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Mid-year report 2016

January–June 2016

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 6 October 2016.

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Highlights

This report describes the results and achievements of the Agency, working closely with the national competent authorities (NCAs), during the first six months of 2016, and thus reflects the situation as of 30 June 2016. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

- **Scientific advice and protocol assistance requests** are on the same level as in 2015, and seem to have reached a plateau level. The expectation for the full year is hence adjusted to the same as 2015.
- **48 applications for PRIME** were received between the launch of the scheme on 7 March and 30 June. By the end of June, of the 26 applications assessed, 6 had been accepted in the scheme. The number of applications received is in line with EMA's expectations. As this scheme is still in its early days, the number of scientific advice requests related to PRIME this year is expected to be limited; the forecast has been adjusted accordingly.
- Following a considerable rise in **protocol assistance requests** in the first half of 2015, the number of requests was slightly lower in 2016.
- The number of **orphan designation applications** reached 164, an increase from 2015, yet this remains in line with expectations.
- Applications for **paediatric procedures** have increased in Q1-Q2 2016 compared to mid-year results from 2015, remaining in line with the expectations for 2016.
- There has been a high demand for **requests for ATMP classification**, reaching **40 requests** in Q1-Q2 2016, exceeding the initial forecasts. The annual forecast has been revised upwards to reflect this trend.
- **42 initial evaluation applications** were received in the first half of 2016 – slightly below the expectation for 2016, yet remaining at a similar level to 2015.
  - New **non-orphan medicinal product applications** saw a slight increase compared to 2015, while the **orphan product applications** remained on the same level as in 2015.
  - **Similar biological medicinal product applications** have remained at the same levels as 2015; the forecast for the year has been adjusted to a similar level to last year, i.e. to higher levels compared to previous years.
  - **Generic products** and **hybrid and abridged applications** have decreased slightly compared to the first half of 2015, yet the annual forecast remains unchanged for these applications.
- **37 MAA pre-submission meetings** were held during the first half of the year. These interactions are essential to facilitate validation and evaluation of applications, thus contributing to an efficient review processes.
- **Variations applications** remained at a similar, slightly increasing level compared to 2015. The annual forecasts for variations were revised upwards, to reflect this trend. **Type IA variations** received a slightly higher number of applications than expected in the first half of the year.

- The number of **pharmacovigilance referrals** received in the first six months of 2016 remained at the level of 2015's mid-year results, while **non-pharmacovigilance referrals** saw an increase, leading to a revised annual forecast.
- The number of **peer-reviewed and validated signals** is higher than expected for 2016, reaching 1,217 reviewed signals and 21 validated signals.
- The number of **PSURs received** (240) decreased compared to 2015, while **PSUSAs** received in Q1-Q2 2016 (129) exceeded the expectation. Annual forecasts have therefore been adjusted accordingly.
- **18 emerging safety issues** were received in the first half of 2016 – a similar result to the previous year.
- **282 products** were on the **list of products subject to additional monitoring** at the end of Q2 2016. Some new active substances/new biological active substances authorised in 2011 were removed from the list in accordance with the criteria established in the legislation (Article 23(3) of Regulation 726/2004).
- The number of **herbal monographs**, both new and revised, stayed at the same level as in previous years.
- **4 consultations** of SAGs/ ad-hoc expert groups **in the context of MAAs** and **7 consultations in the context of post-authorisation activities** were held in Q1-Q2 2016. Based on the results, the annual forecasts were revised downwards for MAA consultations, and upwards for post-authorisation consultations.
- The main **performance indicators** relating to assessment activities for human medicines have been met.
  - There was **no increase** in **scientific advice requests** in the first half of 2016. **25%** of the requests for scientific advice originated **from small and medium-sized enterprises**.
  - **54% of requests for accelerated assessment** were **granted** and **56% of the MAAs initiated under accelerated assessment** (AA) **were completed under the accelerated timetable** during the first half of 2016.
  - **Average clock-stop for new active substances and biosimilars** was 175 days in the first half of 2016.
  - **Average clock-stop for variations that include extension of indication** was 75 days, vs the expectation of 90 days.

Assessment activities for veterinary medicines

- **3 requests for Innovation Task Force briefings** for veterinary products were received in the first half of 2016.
- **Scientific advice requests** for veterinary medicines remained the same as in 2015 – slightly below the expectation for 2016.
- **11 requests for MUMS classification** were received in Q1-Q2 2016, slightly less than in 2015 but in line with the annual expectations.

- **Initial evaluation applications** saw a significant increase in the first half of the year, with 12 applications received (vs 3 in 2015 and 7 in 2014). The annual forecast has been increased to reflect this higher level of activity.
- **New MRL applications** and **MRL extension and modification applications** remained at the same level as in the previous years.
- **Variation applications** for veterinary medicines experienced a decrease in the first half of 2016, in line with the forecasts for the year and compared with the results in 2015.
- **Referral procedures** remained at the same level as in 2015, leading to a slightly decreased annual forecast.
- The number of **PSURs received** increased compared to previous years, exceeding also the expectation for the mid-year results. However, the annual forecast remains unchanged.
- The number of **adverse event reports** continues to increase, exceeding also the mid-year expectation for 2016 and reflecting the success of the measures implemented to promote AER reporting.
- The main **performance indicators** relating to assessment activities for veterinary medicines have been met.

Inspections and compliance

- The number of **GMP inspections** continues to increase, reaching 374 inspection requests in the first half of 2016. The annual forecast has been revised upwards to reflect this continued increase.
- Similarly, **GCP inspections** saw an increase in the first half of the year (56 requests vs 35 in 2015), leading also to an increased annual forecast.
- 3 **pharmacovigilance inspections** were requested in the first half of 2016, a significantly lower number than in 2015 and 2014.
- An **additional 31% of GCP inspections** were addressed through information exchange on inspections carried out by international partners. An **additional 8%** of **routine GMP re-inspections** of manufacturing sites were also addressed through information exchange with international partners.
- **No GLP inspections** were requested in Q1-Q2 2016.
- The number of **notifications of suspected quality defects** remained on the same level as in 2015. 36 **GMP non-compliance notifications** were received in the reporting period, exceeding the annual forecast and resulting in a revised forecast for the year.
- 2,042 **standard certificate requests** were received in the first half of 2016, exceeding the 2015 result and the expectation. The increase is due to the shift from urgent to standard certificates, and has led to an increased annual forecast. The **average time to issue a standard certificate** was **7.9 days**.
- As a result of the shift from urgent to standard certificates, a significant decrease was seen in the **urgent certificate** requests in the first half of 2016. **273 requests** were received by the end of Q2 2016 (39% decrease from 2015), and the annual forecast has been reduced to reflect the trend.

- The number of **parallel distribution initial notifications** continued to increase in the first six months of 2016, as did the **parallel distribution notifications of change**. Annual forecasts for both have been revised upwards.
- **2,202 parallel distribution annual updates** were received in Q1-Q2 2016, a slight increase from 2015. The annual forecast has also been revised upwards.
- The main **performance indicators** relating to inspections and compliance have been met.

