evaluated if the thresholds established in the EMA Financial Implementing Rules are exceeded (i.e. ex ante evaluation if the estimated cost of a project > EUR 1 million, ex post evaluation if the actual expenditure > EUR 3 million). The project governance and procedure were revised and implemented in 2014. The project budget approval process was also revised.

In the gated approval process the idea or concept for a project has to be approved by the Programme Design Board (PDB), taking into account priorities agreed by the Strategy Board (ESB), before resources are assigned to deliver the project business case. The preliminary business case with identified benefits and costs is subject to assessment by the Programme Design Board, which pays particular attention to the business need of the proposal, business architecture fit and the benefits that the proposal aims to achieve. Following this, a project is approved by the EEB at Gate 2. On approval, the project starts and is overseen by the Programme Implementation Board and EEB. As soon as the analysis and design are completed, a final business case is presented for assessment to the PIB. Approval at Gate 3 is by the PIB if the agreed cost threshold is not exceeded, otherwise the EEB is requested to approve. Project progress past Gate 3 continues to be overseen by the PIB and EEB. At the end of the project a closure report is presented to PIB for assessment. The EEB is responsible for final approval at closure.

The framework for evaluations is established in the EMA programme and project governance and gate procedure. Ex ante evaluations are conducted at Gate 2 on the basis of the preliminary business cases (including cost estimates) before projects and budget expenditure are formally initiated. Assessment and discussion in the PDB prior to endorsement and discussion in EEB at approval constitute the evaluation, which should be proportionate to the resources mobilised for and the impact of the project. When the total project costs estimated at Gate 2 exceed EUR 1 million the evaluation is conducted by the PDB against the criteria of the Financial Implementing Rules Article 11(1).

Ex post evaluations are conducted at project closure. Assessment and discussion in the PIB prior to endorsement and discussion in EEB at approval constitute the evaluation, which should be proportionate to the resources mobilised for and the impact of the project. When actual costs at project closure exceed EUR 3 million the evaluation is conducted against the criteria of Financial Implementing Rules Article 11(3).

Interim evaluations are conducted through six-weekly reporting to PIB and quarterly to EEB, where the status of projects is reviewed, and in more detail at Gate 3 when the final project business case is assessed and approved. Modifications to projects are evaluated and controlled by project change requests that are subject to PIB or EEB approval, depending on thresholds established by the Executive Director, and additionally to PDB endorsement of changes in scope prior to approval.

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

The results of ex ante and ex post evaluations are tabled every 6 months at a Management Board meeting. Preliminary business cases approved at gate 2 and closure reports are annexed to the reports. The first report was tabled at the October 2015 meeting and covered the period 1 February to 30 June. The second report for the period 1 July to 31 December will be tabled at the March 2016 meeting.

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

The Advisory Committee on Procurements and Contracts has been set up to examine procurement contracts prior to signature on behalf of the Agency.

The ACPC gave 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.

The total number of ACPC opinions in 2015 increased from 72 to 74. However, the number of opinions with condition increased substantially from 2 to 25. Hence, 34% of all dossiers submitted in 2015 had an opinion with condition.

In May 2015 the ACPC, taking into account experience with its functioning, introduced changes to its meeting frequency and the deadlines for submission of dossiers. In addition, new templates for reporting to the ACPC were implemented. Following a further review of experience with its functioning, the ACPC identified a number of issues in relation to its role, the quality of the submitted dossiers and the timelines for submission. The ACPC agreed on remedial actions to be implemented within its remit

and made suggestions to the Executive Director for his consideration for other remedial actions as they may require organisational and/or operational changes.

During 2015, 27 new procurement contracts exceeding EUR 15,000 in value were concluded by the Agency following procurement procedures, compared to 28 in 2014 and 30 in 2013. The total value of all such new contracts was EUR 18,044,593.38. In addition the Agency signed up to 7 inter-institutional framework contracts run by the Commission. There were 243 specific contracts concluded from framework contracts, making an overall total of 270 new contracts concluded in 2015. There were also 84 contract amendments/renewals.

The inter-institutional contracts signed by the Agency in 2015 related to: internet access services, SAP licences and services, external audits, sustainably produced office furniture for non-managerial staff and management, spare parts for furniture for non-managerial staff and management, supply of work seats, supply of sustainably produced furniture for meeting, training and conference rooms.

No building contracts were signed in 2015.

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.

Continuous improvement

Throughout 2015, the Agency continued the work 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.

Reconciliation of information in financial systems

The Agency's operational systems are interfaced with the SAP system. During 2015, 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.

Staff engagement survey 2015

The results of the staff engagement survey 2015 are promising and have further improved compared to 2013. However, a few of the weak issues remain: collaboration across divisions, objectivity in decision-making processes and trust in senior management. To address these, a new, more integrated approach to interpreting the staff engagement survey 2015 results and creating an action plan has been adopted for 2016.

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 77 processing operations in the data protection register maintained by the EMA DPO. 7 new processing activities were registered in the course of 2015. One new processing activity concerning reporting of fraud and irregularities triggered a notification to the EDPS for prior check under Article 27. The Prior Check Opinion was received on 16 December 2015.

In June 2015, the EDPS performed a general stock-taking exercise, monitoring compliance with data protection legislation of EU institutions. EMA was ranked among the institutions and agencies showing a solid and strong level of performance and receiving two special mentions with regard to the best practices adopted in terms of governance of data protection.

In terms of activities related to data protection, the DPO investigated one complaint concerning the transfer of personal data in HR procedures and a recommendation to the Controller was issued with no follow-up required; short data protection training sessions were offered for staff involved in procurement activities and in EMA infrastructure security services; in September, half-day training session open to all EMA staff was organised on the topic "Big Data and Public Health". The DPO monitored and reported updates on the adoption of the draft General Data Protection Regulation in particular with regard to the provisions governing health data and the research exemption. The DPO has been actively involved in the elaboration of the external guidance on the anonymization of clinical reports for the purpose of publication under Policy on publication of clinical data for medicinal products for human use.