Key achievements

- The scheme providing reinforced regulatory and scientific advice to priority medicines (PRIME products) was launched in March 2016 and discussions on SA for PRIME started in Q2 2016. In the first months after its launch, PRIME generated a lot of interest from medicine developers, particularly from SMEs. The number of applications received so far is in line with expectations. Draft guidance to applicants for the kick-off meeting was also prepared, to ensure that relevant scientific and regulatory aspects are addressed as part of this meeting. Kick-off meetings are expected to start in July 2016.
- A report on the pilot project on adaptive pathways was completed in June and was to be published in Q3 2016.
- The Agency provided scientific support to the evaluation of Truvada for PrEP indication in the first half of 2016. The final opinion is expected in July.
- A 2007-2015 report on the implementation of the Paediatric Regulation was drafted and sent to the European Commission in May 2016. An update with the data for 2016 will be provided at the end of the year.
- The process for early interaction on paediatric development was implemented in the first half of 2016. A pilot finished in June, with 30 applications received.
- Following the earlier analysis of the use and experience with conditional marketing authorisation and accelerated approval, a revised process for accelerated assessment was implemented in the first half of the year, and revised guidelines on conditional marketing authorisation and accelerated assessment were published in March. A report on 10 years of experience with the regulation on conditional marketing authorisation was initiated in the first half of 2016.
- The 'Early background' summary pilot, whereby background information from previous relevant evaluations is provided to rapporteurs and peer reviewers at day 10 of the procedure, continued in the first half of the year, receiving very positive feedback. The outcome of the pilot and the discussion to extend it to more MAAs will take place at the September CHMP meeting.
- A survey on the performance of and satisfaction with the initial marketing authorisation process from the industry and EMA/rapporteur perspectives was developed in the first half of the year and will be launched in September 2016.
- The conceptual framework on the Agency's interactions with EUnetHTA with regard to providing the CHMP assessment report at time of opinion, and particularly the establishment of a robust confidentiality framework under which such exchange can occur, was agreed with the EC in the first half of 2016 and was presented to the industry at EFPIA/EUnetHTA meeting in June.
- The PRAC strategy on measuring the impact of pharmacovigilance activities was adopted and published in January. A workshop with stakeholders will follow in December 2016.

- Preparations for the dry-run of public hearings took place in the first half of the year. The dry-run exercise is scheduled to take place during the PRAC meeting on 5 July.
- In preparation for the new requirements for marketing authorisation holders to monitor the EudraVigilance data for safety signals starting in 2017, the Agency is preparing guidance to support the business process for the receipt, prioritisation, assessment and action of such signals.
- With regard to priority areas for technologies that are new to veterinary medicine, the ADVENT group published for consultation three problem statements on the priority topics of stem cells and monoclonal antibodies. Two of these consultation periods finished in May and the last one will end in Q3.
- The EU Network Action plan to promote the availability of veterinary vaccines was developed in the first half of 2016.
- As part of preparations to upload data on national products into the common European database of veterinary medicinal products, bilateral meetings with eleven NCAs took place throughout the first half of 2016.
- The Agency continued providing support to the EC in relation to the discussions on new veterinary legislation in the first half of the year.
- The revised draft dmentia guideline was published for public consultation in February 2016. The consultation will end in July and, following review of the comments, the final guideline is expected to be released in 2017.
- Within the data-gathering initiative, the review of all fee-generating procedures, as well as major non-fee generating activities (PDCO, COMP, working parties), was launched during Q1 and Q2.
- A dedicated workshop to mark 10 years of the PCWP took place on 14 June 2016.
- A pilot study to explore the process to capture patient input on the value of evidence during benefit-risk evaluation was completed in June and an article on the study is expected to be published in Q3 2016.
- A workshop with a group of GPs was held in April and identified areas for mutually beneficial collaboration between GPs and EMA. The workshop led to the creation of an expert group of general practitioners who will act as facilitators and communicate to their broader communities.
- Following the 10-year report on the implementation of SME Regulation, the development of a 10-year action plan started in Q1-Q2 2016, and is expected to be completed before the end of the year.
- In order to raise awareness of the IGDRP data-sharing pilot among generic medicines applicants, the eligibility outcome letter was amended to include a statement on the data-sharing pilot.
- A study looking at stakeholder awareness, experience and views on the Article 58 procedure was published on the EMA website in April 2016.
- As part of the initiative to enhance involvement of non-EU regulators in EMA scientific reviews and facilitate work-sharing, the assessment report for a centralised product was shared with regulators in Israel, who also participated as observers in the May CHMP meeting during the discussion on the list of questions for the first time.
- Preparations for joint training activity with US FDA on data integrity took place in the first half of the year. The training is scheduled to take place in October and November, in China.

- As part of delivering information systems in accordance with the EU Telematics roadmap, the PSUR repository was delivered in the first half of 2016. Delivery of clinical trial systems and master data services are in development and broadly on track. EudraVigilance, and consequently the audit, are delayed by four months, as highlighted to the Management Board in their June meeting.
- Industry's participation in the EU Telematics at a strategic level was agreed in February 2016, with two meetings per year to take place with the pharmaceutical industry associations.
- The revised policy on competing interests for Management Board members that was adopted in December 2015 came into effect in May 2016.
- Guiding principles for the revision of the Management Board decision on the rules concerning the handling of declared interests for the Agency's staff were agreed at the Management Board meeting in March, and a revised decision was prepared for adoption at the October Management Board meeting.
- The EMA multiannual work programme, translating the Network strategy to 2020 into more specific medium-term objectives and key initiatives to deliver the objectives, was adopted by the Management Board on 16 June 2016.

Detailed mid-year report

Explanation of symbols used in this document

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

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

Linear patterns are assumed for workload indicators, and the mid-year forecast is assumed to be 50% of the annual forecast of the adopted 'Work programme 2015'. For performance indicators that are expressed as a percentage, the mid-year target is assumed to be equivalent to the annual target.

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

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 will be 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 might be used to reflect more accurately the significance of the change. For example, a number of applications falling from 1 to 0 (or vice versa) can be marked green rather than red (blue), if this is in line with regular variations.

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

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Scientific advice/protocol assistance pre-submission meetings	87	75	-	-	180	115	-65	-36%
Scientific advice and protocol assistance requests, of which:	287	291	275	237	546	510	-36	-7%
Parallel scientific advice with international regulators	2	2	1	3	6	4	-2	-33%
Joint scientific advice with HTA bodies	9	21	6	1	33	16	-17	-52%
Post-authorisation scientific advice	61	48	59	-[1]	115	90	-25	-22%
Scientific advice for PRIME products[2]	0	-	-	-	25	2	-23	-92%
Protocol assistance requests	59	82	-[3]	-	141	124	-17	-12%
Novel technologies qualification advice/opinions	8	7	-	-	25	15	-10	-40%
PRIME applications[2]	48	-	-	-	120	120	0	0%
Scientific advice finalised	203	199	-	-	393	385	-8	-2%
Protocol assistance finalised	61	86	-	-	178	122	-56	-31%
Orphan medicines applications, of which:	164	120	138	106	330	330	0	0%
Parallel orphan applications with international regulators	50	48	47	25	100	100	0	0%
Submitted applications on the amendment of an existing orphan designation	3	-	-	-	5	5	0	0%

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Oral explanations for orphan designation	38	-	-	-	90	90	0	0%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	265	229	234	215	500	500	0	0%
Finalised procedures for compliance check on PIPs	37	35	-	-	85	80	-5	-6%
Annual reports on paediatric deferred measures processed	84				170	170	0	0%
EMA paediatric decisions processed	175				350	350	0	0%
Requests for classification of ATMPs	40	13	13	12	25	60	+35	+140%
Innovation Task Force briefing-meeting requests	24	36	12	-	42	42	0	0%
Innovation Task Force Art 57 CHMP opinion requests	2	1	4	-	4	4	0	0%

[1] Since 2014, scientific advice and protocol assistance are split in pre-authorisation and post-authorisation.
[2] PRIME initiative was launched in March 2016.
[3] In previous years, reflected only in total number of scientific advice and protocol assistance; separate indicators introduced since 2015.

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	100%	100%[1]	99%[1]	99%[1]
Orphan designation opinions delivered within the legal timeframe	100%	99%	-[1]	-[1]	-[1]
PDCO opinions sent to applicants within legal timelines	100%	100%	-[1]	-[1]	-[1]
Increase in scientific-advice requests	10%	0%	6%	16%	-
SME requests for scientific advice (percentage of total SA requests)	30%	25%	34%	-	-

[1] In previous years, one combined performance, including scientific advice, protocol assistance, orphan designation and paediatric procedures, was reported.