The DPO has been providing advice to data controllers on a regular basis, in particular with regard to Human Resources activities, Access to Documents procedures, and the WP1 of the WEB-RADR project concerning new digital tools for pharmacovigilance.

Quarterly bilateral meetings took place between the DPO and the Executive Director/Deputy Executive Director in 2015.

Conclusions

Taking into account the review of the elements supporting assurance, the Executive Director is of the opinion that the management and control systems in place at the Agency are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

4.2. Reservations

Based on the assurance provided by the control system results, the Executive Director sees no reason that would justify or require a reservation.

Materiality criteria used

In line with the suggestion of the guidelines on the preparation of the annual activity report, the Agency used the qualitative and quantitative materiality criteria described below, to assess if issues identified merit a reservation.

Qualitative criteria used

The Agency would consider significant the weaknesses in the internal control system that fall under the following qualitative criteria:

- significant errors detected during the control or supervision exercises;
- a significant weakness in one of the control systems;
- situations where the Agency does not have sufficient evidence from internal control systems or audit coverage to be confident of providing the necessary assurance;
- situations where a major issue has been outlined by the European Court of Auditors or the Internal Audit Service of the Commission (critical audit recommendations for underlying weaknesses relevant to the area covered by the declaration of assurance that 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.

4.3. Overall conclusions on assurance

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the Court of Auditors on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Agency can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

5. Declaration of assurance

I, the undersigned, Guido Rasi, Executive Director of the European Medicines Agency, in my capacity as authorising officer:

Declare that the information contained in this report gives a true and fair view.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessments, ex post controls, the work of the internal audit capability, the observations of the Internal Audit Service and the lessons 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, 25 May 2016

[signature on file]

Guido Rasi

(Executive Director)

Annexes

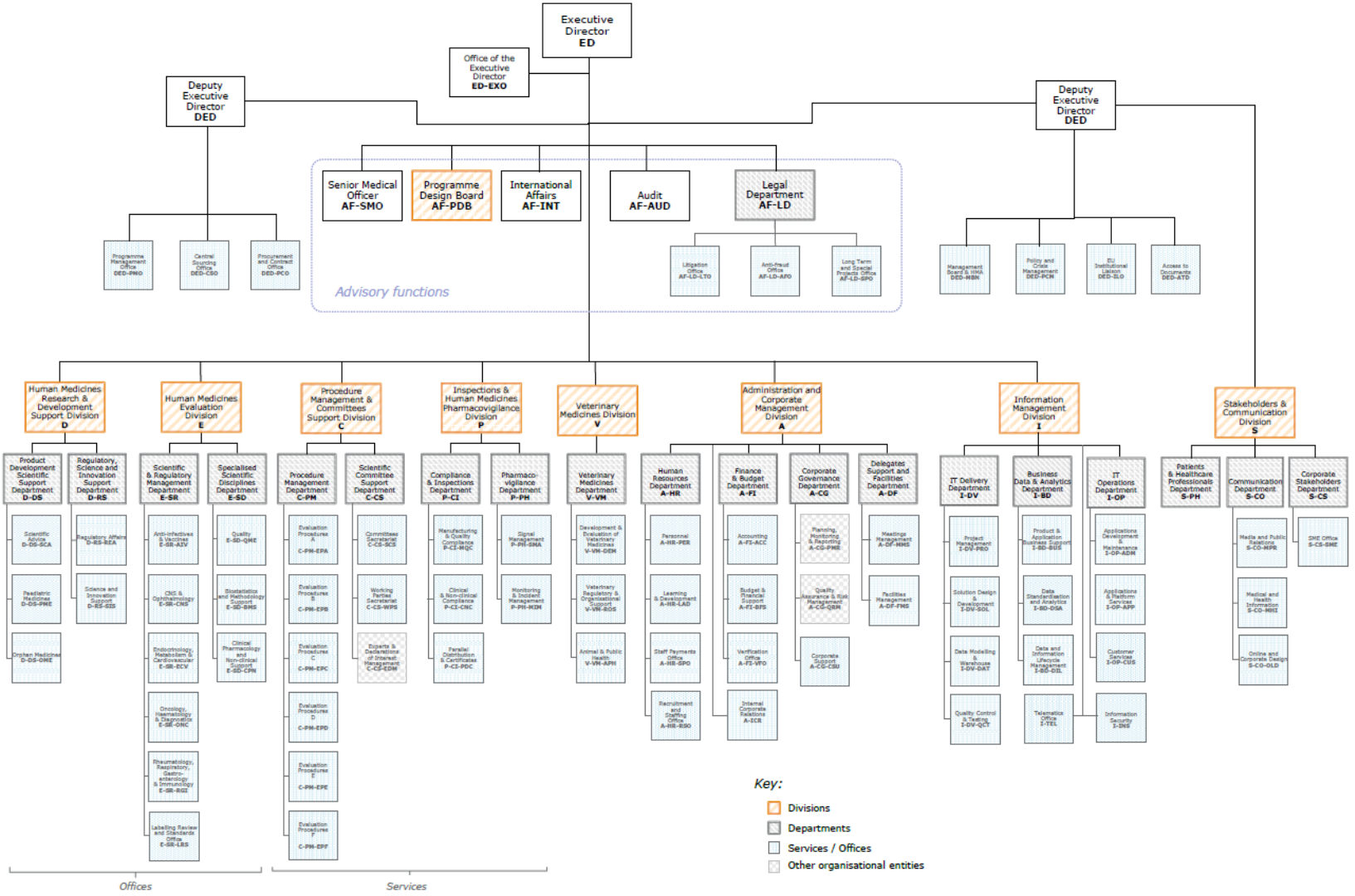
Annex I. Core business statistics

Business statistics can be found in Part 1.