Achievements

Objective	Activity	% complete	Achievements / results
Provide high-quality, efficient and consistent support to medicines development	Develop and implement best practices for significant benefit in protocol assistance letters	60%	COMP working group for protocol assistance was established in Q1 and regular monthly meetings have been held since March. A peer review system was implemented, whereby all protocol assistance reviewed by COMP has not only a coordinator but also a dedicated peer reviewer. A template for protocol assistance answer letters is being developed.
	Organise workshop for the Network and EMA on the definition of orphan condition	10%	In the first half of 2016, the date of the workshop was agreed (December 9), the steering group was set up and the topics for the agenda were collected.
	Revise collaboration between SAWP and SWP to focus it on the most relevant issues for expert input	10%	The activity is put on hold and will be reconsidered once the revision of EMA working parties is completed and the new operational model for the working parties is established.
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle	Draft recommendation documents/white papers and provide regulatory input to the methodology and outcomes of the selected four IMI GetReal Consortium case studies	80%	As part of IMI GetReal project, during Q1-Q2 2016, EMA provided input into the development of a glossary of real world evidence and real world navigator framework for decision making. Publication is expected in Q3, at the end of the project.
	Implement a collaboration framework with HTAs with regard to the maintenance of orphan status at the time of marketing authorisation application	0%	The activity will commence once Joint Action 3 has been defined.
Facilitate research and development of new medicinal products	Identify areas in need of further research and communicate them to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	10%	Processes regarding EMA involvement with externally funded regulatory science projects were agreed in the first half of 2016. Dialogue with DG Sante and the IMI office in Brussels was initiated with the aim of establishing a framework for interaction that helps better plan EMA resource allocation to Horizon 2020 funded projects, including IMI.
	Develop a triage process to increase effectiveness of selection	30%	In the first half of 2016, the EMA Management Board agreed

Objective	Activity	% complete	Achievements / results
	and coordination of EMA involvement in various research activities, including IMI		on the Agency's role and the criteria to feed into the triage process. An Executive Director's decision was prepared to reflect this.
	Develop business forecasting and analysis tools to enhance availability of information on prospective development of medicines	30%	A pilot to interrogate business pipeline intelligence, in order to identify opportunities for better signposting to guidance, develop or refine Q&A, highlight gaps in regulation where guidance may be useful, and other potential action items, was completed in the first half of the year. The analysis was presented to the EMA Medicines Leadership Team and the resulting actions are being implemented. Improvements and fine-tuning, based on the learnings and feedback will be implemented over the remainder of 2016 and 2017.
	Identify recurring questions in areas of highest potential benefit from science and innovation, and develop the relevant Q&A or regulatory guidance documents	30%	During the first half of 2016, recurring questions were identified and development of the relevant Q&A documents and guidance documents was started in the areas of regulatory affairs, labelling and international affairs.
	Develop and implement a scheme to provide reinforced regulatory and scientific advice to priority medicines from the early stages of development	100%	A reflection paper was finalised in the first half of the year, and supportive guidance and templates were launched in March 2016.
	Organise workshop on development of orphan medicinal products for academic researchers	100%	The workshop was successfully held in March.
	Support scientific committee discussions on PrEP (pre-exposure prophylaxis) to combat HIV infection	80%	The Agency provided scientific support to the evaluation of Truvada for PrEP indication in the first half of 2016, including peer reviews, labelling reviews and consultations with patient groups on the actual labelling and educational material. The final opinion is expected in July. Further reflection on the opportunity to further adjust the current draft reflection paper on PrEP will take place in the context of the IDWP activities in 2016.
	Strengthen collaboration and integration across the Network	95%	A draft mandate and work plan were prepared by the

Objective	Activity	% complete	Achievements / results
	and with academia to facilitate the translation of innovation into medicinal products, including through the work undertaken by the Innovation Network		European Innovation Network during the first half of this year. It is expected to be approved by EMA and HMA in September, once HMA comments are incorporated in the document.
	Organise workshops with key opinion leaders and innovators, and involving NCAs, to address specific areas for innovation	50%	One of two planned workshops was successfully organised with the oncology community in the first part of 2016. The follow-up work to ensure achievement of the desired impact, including guidance development on the basis of the findings and workshop discussions, is being carried out.
Support development and availability of medicines for specific target groups	Implement EMA geriatric medicines strategy	50%	The Quality Working Group continued drafting the quality guideline during the first half of the year. The EMA geriatrics group contributed to the drafting for clinical needs aspects of the document.
	Finalise the 10-year report to the Commission on the implementation of the Paediatric Regulation. Identify (2016) and implement (2017) activities to increase compliance and results	80%	The 2007-2015 report was drafted and sent to the EC in May 2016. As per the agreement with the Commission, an update with the data for 2016 will be provided at the end of the year.
	Provide recommendations to the Commission on priority areas for research in paediatrics, in line with the objectives outlined in the Horizon 2020 strategy	30%	The priority areas for research in paediatrics were discussed by the PDCO-COMP working group and some criteria were identified during the first half of the year. The Agency aims to publish the research areas in 2017.
	Develop with the FDA regulatory science approaches for paediatric diseases (including rare diseases), including finalisation of the joint guidance document for Gaucher disease, and formally implement TIGRE	50% 70%	Gaucher disease guidance document: FDA comments were received in the first half of the year. Changes in the agreement with FDA to address the comments received in the public consultation phase are expected to be discussed in September/October. TIGRE project: the scope of the project was redefined during the first half of 2016, as a result of which paediatric development in rare diseases will be addressed under the umbrella of the current paediatric cluster.
	Establish early interaction on paediatric development	90%	The process for early interaction on paediatric development

Objective	Activity	% complete	Achievements / results
			was implemented in the first half of 2016. A pilot finished in June, with 30 applications received. Discussions with FDA on potential expansion into bilateral early interaction are taking place.
	Conduct open regulatory sessions on Alzheimer's disease in academic settings, including a follow-up session at the ECNP congress	50%	An open session was agreed with ECNP as part of their conference in September 2016. The session structure, speakers (EMA, EFPIA and academia) and panel were agreed and communication with the regulatory network was organised in the first half of the year.
	Promote data-sharing from applicants with failed Alzheimer trials, in order to explore pitfalls and opportunities	80%	A series of meetings with the applicants was conducted in the first half of 2016 and an internal report was being prepared.
	Develop a regulatory framework for extrapolation across age groups, supporting informed and efficient drug development	100%	A reflection paper on extrapolation across age groups was published and a workshop with the relevant stakeholders was held.
Optimise use of existing regulatory framework for early access to medicinal products	Coordinate the review of the guideline on conditional marketing authorisation and update of existing guidance documents (Q&As) on conditional marketing authorisation	75%	The guideline on conditional marketing authorisation was adopted by the CHMP and published on the EMA website in March, along with PRIME, the accelerated assessment guideline and the new website for early access tools. Work on a report on 10 years of experience with the Conditional Marketing Authorisation Regulation started, and is expected to be finalised in Q3 2016.
	Review experience gained with the compassionate use procedure at the EU level and identify aspects to optimise use of this procedure through review of existing guidance	50%	In March, a presentation was given at STAMP on the experience with the compassionate use procedure at EU level. Follow-up discussions with Member States need to be organised to understand opportunities for optimising the procedure through the review of existing guidance.
	Provide technical support to the EC in relation to optimisation of the existing regulatory framework, including development and/or implementation of new or amended laws and regulations		The Agency provided close technical support to the revision of the Commission Communication on orphan medicinal products, including comments through public consultation in February. In addition, in April the Agency sent to the EC a proposal for

Objective	Activity	% complete	Achievements / results
			revision of the definition of similar medicinal products.
	Develop implementation strategy on companion diagnostics legislation and related guidance documents for industry	0%	Activity not started due to resource limitations.
	Conduct joint reviews and participate in other support activities with WHO and regulators from LMICs on regulatory aspects related to vaccines and treatments for neglected diseases	50%	In June 2016, EMA took part in the WHO meeting in relation to Zika virus R&D efforts and target product profile for vaccines for Zika virus. Additionally, the Agency contributed to the global forum on immunisation in Africa, in March, and also participated in the SAGE meeting in April and ad hoc meetings on a malaria vaccine.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	Hold early flexible brainstorming discussions with applicants and other stakeholders to explore adaptive ways to optimise development pathways and accelerated patients' access to medicines	95%	The platform for providing scientific advice for PRIME products was implemented in Q1-Q2 and discussions on SA for PRIME started in Q2 2016. A report on adaptive pathways was completed in June and will be published in Q3 2016.
	Reinforce early dialogue with HTAs through existing procedures and finalise guidance for parallel SA with HTAs	75%	The best practice guidance for parallel EMA-HTA scientific advice was published in the first half of the year. Further discussions on interactions within Joint Action 3 (JA3) are expected.
	Implement regulatory advice for promising medicines benefiting from the PRIME scheme from the early stages of development	90%	Draft guidance to applicants for the kick-off meeting was prepared, to ensure that relevant scientific and regulatory aspects are addressed as part of this meeting. Kick-off meetings are expected to start in July 2016, and the guidance will be finalised and adjusted based on the experience gained with these meetings.
	Lead and coordinate EMA's input into and engagement with HTA Joint Action 3	20%	During the first half of the year, EMA provided input into the setting of objectives and milestones of Joint Action 3, specifically with regard to the activities that are relevant for regulators and might facilitate regulator-HTA interactions (e.g. data and information sharing, joint scientific advice, etc).

Objective	Activity	% complete	Achievements / results
	Provide scientific leadership to the ADAPT-SMART project	33%	Successful workshops were held in the first half of the year, resulting in timely completion of the initial deliverables.

1.2. Initial evaluation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Number of MAA pre-submission meetings	37	-	-	-	50	50	0	0%
Initial evaluation applications, of which:	42	45	43	36	111	114	+3	+3%
New non-orphan medicinal products	18	14	20	24	46	44	-2	-4%
New orphan medicinal products	11	12	9	5	24	26	+2	+8%
Similar biological products	3	3	2	1	8	13	+5	+63%
Generic products, hybrid and abridged applications	10	16	11	5	31	30	-1	-3%
Scientific opinions for non-EU markets (Art 58)	0	0	1	0	1	0	-1	-100%
Paediatric-use marketing authorisations	0	0	0	1	1	1	0	0%
Number of clarification meetings during MAA evaluations	50	-	-	-	35	60	+25	+71%
Number of granted requests for accelerated assessment	7	-	-	-	18	15	-3	-17%
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	4	-	-	-	15	10	-5	-33%
Reviews on the maintenance of the orphan designation criteria at MAA stage	12[1]	-	-	-	35	28	-7	-20%

[1] Lower results due to change in criteria (based on applications reviewed by COMP instead of submitted orphan marketing authorisation applications).

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of applications evaluated within legal timeframes[1]	100%	100%	100%	100%	99%
Average assessment time for new active substances and biosimilars (days)	205	210	205	-	-
Average clock-stop for new active substances and biosimilars (days)	180	175	142	-	-
Labelling review of the English product information annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	90%	100%	-	-	-
Percentage of requests granted for accelerated assessment	70%	54%	-	-	-
Percentage of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	70%	56%	-	-	-
Percentage of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	75%	60%	77%	-	-

[1] Includes marketing authorisation and plasma master file applications.

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound and consistent scientific opinions to the EC	Consolidate use of patients' preferences in benefit-risk assessment for initial marketing authorisation applications	60%	A study on understanding and using patient preferences in benefit-risk assessment in patients with myeloma continued over the first half of the year. It is expected to be completed by Q3 2016.
	Discuss with HTA bodies the use of and experience with the effects tables, identifying improvement opportunities	0%	The activity is expected to commence in the second half of the year.
	Organise workshops to identify areas for improvement in the assessment reports and develop a toolkit for improvement of	90%	A workshop and follow-up subgroups were organised in the first half of the year. The updated benefit-risk assessment

Objective	Activity	% complete	Achievements / results
	quality, consistency and robustness of benefit-risk assessments		report template and guidance were published.
	Develop and implement a specific benefit-risk guidance document to support evaluation of biosimilar medicines	60%	Draft guidance for writing a benefit-risk assessment specific to biosimilar medicinal products was being adjusted on the new version of the template.
	Implement and monitor provision of early background summaries	60%	Regular calls for candidates for producing early background summaries have been implemented since the end of 2014. A survey on experience with the early background summaries and opportunities for improvement from the perspective of rapporteurs/assessors was conducted in the first half of the year. Reporting to the committees will start in July.
	Improve the tools (guidance, templates, databases) available to assessors and EMA staff supporting scientific evaluation activities of the committees	60%	The tools for assessors and EMA staff supporting scientific evaluation activities of the committees are regularly updated. In the first half of 2016, the updates included guidance on the RMP assessment process in the framework of initial marketing authorisations, modifications to the SOP/WINs, and the regular addition of knowledge-sharing bulletins to the repository.
	Review and optimise the conduct of pre-submission meetings to improve support for the later evaluation process	60%	Analysis of the experience with pre-submission meetings was conducted and presented at the industry stakeholder platform meeting in April. The feedback was presented to CHMP in May and the follow-up activities are being prepared.
	Develop guidance to ensure early availability of a core (overview) document to deliver high-quality assessment reports in the area of quality of medicines	100%	In the first part of the year, internal assessment report templates were implemented and are now being used as overview guidance. Quality office peer review and quality control processes were enhanced, to improve topic lead input and tracking.
	Streamline and strengthen the process for input by the Quality Working Party and other quality of medicines working groups to the relevant parts of assessment reports	40%	Internal templates for preparation of CHMP assessment reports for chemical and biological human medicines were prepared and implemented in the first half of 2016. Experience gained with the templates will contribute to the development

Objective	Activity	% complete	Achievements / results
			of overview guidance.
	Strengthen the support for clinical pharmacology aspects of centrally authorised products along their lifecycle, with a special focus on innovative medicines, including GMOs	50%	All clinical pharmacology peer reviews for centrally authorised products requested in the first half of the year have been performed. In addition, proactive and ad hoc clinical pharmacology support was provided for other products during their lifecycle.
	Coordinate and develop the capability of the Network in the area of new methodological approaches to clinical trials	20%	The Agency coordinated and participated in the discussions between statisticians of the Network on the methodology approaches for clinical trial design and analysis (e.g. in paediatric development and single-arm trials in oncology).
Ensure and run highly effective and efficient processes to deliver initial evaluation activities	Implement (2016) and optimise (2017) a process performance management system, with strong customer focus on quality, simplification and regulatory procedural excellence	40%	A process performance tool for tracking agreed KPIs for marketing authorisation applications was developed in Q1 through business intelligence, using SIAMED data. Technical improvements to the tool are being implemented. Results of the KPI monitoring will be used to assess the appropriateness of the KPIs in 2017.
	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency	50%	Internal procedural training for marketing authorisation applications was delivered in Q1-Q2 2016. A knowledge-sharing system based on interesting cases identified during process review meetings is being developed to ensure continuous training. Implications from such cases for external guidance are systematically being considered. An IT knowledge-sharing tool in JIRA is being developed to support the management of the cases.
	Establish an internal system of knowledge-sharing with the aim of providing consistent regulatory advice to NCAs and MAHs	50%	An internal pre-submission query service was established in Q1-Q2 and will be launched in Q3, to ensure accuracy and consistency of support provided to the procedure managers. The IT support through JIRA is in development as part of the knowledge-sharing tool.
	Identify improvement opportunities and optimise regulatory	50%	During the first half of 2016, a revised process for accelerated

Objective	Activity	% complete	Achievements / results
	procedures supporting initial evaluation		assessment was developed and implemented. A revised process for EPAR preparation for initial MAAs was also finalised. The early background summary pilot, whereby background information from previous relevant evaluations is provided to rapporteurs and peer reviewers at Day 10 of the procedure, continued in the first half of the year, receiving very positive feedback. The outcome of the pilot and the discussion to extend it to more MAAs will take place at the September CHMP. A tri-partite survey with industry rapporteurs and EMA has been prepared, to define the level of satisfaction with the current process for initial MAAs and identify further improvement opportunities. The survey will start in September 2016 and will last for six months.
	Develop and implement a complexity-based approach to handling generic product applications	50%	As part of redesigning the generic product marketing authorisation application process, roles and responsibilities within the product team were agreed in the first half of the year. It was also agreed that the risk-management plan process for generics would not require PRAC plenary discussion in the first phase. Workflow simplification that was agreed in Q1-Q2 will be implemented in Q3 2016.
	Develop regular interactions with industry focusing on the centralised procedure, and engage with industry in optimising the operation of evaluation activities	60%	The third meeting of the industry stakeholder platform on the centralised procedure for medicines took place in April. A survey on the performance and satisfaction of the initial marketing authorisation process from both the industry and EMA/rapporteur side was developed in the first half of the year and presented at the platform meeting. The survey will be launched in September 2016 und will run for six months.
Provide high-quality,	Develop and maintain guidance and other tools (training	50%	In June, the Agency, together with MHRA, organised the first