Annex II. Statistics on financial management

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

Annex III. Organisation chart as at 31 December 2015



Annex IV. Establishment plan

Category and grade	Authorised for 2014		Occupied as of 31/12/2014			Authorised for 2015		Occupied as of 31/12/2015[1)]			Authorised for 2016	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts
				Grade filled	Actual grade				Grade filled	Actual grade		
AD 16	-	0	-	0	0	-	0	-	0	0	-	0
AD 15	-	4	-	4	2	-	4	-	3	2	-	4
AD 14	-	6	-	6	1	-	6	-	5	1	-	6
AD 13	-	8	-	7	9	-	9	-	9	10	-	9
AD 12	-	42	-	39	29	-	42	-	41	24	-	42
AD 11	-	38	-	36	20	-	37	-	36	22	-	38
AD 10	-	36	-	35	34	-	40	-	39	33	-	44
AD 9	-	37	-	34	28	-	36	-	36	33	-	37
AD 8	-	49	-	47	52	-	52	-	51	51	-	54
AD 7	-	51	-	51	45	-	52	-	51	50	-	54
AD 6	-	39	-	39	71	-	36	-	36	77	-	37
AD 5	-	30	-	29	27	-	26	-	26	20	-	18
Subtotal AD	***0***	***340***	***0***	***327***	***318***	***0***	***340***	***0***	***333***	***323***	***0***	***343***
Total AD	**340**		**0**	**327**	**318**	**340**		**0**	**333**	**323**	**343**	
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	5	-	5	2	-	5	-	5	3	-	5
AST 9	-	7	-	7	2	-	7	-	6	2	-	7
AST 8	-	15	-	14	7	-	16	-	16	5	-	16
AST 7	-	19	-	19	14	-	19	-	18	14	-	19
AST 6	-	36	-	34	16	-	39	-	38	19	-	39
AST 5	-	37	-	36	33	-	42	-	42	33	-	43
AST 4	-	55	-	55	30	-	49	-	49	33	-	49
AST 3	-	39	-	38	65	-	43	-	41	65	-	47
AST 2	-	34	-	33	34	-	37	-	37	34	-	32
AST 1	-	10	-	10	59	-	0	-	0	56	-	0
Subtotal AST	***0***	***259***	***0***	***253***	***262***	***0***	***259***	***0***	***254***	***264***	***0***	***259***
Total AST	**259**		**0**	**253**	**262**	**259**		**0**	**254**	**264**	**259**	
AST/SC1	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC2	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC3	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC4	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC5	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC6	-	-	-	-	-	-	0	-	-	0	-	0
Subtotal AST/SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Total AST/SC	**0**		**0**	**0**	**0**	**0**		**0**	**0**	**0**	**0**	
Grand subtotal	***0***	***599***	***0***	***580***	***580***	***0***	***599***	***0***	***587***	***587***	***0***	***602***
Grand total	**599**		**0**	**580**	**580**	**599**		**0**	**587**	**587**	**602**	

1) Data as per draft provisional accounts of 20/01/2016

Information on the entry level for each type of post

Interims: from 1 January 2015 to 31 December 2015, there have been 104 different interims, and on average their interim assignment was for 8.4 months.

Contractors: from 1 January 2015 to 31 December 2015, there have been 236 different contractors under IT budget, and on average their contract duration was for 7 months.

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

Annex V. Results of the screening exercise as of December 2015

Article 29(3) of the Framework Financial Regulation sets the obligation for all European Union Institutions and Agencies to carry out a benchmarking exercise with the aim of justifying administrative expenditure in a structured way using a common methodology.
The first phase of the implementation process for Agencies consists of a staff screening exercise categorising human resources according to the organisational role each job is serving. Jobs are grouped according to the Commission Screening methodology under three main types: Administrative Support and Coordination, Operational and Neutral.
The jobs screened include all establishment plan posts (TA) occupied full time or part time and all other types of contracts occupied by a jobholder (contract agents, seconded national experts, Interims, trainees and long-term contractors and consultants) fulfilling all or most of these criteria: minimum 3 months contract, have a badge, occupy an office space, have a phone (personal number) and have a computer (personal identification (username and password), e-mail).

Job type (sub) category	2014 (%)	2015 (%)
Administrative support and coordination	**16.36%**	**16.73%**
Administrative support	15.24%	16.01%
Coordination	1.12%	0.72%
Operational	**79.47%**	**79.25%**
Top level operational coordination	1.52%	1.16%
Programme management & implementation	19.61%	23.08%
Evaluation & impact assessment	45.53%	41.32%
General operational	12.80%	13.69%
Neutral	**4.17%**	**4.03%**
Finance / control	4.17%	4.03%
Linguistics	0.00%	0.00%
Total	**100%**	**100.00%**

Annex VI. Human and financial resources by activity

Activities	[1]FTEs	Staff Cost (incl. overheads)	Meetings cost (incl. overheads)	Evaluation cost (NCAs)	Miscellaneous expenditure	TOTAL[2]
		€'000	€'000	€'000	€'000	€'000
1 Evaluation activities for human medicines	**389**	**66,275**	**11,312**	**102,776**	**19,243**	**199,607**
1.1 Pre-authorisation activities	86	14,624	4,288	17,143	417	36,473
1.2 Initial evaluation activities	78	14,252	1,454	15,355	1,185	32,245
1.3 Post-authorisation activities	82	13,840	1,482	59,526	2,462	77,310
1.4 Referrals	13	2,120	454	0	288	2,862
1.5 Pharmacovigilance activities	108	17,102	1,897	10,753	12,776	42,528
1.6 Other specialized areas and activities	22	4,338	1,736	0	2,115	8,189
2 Evaluation activities for veterinary medicines	**46**	**7,750**	**2,397**	**3,133**	**808**	**14,088**
2.1 Pre-authorisation activities	1	298	634	359	8	1,298
2.2 Initial evaluation activities	17	2,958	435	732	257	4,383
2.3 Post-authorisation activities	13	2,096	220	2,042	308	4,665
2.4 Arbitrations and referrals	3	536	198	0	198	932
2.5 Pharmacovigilance activities	5	640	270	0	14	924
2.6 Other specialized areas and activities	7	1,222	640	0	24	1,885
3 Horizontal activities and other areas	**136**	**22,636**	**4,105**	**5,760**	**3,266**	**35,767**
3.1 Committee coordination	23	3,577	1,373	0	128	5,078
3.2 Inspection and Compliance	36	4,647	1,254	5,760	1,247	12,909
3.3 Partners and Stakeholders	17	3,198	1,478	0	779	5,455
3.3a Transparency and access to documents	22	3,965	0	0	753	4,718
3.3b Information	23	4,137	0	0	359	4,496
3.4 International activities	14	3,111	0	0	0	3,111
4 Corporate Governance and Support activities	**186**	**32,419**	**638**	**0**	**1,790**	**34,847**
4.1 Governance, Quality Management and Internal Audit	30	5,981	433	0	97	6,512
4.2 Finance	24	3,805	0	0	422	4,228
4.3 Information technology	61	11,962	4	0	233	12,200
4.5 Human resources	39	5,784	0	0	328	6,112
4.6 Infrastructure services	14	2,068	0	0	0	2,068
4.7 Communication (corporate)	18	2,818	201	0	710	3,729
Total	**757**	**129,080**	**18,452**	**111,670**	**25,107**	**284,309**

[1] Full Time Equivalence (FTE) represents the establishment plan adjusted for part-time schedule, long term absences and time worked in excess of the standard working hours. In 2015 the extra time worked was equivalent to 39 FTEs, which means that 757 staff worked the equivalent of 796 FTEs.
[2] Excluding exceptional investment cost of €9.0 million related to the move to the new building. The total expenditure is based on the payments made in 2015 (C1 and C8) plus the commitment to the National Competent Authorities related to Pharmacovigilance of approximately €2.0 million

Annex VII. Statistics on flexi leave according to grade

Grade	Staff members on 31.12.2015	Total flexi leave days taken	Average flexi leave days per staff member
AD15	2	0	0
AD14	1	0	0
AD13	10	12	1
AD12	24	40.5	2
AD11	22	84	4
AD10	33	88.5	3
AD09	33	174.5	5
AD08	51	211	4
AD07	50	205	4
AD06	77	266	3
AD05	20	85	4
AST10	3	7	2
AST09	2	1	1
AST08	5	3.5	1
AST07	14	18	1
AST06	19	49	3
AST05	33	50.5	2
AST04	33	51.5	2
AST03	65	140	2
AST02	34	48.5	1
AST01	56	111.5	2

Grade	Staff members on 31.12.2015	Total flexi leave days taken	Average flexi leave days per staff member
FGIV.18	1	0.5	1
FGIV.16	2	12.5	6
FGIV.14	34	110.5	3
FGIV.13	18	52	3
FGIII.10	1	6	6
FGIII.09	12	28.5	2
FGIII.08	5	12.5	3
FGII.06	6	22	4
FGII.05	36	49	1
FGII.04	38	42.5	1
SNE	35	122	3
Grand Total	775	2,105	3

Annex VIII. Report for 2015 on staff 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. National experts are also required to seek permission, although the period is restricted to the equivalent duration of the secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

For the period from 1 January 2015 to 31 December 2015, a total of 28 applications were made, resulting in 23 authorisations without restrictions and 5 applications with restrictions. Examples of restrictions imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff 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 will be applied on a case-by-case basis. Information on restrictions applied to applications in 2015 is given in the table below.

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	Trainee + Contract Agent / Procedure Management Department	9 months + 2 years 5 months	19/06/2015	Authorisation with restrictions	24/06/2015	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. To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on any 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	16/07/2015

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
						for a period of 12 months to be counted as of the date of leaving service.	
2	Contract Agent / Product Development Scientific Support Department	18 months	28/08/2015	Authorisation with restrictions	23/09/2015	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. To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on any BioMarin product s/he worked on in the performance of his/her responsibilities at the Agency during his/her last three years of service. This provision includes a restriction on assisting any third party in any legal case concerning any BioMarin product.	05/10/2015
3	Temporary Agent / IT Division	3 years	13/07/2015	Authorisation with restrictions	22/07/2015	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. S/he and Remagine BVBA is prohibited from taking part in/bidding for or contributing to a service provider or contractor offering services to, or proposing to offer services to the EMA in matters for which s/he was responsible.	29/07/2015

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
						Refrain from holding managerial or executive roles in companies that provide IT services to the Agency.	
4	Contract Agent / Regulatory, Science and Innovation Support Department	18 months	16/10/2015	Authorisation with restrictions	04/11/2015	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 one year and six months of service. To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on the specific products s/he worked on in the performance of his/her responsibilities at the Agency during his/her one year and six months of service.	16/11/2015
5	Trainee + Contract Agent / Legal Department	10 months + 1 year	19/11/2015	Authorisation with restrictions	04/12/2015	Should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her one year and then months at the Agency. In line with professional ethics applied at the level of bar associations throughout Europe, s/he should not, on a permanent basis, represent/assist a third party in any case lodged	16/12/2015

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
						with the European Court of Justice, national or international courts which s/he dealt with while in service at the Agency.	