Objective	Activity	% complete	Achievements / results
robust, scientifically sound and consistent product information	material, checklist, metrics or labelling review guide) supporting SmPC review		of two training sessions for EMA staff on aspects related to the handling of labelling/package leaflet from the perspective of a national competent authority (NCA). The aim was to give an insight into aspects of labelling review to support safe and effective use of medicines from an NCA's point of view. In addition, five SmPC advisory group Q&As were produced, covering aspects of interpretation of the SmPC guideline, and three webinars were organised in the first half of the year: - on general principles and readability of SmPC; - on a CHMP reflection paper on the wording of the therapeutic indication in the centralised procedure; - on SmPC information in subpopulations, from data to labelling.
	Develop tools for improved oversight of labelling development during the lifecycle, supporting consistent and evidence-based reviews	0%	The activity has been postponed.
	Monitor implementation of the new labelling review process to ensure scientific committees' labelling review is based on evidence from the scientific review	100%	A report on implementation of the new labelling review for new MAAs and renewals during June 2015 to June 2016 was prepared and shows high uptake of EMA labelling comments by both the assessors and applicants.
	Update the internal reflection paper describing elements to consider when assessing the 'therapeutic indication'	100%	The reflection paper was finalised and endorsed by the CHMP in February 2016. A pilot to verify suitability and appropriateness of the reflection paper to guide finalisation of indication wording started in May and will continue until May 2017.
	Analyse external requests regarding the contents of approved SmPCs and provide consistent responses	0%	No external requests were received in the first half of 2016.
	Review the use of patient-reported outcomes in approved SmPCs and develop guidance, based on the outcomes of the review	80%	The first phase of the review was completed in Q1-Q2 2016 and an inventory of patient-reported outcomes was set up. 124 oncology centrally approved products that were

Objective	Activity	% complete	Achievements / results
			authorised between 2005 and 2015 were analysed and patient-reported outcome statements were extracted.
	Provide technical and scientific support to the review of safety concerns of excipients and their appropriate labelling	70%	Most of the excipients have been reviewed according to the workplan. The review of some (ethanol and polyethylene glycol (PEG)) is delayed due to availability of experts and/or additional difficulty in agreeing on the final wording. Lack of availability of experts and workload may also cause delays in the review of new excipients.
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	Analyse application of accelerated assessment, including acceptance outcomes and reasons for changing from accelerated to standard review	60%	Regular monitoring of accelerated assessment is conducted and an annual report, including analysis of the application, acceptance outcomes and reasons for changing will be prepared.
	Develop and implement a framework to provide CHMP assessment reports to HTA bodies	60%	Agreement on the conceptual framework was achieved in the first half of 2016.
	Support activities stemming from Joint Action 3 to facilitate the provision of relevant information from regulatory assessments to HTA bodies for relative effectiveness assessments	40%	A conceptual framework for the Agency's interactions with EUnetHTA with regard to providing the CHMP assessment report at time of opinion, and particularly the establishment of a robust confidentiality framework under which such exchange can occur, was agreed with the EC in the first half of 2016 and presented to industry at the EFPIA/EUnetHTA meeting in June. The Agency is aiming to enter into these agreements with HTA bodies in the second half of 2016 and for this purpose is preparing a request to EUnetHTA to identify those HTA bodies with whom such agreement is needed, as these bodies will be participating in EUnetHTA's work.
Improve knowledge on the risks of medicinal products' use for the environment	Revise the Safety Working Party guideline on environmental risk assessment for human medicinal products	10%	The revision of the guideline started in 2016 and the concept paper was published, as planned. The review of the guideline will continue over the next few years.

1.3. Post-authorisation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast			
					Initial	Revised	Change	
Variation applications, of which:	3,041	2,941	2,553	2,675	5,555	6,011	+456	+8%
Type IA variations	1,578	1,483	1,253	1,480	2,665	2,757	+92	+3%
Type IB variations	968	896	805	817	1,913	2,051	+138	+7%
Type II variations	495	562	485	370	977	1,203	+226	+23%
Line extensions of marketing authorisations	11	8	10	8	20	20	0	0%
PASS scientific advice through SAWP	2	-	-	-	30	5	-25	-83%
Number of consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	7	-	-	-	5	12	+7	+140%
Renewal applications	43	-	-	-	85	66	-19	-22%
Annual reassessment applications	7	-	-	-	26	25	-1	-4%
Transfer of marketing authorisation applications	8	-	-	-	25	41	+16	+64%
Article 61(3) applications	102	-	-	-	190	190	0	0%
Post-authorisation measure data submissions	490	-	-	-	900	900	0	0%
Plasma master file annual update and variation applications	10	-	-	-	20	17	-3	-15%

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of post-authorisation applications evaluated within legal timeframes	100%	99%	100%	100%	100%
Average assessment time for variations that include extension of indication	180	169			
Average clock-stop for variations that include extension of indication	90	75			
Percentage of submitted risk-management plans peer-reviewed by the Agency as part of the extension of indication and line extensions	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, efficient and consistent scientific assessment of post-authorisation changes to marketing authorisations	Explore opportunities for peer review in later phases of the MAA review process and in case of substantial changes to the marketing authorisation	40%	In the first half of the year, agreement was reached to conduct this work and CHMP members to participate were identified. A workshop with CHMP members was being prepared and is planned to take place in July.
	Streamline and coordinate the clinical pharmacology support to centrally authorised products throughout their lifecycle	50%	The process for review of assessment reports was streamlined in the first part of the year, with extraction of the relevant information in a dedicated template leading to more efficient screening of the issues. Following previous staff training on clinical pharmacology conducted in 2015, the proportion of EPL requests for peer review support vs proactive support in clinical pharmacology has increased as compared to 2015.
	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency	50%	Internal procedural training for post-authorisation procedures was delivered to all Agency staff in procedure management in Q1-Q2 2016. A knowledge-sharing system based on interesting cases identified during process-review meetings is

Objective	Activity	% complete	Achievements / results
			being established to ensure continuous training. Implications from such cases for external guidance are systematically being considered. An IT knowledge-sharing tool in JIRA is being developed to support the management of the cases.
	Develop a process for monitoring the fulfilment of specific obligations for conditional marketing authorisations to ensure timely switch to full marketing authorisation	40%	A 'track and chase' process was developed to establish an active monitoring system that allows the Agency to act in case of an outstanding obligation from the MAH. A SIAMED dashboard based on the track and chase implementation was also developed to monitor and improve compliance (Jan-Dec 2015: 100% compliance (96 obligations); Jan–May 2016: 100% compliance (48 obligations)). In May 2016, an update on compliance in 2016 and a demonstration of the tool used was provided.
	Establish an internal system for knowledge-sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs	50%	An internal pre-submission query service was established in Q1-Q2 and will be launched in Q3, to ensure accuracy and consistency of support provided to the procedure managers. The IT support through JIRA is in development as part of the knowledge-sharing tool.
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)	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indications	0%	Activity not started due to resource limitations.
	Implement a procedure for non-imposed PASS through the SAWP and finalise the guideline on PAES	50%	Scientific guidance on PAES was published for comments in the first half of the year. A Q&A document on procedural and regulatory guidance was also finalised and published in the first half of 2016. Non-imposed PASS through the SAWP have had very limited uptake since their establishment.