Annex IX. Risks

Operational activities

Risk	Mitigating actions and controls
Product assessment – procedure management	
Incorrect scientific opinions due to lack of required competences and expertise of experts	In place: • Legal requirements regarding expertise and competence • Appointment process for CxMP, working party and SAG members • Management Board review of CHMP, CVMP and PRAC competencies • Criteria for competence and expertise of committee members and alternates for CHMP and PRAC • Defined roles and responsibilities of experts and committees • Establishment of specialised forums for experts (including SAGs) • Proactive search for expertise from academia/learned societies • Possibility for expert witnesses having limited controlled role • Revised policy on CoI to improve balance between reducing risk for CoI and using best available expertise In progress: • Joint EMA-HMA training strategy
Product assessment – Conflict of interest / independence	
NCA experts participating in the assessment work at the level of national agencies influence the outcome due to a failure to disclose conflicts of interest	In place: • Legal requirements for independence • Contractual arrangements and memorandum of understanding with NCAs • Agreement by HMA that EMA standards should be the minimum standards applied at NCAs
Experts attending and providing advice or opinions during EMA committees, working parties and other groups, influence the outcome due to a failure to disclose conflicts of interest	In place: • Legal requirements for independence • Code of conduct and Guidance on handling declaration of interest in case of a committee or other scientific forum member's intention to become employee in pharmaceutical company • Framework for decision-making process at CxMP • Policy on handling declarations of interests of scientific committees' members and experts • Check of interests declared by members and experts participating in meetings • Publication of DoI and eCVs of committee members and experts on Agency website • Breach of trust procedures on conflicts of interest for scientific committee members and experts • Comparing eCVs and DoI to uncover discrepancies regarding conflict of interest • KPIs to monitor conflicts of interests declared Planned: • Improvements to the Experts database to incorporate DoI evaluation forms and overview of involvement of the experts
Product assessment – Applicant fraud	
Incorrect scientific opinion due	In place:

Risk	Mitigating actions and controls
to infringement of compliance involving data fraud by applicant or third party supplying data	• Cross-Agency infringement action group In progress: • Active publication of clinical trials data post-authorisation • Policy and procedures for handling whistle-blowers/parties raising concerns Planned: • Policy and procedures on EMA activities relating to prevention, detection, investigation and action relating to infringement • Procedures for implementing Penalties Regulation • Standards for documentation of investigations and ensuing procedures to ensure integrity of any future infringement procedures
Inspections	
Inadequate quality of medicines due to framework for compliance with GxP from non-EU countries not meeting the EU standards at all times	In place: • EU Network / cooperation (Inspection Working Groups, inspections planning – EudraGMDP Planning Module, PhV inspection programme, CMDh subgroup on Bioequivalence trials) • International cooperation in GxP area: - The ICH process (GMP, GCP, PhV) - The OECD programme (GLP) - Mutual Recognition Agreements and Agreement on Conformity assessment (GMP) - International collaboration on GMP inspections of API manufacturers - EMA-FDA GCP initiative and EMA/EU MS/FDA initiative on inspections for generic applications - Exchange of inspections information and reports with non-EU Authorities with Confidentiality Agreements or other bilateral relations - Joint inspections with non-EU Authorities - Training and capacity building activities • Legal and regulatory requirements • Risk based approach for GxP inspections allowing better use of available resources In progress: • Mutual reliance initiative between FDA and EU on GMP inspections
Pharmacovigilance	
lack of additional post-marketing authorisation data on human medicines to proactively identify, qualify and quantify risks	In place: • Launch of post-authorisation studies using ENCePP network • Independency, transparency and methodological standards of ENCePP studies ensured • Implementation of pharmacovigilance legislation (PASS and PAES) • 'Best evidence' procedure to support PRAC discussions In progress: • Longitudinal patient record databases used for EMA studies (in-house and commissioned studies) • Registries initiative
Inability of the Agency to effectively conduct veterinary pharmacovigilance if suitable IT system is not developed to replace EVVet2	In place: • Maintain expertise and knowledge in house to ensure EVVet2 can continue to operate until a replacement system is developed Planned: • Replace existing technology for EVVet2 with more modern technology as a

Risk	Mitigating actions and controls
	first step to a complete revision/replacement of the system

Support activities

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

Risk	Mitigating actions and controls
	• Creation of data protection network within the Agency • Regular bilateral meetings between Executive Director and Data protection officer Planned: • Review of the system of EMA management responsibilities for processing personal data
Data management – data quality	
Data required for scientific and regulatory procedures and decision making is of poor quality, incomplete, inaccurate and/or lacks integrity	In place: • Validation of data entry in SIAMED and EudraVigilance • Data analytics tool and processes for monitoring data quality • Governance structure for data management In progress: • Data cleaning of existing data to ensure reference quality level • Agency quality standard and reference for data based on ISO standards • Single trusted, identifiable master copies of substances, referentials, organisations and products data available as service • Data quality control level based on risk assessment of individual data assets
Data management – document management	
Loss of information due to inadequate document management system and processes	In place: • EMA Records management policy and business classification scheme • Basic back-up procedures undertaken on shared drives, Outlook and document management system • Awareness and training session on document/records management best practices • Procedure on Core Master File Product In progress: • Identification of data sets owner and definition of clear roles and responsibilities Planned: • Records management embedded in redesigned human medicines evaluation processes • Compliance assessment of Agency's document/records management IT systems • Automatic assignment of retention policy and classification • KPIs to monitor compliance with EMA Records management policy • Reporting tools in the Document Management system to automate monitoring and control measures
IT development and management	
Loss of knowledge due to contractors leaving the Agency	In place: • Reducing reliance on contractors for critical skills and knowledge In progress: • Review of IT operating model to insource further critical skills and knowledge Planned: • Outsourcing less critical skills and services, managed by strict contracts and SLAs
Finance - Revenue collection and Treasury management	

Risk	Mitigating actions and controls
Loss of revenue due to inability/difficulty collecting pharmacovigilance fees from new customers	In place: • Proactive communication/engagement with stakeholders, including guidance/workshop with industry • New SAP technology for debt collection Planned: • Establishment of acceptable level of non-payment/to write-off debts (waiver of recovery)
Loss on currency exchange rate fluctuations	In place: • Hedging/other exchange mechanisms • Forward exchange contracts • Treasury policy • Minimum cash flow level kept • Subsidy claimed only as required • Regular meetings with treasure committee
Agency operation interrupted due to significant system failure	In place: • Monitoring, preventive maintenance and resilience • Trained teams to repair/fix systems, external support from companies In progress: • Tested disaster recovery systems and procedures
Clinical data publication	
Non-compliance of MAHs/pharmaceutical industry with the policy	In place: • Information sessions with industry prior to implementation • Consultation with stakeholders In progress: • Identification of non-compliance scenarios and remedial actions Planned: • Targeted consultations with stakeholders • Annual report on implementation experience, including non-compliance data
Stakeholder relationships	
Failure to meet stakeholder expectations	In place: • Framework for interaction with patients and consumers • Frameworks for interaction with healthcare professionals • Framework for interaction with academia • SME surveys and other initiatives • Communication perception surveys • Targeted stakeholder meetings • Tools including website/media monitoring/google alerts In progress: • Framework for interaction with industry stakeholders

Annex X. Implementation of the internal control standards in 2015 and actions planned for 2016

Standard	Actions planned for 2015: follow up	Actions planned for 2016
Mission	n/a	n/a
Ethical and Organisational Values	n/a	The decision on rules relating to Art.11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the EMA and candidates before recruitment is currently under revision.
Staff Allocation and Mobility	n/a	n/a
Staff Evaluation and Development	• Review job descriptions of all staff. *2014 update: Following the Review and Reconnect exercise, many entirely new job descriptions were written and other substantially modified and updated, with an Agency-wide exercise to be completed by end of Q3 2015.* *2015 update: Completed* • Design a longer term staff competence development and recruitment plan to reflect scientific and technological development in the Agency's environment. *2014 update: New technical competences, as well as a managerial competence framework are being defined (target date 05/2015).* *2015 update: The management and leadership competency framework is now in place. A number of different strands of work are ongoing to define priority scientific, regulatory, and other technical requirements of different EMA roles (target date 12/2016).* • Introduction of self-development workshop for staff and a workshop for managers.	n/a

Standard	Actions planned for 2015: follow up	Actions planned for 2016
	Implemented • Creating Divisional Learning and Development plans. *In order for the plans to include the output of the appraisal discussions, before finalising, individual meetings have been held with all Heads of Division with an agreed date of April for the planning for the remainder of the year (target date 04/2016).*	
Objectives and Performance Indicators	• Develop and agree with senior management a performance indicator list and regularly report on their status. *2014 update: 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).* *2015 update: Review of KPIs is expected to take place in 2016, as part of the multiannual work programme development as well as within the scope of developing integrated planning and reporting in the Agency.* • Strengthen the link between the results of the risk management activities and the work programme. *2014 update: Improvement activities in the risk register map to the work programme. Certain aspects will be taken further within the 2015 actions.* *2015 update: The format of the work programme has been updated and now includes an annex containing information on the significant risks highlighted in the risk register and their mitigating actions.* • Integration of monitoring activities into one system (work programme, risk management, ICS, anti-fraud activities, audit, etc.). *Completed*	In order to improve planning and reporting throughout the agency, and in line with the recommendation from the audit on building blocks of assurance carried out in November-December 2015, mechanism/templates/tools for improved cascade of the strategy and agency's work programme in the divisions/departments will be considered within the scope of developing integrated planning and reporting in the Agency.

Standard	Actions planned for 2015: follow up	Actions planned for 2016
	• New format of the work programme joining operational, financial and staff information will be developed. *The format of the work programme has been updated to reflect the EC requirements for the programming document, including adding information on the significant risks and their mitigating actions in an annex. Further review of the work programme format will be carried out as deemed necessary.* • New template for multi annual work programme will be developed. *Following the adoption of the network strategy, the template and content of the multiannual work programme will be developed in the first half of 2016.* • A system integrating information on workload, allocated staff resources and KPIs will be delivered for decision making. *The above-mentioned system, including dashboards for strategic decision-making will be delivered as part of the integrated planning and reporting design in the agency (2016).*	
Risk Management Process	n/a	n/a
Operational Structure	• The telematics governance is complicated and will require review (target: Q1 2016). *The revised telematics governance will be presented for adoption to the EU TMB on 2 February 2016.* • Develop/update IT strategy. *The information management strategy was developed and adopted by the Executive Board on 20 October 2015.* • Project management framework.	n/a

Standard	Actions planned for 2015: follow up	Actions planned for 2016
	Revised target end of Q3 2016 • Develop IT master plan. *The revised target is to complete it by the end of Q1 2016.* • Delegations: Complete charter for initiating agents and implement for existing initiating agents as well as any future initiating agent from then on (by 2nd semester of 2015). *Completed*	
Processes and Procedures	n/a	Quality framework to be reviewed including the quality manual.
Management Supervision	n/a	n/a
Business Continuity	• Administration/IT/communications exercise for the management of the very first hours of an incident (planned for 2015). *Completed*	n/a
Document Management	• A strategy for unstructured information management and roadmap as well as the record management operational model will be drafted and proposed for endorsement in 2015. *The Specific roadmap for document management has been put on hold since it needs to be clarified whether Documentum is a sustainable Document and Records Management a solution for the Agency and the network. This new roadmap, part of the Information Management strategy, will be followed up and deployed by Q3 of 2016 depending on the availability of IT resources.*	Full implementation of the ED decision on corporate controlled documents to be achieved by the end of 2016.
Information and Communication	• Deliver on-line programme, specifically European Medicines web portal *2014 Update: 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*	To develop new strategic framework for corporate communications for the period 2016-2020. IT systems: Cloud policy to be approved in 2016.