Objective	Activity	% complete	Achievements / results
Improve the knowledge of the impact of medicines' use on the environment	Implement a framework to monitor implementation of imposed PAES	20%	The advisory group on classification of post-authorisation studies (CPAS) was established in February 2016 to provide guidance on post-authorisation studies imposed on marketing authorisation holders. This group supports product teams in the context of evaluation activities by advising on classification and objectives of such studies, and allows for capacity-building and oversight. Development of metrics started in June 2016.
	Implement (2016) and optimise (2017) a process-performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	40%	A process-performance tool for tracking agreed KPIs for post-authorisation applications involving CAPs was developed in Q1 through business intelligence, using SIAMED data. Technical improvements to the tool are being implemented. Results of the KPI monitoring will be used to assess the appropriateness of the KPIs in 2017.
	Conduct surveys and meetings with NCAs to capture their satisfaction level and improvement opportunities in handling procedures for CAPs and NAPs	0%	The activity is scheduled to start in September.

1.4. Referrals

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	4	3	13[1]	25	8	8	0	0%
Non-pharmacovigilance referrals started	8	4	-[2]	-	8	12	+4	+50%

[1] Lower numbers than before due to change in legislation and accounting/grouping of products in the procedures.
[2] Separation between pharmacovigilance and non-pharmacovigilance referrals introduced in the work programme only in 2015. For previous years, all referrals counted under a single entry.

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide high-quality, robust, scientifically sound and consistent scientific assessments of referrals	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency	75%	In Q1-Q2 2016, internal guidance (WINs, templates, lessons learned, etc.) were developed and internal training was given to EMA staff involved in managing referral procedures, with the aim of increasing the effectiveness, quality and regulatory excellence of the referral process. Knowledge-sharing through a 'buddy' system was implemented and is expected to move to fully functional tier meetings in the second half of the year. Process optimisations were completed and new and improved guidance (Q&As) was published to ensure regulatory procedural consistency for marketing authorisation holders. Further process improvements and simplifications will take place in the second part of 2016.
Ensure and run highly effective and efficient processes to deliver assessment of referrals	Implement (2016) and optimise (2017) a process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	30%	A first set of KPIs were defined in Q1-Q2 and are currently being tracked via Excel. A dashboard is expected to be developed as part of a SIAMED upgrade.
	Conduct surveys and meetings with NCAs to capture satisfaction levels and improvement opportunities in handling procedures for CAPs and NAPs	0%	The activity is scheduled to start in September.

1.5. Pharmacovigilance activities

Workload indicators

Procedure		2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast			
						Initial	Revised	Change	
	Number of signals peer-reviewed by EMA	1,217	1,354	1,095	1,400	1,800	1,800	0	0%
	Number of signals validated by EMA	21	29	11	22	35	35	0	0%
	PSURs (standalone CAPs only) started	240	275	302	256	566	475	-91	-16%
	PSUSAs started	129	115	-	-	210	266	+56	+27%
	Number of imposed PASS protocol procedures started	10	13	21[1]	-	40	20	-20	-50%
	Number of imposed PASS result procedures started	1		-	-	20	8	-12	-60%
	Number of emerging safety issues received	18	19	-	-	35	35	0	0%
	Number of notifications of withdrawn products received	102	83	-	-	165	175	10	6%
	Cumulative number of products on the list of products to be subject to additional monitoring	282	231	-	-	321	300	-21	-7%
	Number of incident-management plans triggered	5				4	9	+5	125%
	Number of non-urgent information (NUI) or rapid alert (RA) notifications submitted through EPITT	25				64	55	-9	-14%
	Number of external requests for EV analyses	24				60	50	-10	-17%
	Number of MLM ICSRs created	3,826				5,800	7,000	+1,200	+21%

[1] New procedures established in 2014.

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%			
Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	95%	100%			
Percentage of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%	100%
Percentage of reaction monitoring reports supplied to the lead Member State monthly	100%	100%	100%	100%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%			

Achievements

Objective	Activity	% complete	Achievements / results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes and services	Coordinate collection and analysis of data to measure pharmacovigilance impact	100%	The PRAC strategy on measuring the impact of pharmacovigilance activities was adopted during the January PRAC meeting and published on 15/01/2016.
	Finalise the update of the GVP module V on risk-management systems and the revision of the marketing authorisation holders' template for risk-management plans	60%	Public consultation of the GVP module V on risk-management systems and the revised MAH template for risk-management plans was completed in the first half of the year. Both the GVP module and the template are expected to be finalised in Q4 2016.
	Draft and implement GVP on pregnancy, to enhance drug safety in pregnancy considerations throughout a product's lifecycle	30%	Monthly teleconferences with the drafting group have been held in the first half of the year, each time discussing a particular topic of the GVP. The topic of 'long-term pregnancy outcomes' has been agreed for inclusion in the GVP and a workshop will be organised in December to progress with this

Objective	Activity	% complete	Achievements / results
			topic of the GVP module.
	Conduct public consultation on the GVP module on biological medicines and on updates for ADR reporting and signal management	90%	A draft of chapter P.II of the GVP module on biological medicines was discussed at the Biologicals Working Party in May and at the PRAC in June. It is expected to be published by Q3 2016. Other modules on ADR reporting and signal management are being finalised for public consultation in Q3 2016.
	Finalise draft proposals on governance and code of conduct for vaccine benefit-risk studies from the ADVANCE project	100%	In the first half of 2016, draft documents on governance and code of conduct for vaccine benefit-risk studies were finalised for consultation, in collaboration with the ADVANCE consortium. The governance and code of conduct will be included in the good practice guide (deadline September 2016), and the publication of the code of conduct is expected before the end of 2016.
	Develop and integrate a sustainable process to collect information on clinical use, based on the experience gained and on collaboration with NCAs and academics	85%	Draft results of the codeine pilot study were discussed in June 2016 and the final public results are expected in Q4 2016.
	Organise a follow-up workshop on medication errors (2016). Revise as necessary the guidance and Q&As on medication errors (2016-2017)	25%	EudraVigilance analysis on medication errors was initiated in Q1-Q2 2016, to support a decision on the need for a revision of the guidance and Q&As on medication errors. A DIA info day on medication errors will be held on 20 October 2016.
	Conduct a dry run and implement public hearings in PRAC	50%	Preparations for the dry run of public hearings took place in the first half of the year. The dry-run exercise is scheduled to take place during the PRAC meeting on 5 July.
Maximise benefits to public-health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and	Finalise and publish revised guidance for signal detection methods	70%	The GVP module M IX Rev 1 on signal management, including its addendum, was drafted in the first half of the year, and the public consultation is expected to start in Q3 2016.
	Organise a second workshop with stakeholders to review interim WebRADR project deliverables and obtain feedback on recommendations of the draft policy on the use of social media	50%	Within the IMI Web-RADR project, preparation of the final draft report on use of social media and other tools taking into account various analyses conducted in 2015 continued in the

Objective	Activity	% complete	Achievements / results
pharmacovigilance decision-making through use of high-quality data, information and knowledge	and other tools in ADR reporting		first half of 2016. The final draft report will be discussed during the IMI Web-RADR workshop on 19 October.
	Finalise operational aspects for the registries strategy, to support decision-making	25%	Discussions with industry and registries managers are being held during the pilot phase, enabling the preparation of the draft recommendations for supporting patient registries. The draft recommendations will be discussed at the registries workshop on 28 October 2016 and is foreseen for publication in 2017.
	Finalise (2016) and implement (2017) a proposal for an integrated system for management of notifications and alerts	25%	Analysis of the options for an integrated webpage to signpost for management of notifications and alerts continued in the first half of 2016.
	Develop (2016) and implement and manage (2017) a new process for reception, prioritisation, assessment and action of signals detected by MAHs	50%	Work started on drafting the business process for receipt, prioritisation, assessment and action of signals detected by marketing authorisation holders. The draft process is expected to be finalised in early 2017.
Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners	Publish annual reports on EudraVigilance	100%	The 2015 EudraVigilance annual report was published in March 2016.
Provide high-quality, robust, scientifically sound and consistent post-authorisation scientific assessments	Implement improved scientific support to imposed and non-imposed PASS protocol review	40%	The review of the process for PASS protocol review was begun, to identify improvement opportunities, and drafting of a scientific guidance document began in the first half of 2016. These are expected to be completed in Q3 2016.
	Develop guidance on PASS and complete reflection on the use of registries for regulatory purposes	50%	Consultation on GVP module VIII on PASS was finalised in late 2015, and the revised final guidance will be published in Q3. The pilot phase of the patient registries continued in Q1-Q2 2016. The results of this, together with the workshop on registries (scheduled for 28 October 2016) will form the basis for a reflection paper on the use of registries for regulatory

Objective	Activity	% complete	Achievements / results
			purposes.

1.6. Other specialised areas and activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Herbal monographs, new[1]	6	6	7	4	10	10	0	0%
Herbal monographs, revised	3	1	3	4	15	10	-5	-33%
List entries	2	0	0	0	1	2	+1	+100%

[1] Where assessment does not lead to the establishment of a monograph, a public statement is prepared.

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
n/a					

Achievements

Objective	Activity	% complete	Achievements / results
Implement the new Clinical Trials Regulation	Review existing and prepare new procedures and guidance documents supporting full implementation of the Clinical Trial	50%	A document on risk-proportionate approaches in clinical trials was developed and launched for public consultation by the

Objective	Activity	% complete	Achievements / results
(EU) No 536/2014	Regulation		Commission in June. Detailed draft guidelines on good clinical practice specific to advanced therapy medicinal products were prepared and are undergoing internal consultation. Further guidance and recommendations on the content of the trial master file and archiving were prepared and will be released for public consultation in the second half of the year. Various guidance documents on serious breaches and inspection-related procedures were also prepared in the first half of 2016. In addition, 12 procedures of Eudralex Volume 10, chapter IV – inspections are being revised.
Support a high level of coordinated cross-European preparedness to act on public-health threats	Interact with ECDC and VE to develop a new platform for influenza vaccines effectiveness	40%	In the first half of the year, EMA gave a presentation at the I-MOVE meeting on the Agency's perspective on public-private partnership for vaccines effectiveness studies and held meetings with the EC C3 and ECDC on the Agency's position regarding such partnerships and how studies could be conducted.
	Continue discussion with ECDC and EC on development of a sustainable framework for vaccines benefit-risk monitoring in the EU	10%	Interactions with the EC have been limited due to their current difficulty in proceeding with this topic. However, the topic has been added to the list of potential activities in a draft EC document on vaccine policies.
	Deliver the pandemic-plan revision, transforming the previous pandemic influenza preparedness plan into a wider-ranging preparedness for emerging health threats	-	-
	Develop a revised policy for dealing with emerging health threats (2016) and issue specific working procedures, in accordance with the new structure and plan (2016-2017)	90%	The revision of the pandemic plan continued and was reaching completion in the first half of 2016. A few additional aspects relating to SOPs and refinement of roles and responsibilities will be addressed in the second half of the year.
Facilitate development of	Organise workshops or discussions with interested parties (e.g.	70%	In April, a draft addendum to the note for guidance on

Objective	Activity	% complete	Achievements / results
new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	CPTR and IMI PREDICT-TB) to obtain the latest scientific input for revision of the guideline for developing medicines for tuberculosis		evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to mycobacterium tuberculosis was agreed by the Infectious Diseases Working Party. The Agency contributed to the WHO meeting for the definition of target regimens for tuberculosis. Preparations for the workshop (scheduled for November) started in the first half of the year.
	Provide scientific support to writing a new guideline on paediatric aspects of new antibiotics and to revision of SmPCs for already approved antibiotics	20%	A concept paper was adopted in the first half of the year and was released for consultation.
Facilitate availability of herbal medicines in the European Union	Compile an overview of herbal substances/preparations from non-European traditions, related to pharmacopoeia, as tools to identify candidates for future EU herbal monographs	30%	A list for ayurvedic herbal substances and a discussion paper for HMPC were drafted by a rapporteur in the first half of the year.
Contribute to minimising the need for animal testing of human medicinal products	Improve the guidance on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches	80%	Drafting of the guideline continued in Q1-Q2. Some final aspects are expected to be addressed at the next JEG 3Rs meeting.
	Engage with scientific advances in experimental models to refine or replace in vivo animal studies	0%	Involvement of scientific stakeholders is planned in the second half of the year.
Effectively manage risks to the environment arising from the use of human and veterinary medicines	Provide technical support to the European Commission as part of the development of a Commission strategy for managing risks to the environment related to the use of medicines (both human and veterinary)	50%	All requests received from the EC in the first half of the year were addressed. Engagement in the development of the EC strategy has been minimal, as this is not yet mature.
Promote the application of harmonised international standards	Provide technical and scientific contribution to the development of an addendum to the ICH statistical principles guideline E9 and of an addendum to the ICH Paediatrics guideline E11, relating to the design and analysis of clinical trials	40%	In February 2016, the Agency organised and contributed to an EMA/Biostatistics Working Party workshop on estimands, to discuss the concept of estimand and its impact on regulatory assessment.

Objective	Activity	% complete	Achievements / results
			In May, the Agency organised an EMA workshop and participated in an FDA workshop on the framework of extrapolation of efficacy from adult to paediatric populations. In addition, the Agency participated in the ICH expert working group and contributed to development and drafting of the E9 addendum.
	Provide technical and scientific contribution to the development of ICH safety guidelines (carcinogenicity assessment document evaluation for ICH S9)	40%	Over the first half of the year, the Agency organised and contributed to the monthly teleconferences, as well as contributed to the ICH meeting in June to advance drafting of the E9 addendum.

2. Evaluation activities for veterinary medicines

2.1. Pre-authorisation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	3	2	1[1]	-	4	4	0	0%
Scientific advice requests received	8	10	11	19	30	20	-10	-33%
Requests for classification as MUMS/limited market	11	14	9	13	25	25	0	0%

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

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Provide support and incentives to development of new medicines for MUMS/limited markets	Publish annual report on MUMS/limited markets activities	100%	The 6th annual report on veterinary MUMs/limited markets was adopted by the EMA Management Board at its March meeting, and was subsequently published on the Agency's website.
	Finalise review of the MUMS/limited markets guidelines	50%	Draft revised guidelines on data requirements for veterinary medicinal products intended for MUMS/limited market (quality, safety, efficacy, immunologicals) were adopted in January

Objective	Activity	% complete	Achievements / results
			2016 for consultation until July 2016.
Promote innovation and use of new approaches in the development of veterinary medicines	Promote access the Agency's Innovation Task Force through presentations to industry and as part of existing pre-authorisation procedures	50%	The Innovation Task Force (ITF) was presented at several events involving industry, such as the EMA/IFAH Europe info day in March 2016. ITF was also continuously promoted on a bilateral basis in pre-submission meetings and in response to individual queries.
	Evaluate the impact of measures recently put in place to support innovation (ADVENT, ITF) and plan improvements in measures to support innovation	50%	Analysis of existing pre-authorisation procedures was conducted during Q1-Q2 2016, with the aim of providing recommendations for additional support, if such need is identified. The report on implementation of measures in place to support access will be prepared in the second half of the year.
	Develop regulatory guidance in priority areas for technologies that are new to veterinary medicine (including cell-based therapies, monoclonal antibodies for veterinary use)	50%	ADVENT has published for consultation three problem statements on the priority topics of stem cells and monoclonal antibodies. Two of these consultations finished in May and the last one will end in Q3. Following this, the topic groups will develop answers to the comments on the problem statements.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	Analyse the outcomes of the survey on recipients' views regarding the usefulness and quality of the scientific advice received, and decide on the potential for improvement	0%	The activity is to begin in Q3 2016.
	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice	50%	Parallel scientific advice with FDA has been actively promoted in early contacts, business meetings with companies, pre-submission meetings and ITF meetings. Analysis of the existing pre-authorisation procedures was being conducted during Q1-Q2 2016, and may include recommendations concerning parallel scientific advice.
Support development and availability of veterinary medicines	Identify (2016) and implement (2016-2020) the EMA's contribution to the EU Network Strategy to 2020 in the area of promoting availability of vaccines within the EU, with particular emphasis on vaccines against transboundary diseases and	50%	A Network action plan on availability of veterinary vaccines was developed in the first half of 2016. The mandates of the HMA steering group and ad hoc CVMP group of experts were adopted in Q1 and Q2, respectively.