Standard	Actions planned for 2015: follow up	Actions planned for 2016
	February HMA meeting (2015) *2015 Update: A reflection paper on the European Medicines Web Portal was developed taking into account feedback from NCAs gathered in early 2015. The reflection paper will be presented for endorsement at the EU Telematics Management Board on February 2, 2016 and for adoption at the HMA and EMA MB during the first half of 2016.* • IT Systems: A Full Pen Test exercise is planned for 2015 to attest the effectiveness of the security controls. *Postponed to Q1 2016*	Information classification policy to be approved in 2016.
Accounting and Financial Reporting	n/a	n/a
Evaluation of Activities	n/a	n/a
Assessment of Internal Control Systems	n/a	n/a
Internal Audit Capability	n/a	n/a

Annex XI. Consolidated list of new public procurement contracts > €15,000 concluded by the Agency during 2015

(Those contracts signed during reference period 01/01/2015 – 31/12/2015)

Contract no.	Type of contract	Name of Contractor	Subject	Value (or estimated value, where applicable)	Procurement procedure and justification if negotiated procedure	Organisational entity / Authorising Officer	Budget line, commitment and payment orders *(as applicable)*
EMA/2014/58/HR	Framework contract	STS Complete Health & Safety (Lot1) Assured Fire Services LTD (Lot2)	Training (first aid)	GBP 11,750 (lot 1) GBP 7, 850 (lot 2)	Negotiated under EUR 60,000	A-HR K Roskilly	Budget line 1120; Lot1 PO4800005693 Invoice 5105641954 PO4800006183 Invoice pending PO4600002541 Invoice pending Lot2 PO4800005533 Invoice 5105638964 Invoice 5105638965 PO4800005700 Invoice 5105641719
EMA/2014/63/COM	Shortform contract	Service Point (Paragon)	Printing services	EUR 60,000 (ceiling of framework contract)	Negotiated under EUR 60,000	S-CO B Fayl von Hentaller	Budget line 3040; PO4500001621 – invoice 5105637090 PO4600002190 – invoice 5105637102 PO4600002192 – invoice

Contract no.	Type of contract	Name of Contractor	Subject	Value (or estimated value, where applicable)	Procurement procedure and justification if negotiated procedure	Organisational entity / Authorising Officer	Budget line, commitment and payment orders *(as applicable)*
							5105637103 PO4600002204 – invoice 5105638285 PO4600002206 – invoice 5105637089 + credit note 5105639159 PO4600002223 – invoice 5105638286
EMA/2015/01/RE	Service contract	IMS Information Solutions Medical Research Ltd	Clinical event history database	EUR 539,032	Negotiated Art 134 1(a)	PV A Pott	Budget line 3031; PO4500001758 – invoices 5105640526, 5105643746
EMA/2015/03/IS	Framework shortform contract	Arthur J Gallagher Insurance Brokers Ltd	Insurance advisory services	GBP 42,966	Negotiated under EUR 60,000	A-ISERV A Brandt	Budget line 2010; PO46/2263 – Invoice 5105643802 PO46/2282 – Invoice 5105643801
EMA/2015/13/LD	Framework contract	Trowers & Hamlins LLP	Legal services (contracts and procurement)	GBP 150,000	Negotiated under Articles 134(1)(i) and 128(2)(b) RAP	AF-LD T Jablonski	Budget line 2330; PO 4500001754 – invoices 5105644107, 5105644108

Annex XII. Annual report 2015

Please see the Agency's 'Annual report 2015', attached as a separate document.

Annex XIII. Administrative Appropriations – Building Policy

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

	30 Churchill Place, London, E14 5EU	Comments
Total area (in square meters) - of which office space - of which non-office space and below ground space	26,450 18,448 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 to level 10.
Annual rent	GBP 13,669,649 - rent: GBP 11,759,937 - service charge: GBP 1,909,712	Rent for level 10 is payable from 2018.
Type and duration of rental contract	Rental lease of 25 years duration; term commencement is 1 July 2014.	
Host country grant or support	None	
Present value of building	Not applicable	

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

There were no building projects in planning phase in 2015.

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

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

The financial impact of "Project 2014" over the term of the lease, including Basement to Level 10 is estimated to be EUR 565,218,810, compared to the initial EUR 554,600,000 which corresponds to an annual impact of EUR 424,752, in line with what was communicated to the European Commission in January 2015 in regards to the 2016 Preliminary draft budget. Note that the Euro values are based on a GBP/EUR exchange rate of GBP 0.858117/EUR which corresponds with the European Parliament buildings questionnaire submitted by the Agency in April 2011.

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

Description	2015, €	Forecast 2016, €
Activities to be covered by the Annual Fee	22,514,476	22,159,043
Periodic Safety Update Reports (PSUR & PSUSA)	13,054,156	12,814,279
Post-Authorisation Safety Studies (PASS)	511,810	858,116
Referrals	1,527,436	1,873,413
Total	**37,607,878**	**37,704,851**

Annex XV. Environmental performance

Environmental Management at the Agency

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

The Agency aims to register to the European Commission's Eco-Management and Audit Scheme (EMAS) in 2016 and in preparation for this has prepared an environmental statement, which is a requirement of EMAS.

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

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

Overview of EMA performance in 2015

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

Indicator	Units	2014		2015	
		Overall	Per workstation	Overall	Per workstation
Energy consumption	kWh	3,321,927	2,844	3,635,921	2,990
Water consumption	m^3	2,429	2.08	2,607	2.14
Paper consumption	kg	41,287	35.35	26,554	21.84
Waste (incl. non-recyclable, recyclable and confidential)	kg	240,130	205.6	176,530	145.2
Work-related travel (incl. delegates, missions, training and candidates)	miles	9,229,023	7,902	9,785,507	8,048
Overall net CO_2e	kg CO_2e	2,724,461	2,333	2,842,558	2,338

Annex XVI. Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AAR	annual activity report
ACPC	Advisory Committee on Procurement and Contracts
AD	administrators' function group
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
AGES	Austrian Medicines and Medical Devices Agency
Art	article
AST	assistants' function group
ATD	access to documents
ATMP	advanced-therapy medicinal product
Board	Management Board of the EMA
BWP	Biologics Working Party
ca.	Circa, approximately
CA	contract agent
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCI	commercially confidential information
CCTV	closed-circuit television
CDISC	Clinical Data Interchange Standards Consortium
CHMP	Committee for Medicinal Products for Human Use
CIOMS	Council for International Organisations of Medical Sciences
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CoI	conflict of interests
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
Court	European Court of Auditors
CTR2	Clinical Trial Registry, CDISC project for structuring clinical trial registrations in electronic format
CV	curriculum vitae
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	committee for assessment of medicines

Term / abbreviation	Definition
DCDA	defined course dose for animals
DDDA	defined daily dose for animals
DG	Directorate-General of the European Commission
DoI	declaration of interests
DPO	Data Protection Officer
DTS	Draft Technical Standards
eAF	electronic application form
EC	European Commission
ECA	European Court of Auditors
ECCA	European cancer organisation
eCTD	electronic common technical document
e-CV	electronic curriculum vitae
ED	Executive Director
e-DoI	electronic declaration of interests
EDPS	European data protection supervisor
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EEB	Agency's Executive Board
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
e.g.	for example
EHS	European Society of Haematology
EMA	European Medicines Agency
EMAS	European Commission's Eco-Management and Audit Scheme
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
EPL	EMA product lead
CeRMR	Electronic reaction monitoring reports
ESB	Agency's Strategy Board
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU contribution	EU special contribution for orphan medicines
EU-CTR	EU Clinical Trials Register
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice database
EudraLink	European Union Drug Regulating Authorities secure file sharing
EudraPharm	European Union Drug Regulating Authorities Pharmaceutical Database
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUGenMed	European Gender Medicine Network
EU NDB	EU Network Data Board
EUnetHTA	European network for health technology assessment
EUR	euro
EURS	EXTEDO universal review system

Term / abbreviation	Definition
EU TMB	Eu Telematics management board
EVVet	EudraVigilance veterinary
EVMDP	EudraVigilance Medicinal Product Dictionary
FDA	United States Food and Drug Administration
FG	function group
Executive Board	Agency's Executive Board
GBP	pound sterling
GCP	good clinical practice
GLP	good laboratory practice
GMDP	good manufacturing and distribution practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
GxP	good practice (e.g., laboratory, clinical, manufacturing etc)
HCPWP	Healthcare Professionals Working Party
HL7 CPM	Health Level 7 Common Product Model
HL7 SPL	Health Level 7 Structured Product Labelling
HMA	Heads of Medicines Agencies
HMLT	Human medicines leadership team at the EMA
HMPC	Committee on Herbal Medicinal Products
HR	human resources
HTA	health technology assessment
IAC	internal audit capability
IAM	identity and access management
IAS	Internal Audit Service
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICS	internal control standards
ICSR	individual case-safety report
ICT	information and communication technologies
IDMP	Identification of Medicinal Products
IFAH-Europe	International Federation for Animal Health Europe
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
IMI JU	Innovative Medicines Initiative Joint Undertaking
IPD	Individual patient data
IRM	Institute of Risk Management
ISERV	Infrastructure Services
ISO	International Organisation for Standardisation
ISO IDMP	international standards for the identification of medicinal products
ISO/DTS	Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances
IT	information technology
ITF	Innovation Task Force
IWG	inspectors working group
KPI	key performance indicator

Term / abbreviation	Definition
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MB	Management Board of the EMA
MDEG	Medical device expert group
MDM	master data management
MedDRA	Medical Dictionary for Regulatory Activities
Member State	Member State of the European Union
MHRA	Medicines and Healthcare products Regulatory Agency, UK
MLM	medical literature monitoring
MLWP	Monograph and list working party
MRL	maximum residue limit
MS	Member State of the European Union
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NGO	Non-governmental organisation
NTC	EU Network training centre
OECD	Organisation for Economic Cooperation and Development
OLAF	European Anti-Fraud Office
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PCO	patients'/consumers' organisation
PCWP	Patients' and Consumers' Working Party
PDB	Programme Design Board at the EMA
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIB	Programme Implementation Board at the EMA
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSMF	Pharmacovigilance System Master Files
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
OPPV	Qualified Persons for Pharmacovigilance
Q&A	questions and answers
QWP	Quality working party
RFI	request for information

Term / abbreviation	Definition
SA	scientific advice
SAG	Scientific Advisory Group
SAP	Systems, Applications & Products (budgetary system)
SAP FIN	finance module of SAP system
SC	secretary/clerk function group
SCOPE	'Strengthening Collaboration for Operating Pharmacovigilance in Europe' project
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SMART WS	signal management review technical work stream
SME	small and medium-sized enterprise
SmPC	summary of product characteristics
SNE	seconded national expert
SPOR	Substances, Products, Organisations, Referentials
SMQ	Standardised MedDRA Query
SOP	standard operating procedure
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
Strategy Board	Agency's Strategy Board
TA	temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TGA	Therapeutic Goods Administration, Australia
TIGRE	Team of International Global Rare Disease Experts initiative
UK	United Kingdom
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WG	working group
WHO	World Health Organization
WP	working party
WPx (x=1,2,3…)	work package