Objective	Activity	% complete	Achievements / results
	diseases with limited markets		Impact analysis of measures proposed by industry for promoting the availability of vaccines was started by the HMA steering group in the first half of the year. It is expected to be presented to HMA in September and to industry thereafter.

2.2. Initial evaluation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Initial evaluation applications	12	3	7	11	18	28	+10	+56%
New MRL applications	3	2	3	3	2	5	+3	+150%
MRL extension and modification applications	0	1	1	3	2	1	-1	-50%
MRL extrapolations	0	0	2	0	1	1	0	0%
Art 10, Biocides	0	0	0	0	2	2	0	0%
Review of draft Codex MRLs	0	0	0	0	5	7	+2	+40%

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of procedures completed within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements / results
Provide high-quality and consistent scientific opinions to EC	Finalise development (2016) and promote uptake (2016-2017) of the revised guideline, procedures and templates for CVMP assessment reports	50%	The guideline and templates for pharmaceutical products that were adopted by the CVMP in December 2015 were implemented in SIAMED templates in the first half of 2016. Training on the use of these is to take place in 2016. Development of a guideline and templates for immunological products also started in the first half of the year.
Ensure the establishment of MRLs supports the safe use of veterinary medicines with regard to their impact on human health	Provide technical support to the European Commission in drafting the implementing acts specified in Regulation (EC) No 470/2009	50%	Technical support on three draft implementing measures prepared by the Commission based on CVMP recommendations continued in the first half of 2016, including participation at a Standing Committee meeting in Q2 2016. These three (out of four) implementing measures are to be released for public consultation by EC. The Agency expects to participate in another Standing Committee meeting for adoption of the implementing measures in Q4. Preparation of the fourth implementing measure (methodological principles for risk-assessment and risk-management in the establishment of MRLs) was initiated in Q1 2016, with the aim of submitting the recommendation to the EC by December.
	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products	50%	A draft guideline on limits for genotoxic impurities in veterinary medicinal products was prepared in Q2 2016 and submitted for consultation to the QWP and EWP. Comments are expected by Q4 2016, and, following the revision of the comments, the guideline is expected to be finalised by SWP-vet and CVMP in 2017.
	Finalise, in collaboration with ECHA and EC, the procedure for the establishment of MRLs for biocidal substances used in animal husbandry included in the 10-year review programme	0%	The European Commission has initiated a review of the procedure for the establishment of MRLs for biocides, with a particular focus on the workshare between EMA and ECHA

Objective	Activity	% complete	Achievements / results
	(long-used substances)		within the procedure. The discussions with the EC continue on how this procedure would be shared and performed by EMA and ECHA.

2.3. Post-authorisation activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Variations applications, of which:	132	215	146	105	350	350	0	0%
Type IA variations	80	115	72	44	180	180	0	0%
Type IB variations	40	72	54	46	125	125	0	0%
Type II variations	12	28	20	15	45	45	0	0%
Line extensions of marketing authorisations	2	2	2	3	5	3	-2	-40%

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements / results
Ensure efficient delivery of post-authorisation procedures	Start a review of post-authorisation procedures other than variations, and introduce necessary improvements	50%	The review of post-authorisation procedures has been incorporated in the veterinary change programme and will be carried out within this project. SOPs on processing type-IB variations and annual reassessments were reviewed in the first half of the year. Three other SOPs (on type-IA applications, renewals and veterinary applications) have been published for consultation.

2.4. Referrals

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated[1]	4	3	4	9	10	8	-2	-20%

[1] 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

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Facilitate prudent and responsible use of antimicrobials and other classes of products	Engage with the EC and Member States to identify and, where possible, prioritise referrals of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues	50%	In the first half of 2016, the CVMP updated its joint advice with the CHMP on the use of colistin in veterinary medicine; the publication is expected in July. Four of the 6 procedures started in the first half of 2016 were triggered in the interest of the Community regarding antimicrobials (i.e. gentamicin, zinc oxide, tylosin and girolan).

2.5. Pharmacovigilance activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	88	73	80	80	150	150	0	0%
Total adverse-event reports, of which:	19,168	15,383	13,000	10,139	29,400	29,400	0	0%
Adverse-event reports (AERs) for CAPs	9,230	6,949	5,282	3,731	13,000	13,000	0	0%

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of PSURs evaluated within the established timelines	90%	95%	99%	97%	97%
Percentage of AERs for CAPs monitored within the established timelines	95%	98%	94%	97%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes	Develop an approach to systematically ensure quality-control and data verification of product data in the common European database of veterinary medicinal products, and link these data to adverse event information related to CAPs and non-CAPs in the EudraVigilance Veterinary data warehouse to allow signal detection in preparation for the new veterinary legislation	20%	Bilateral meetings with eleven NCAs took place throughout the first half of 2016, to prepare for uploading of data on national products into the common European database of veterinary medicinal products.
	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	25%	Planning and preparations for the focus group meeting where experts, industry and veterinarians will discuss the reasons for under-reporting AERs of veterinary medicinal products were done in Q1. The meeting is scheduled for Q4 2016 and the reflection paper will be revised following this meeting.
	Revise the surveillance strategy for centrally authorised products to link signal-detection and PSURs, and ensure better use of pharmacovigilance resources	0%	The Pharmacovigilance Working Party has decided to postpone further work until the new veterinary legislation is adopted.
Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners	Publish the veterinary pharmacovigilance annual bulletin	100%	The veterinary pharmacovigilance bulletin 2015 was published in February 2016.

2.6. Other specialised areas and activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast			
					Initial	Revised	Change	
n/a								

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
n/a					

Achievements

Objective	Activity	% complete	Achievements/results
Support increased availability of veterinary medicines	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation	50%	In the first half of 2016, EMA provided technical advice to the EC during the Council Working Party discussions on new veterinary legislation.
Promote uptake of harmonised standards at international level	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	100%	In June, the Agency co-chaired the 7th VICH Outreach forum in Brussels, attended by 22 delegates from 12 countries around the world and 3 international organisations, as well as the 7 VICH member countries. EMA also chaired the 33rd VICH steering committee meeting.
	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes	50%	A liaison meeting with JECFA took place in March, to discuss differences in specific scientific approaches for the establishment of MRLs. A second meeting is scheduled for September 2016.
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine, and publish the outcome in the annual ESVAC report	60%	During the first half of 2016, the data from Member States were received and validated. A draft report was being prepared and circulated to experts for comments. The final annual ESVAC report is expected in Q3 2016.
	Prepare and deliver a joint EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species	50%	A targeted consultation (in the form of a questionnaire) of interested parties was conducted in the first half of 2016, and the input was used by experts working on the scientific opinion. Close collaboration continued between EMA and EFSA

Objective	Activity	% complete	Achievements / results
			(biohazards panel) to progress the work on the report/opinion.
	Draft and validate a methodology to measure the use of antimicrobials in poultry	50%	The DDDA and the DCDA for poultry was published in Q2 2016. The Expert Advice working group started drafting the guidance covering cattle, pigs and poultry in Q2. Also in Q2, the Agency started preparing an inventory of currently existing systems used to collect data on consumption in poultry in the EU. This is expected to be completed in Q4 2016.
Effectively manage risks to the environment arising from the use of veterinary medicines	Continue scientific reflections on the management of risks related to the use of veterinary medicines where concerns have been raised regarding the potential for harmful effects on the environment	50%	A reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances was adopted for consultation at the February CVMP. Following the end of consultation (in May), a revision of the reflection paper was initiated to take into account the comments, and is expected to be finalised in Q4. A workshop on aquaculture with experts from regulatory authorities on environmental risk-assessment for aquaculture took place in June 2016. Recommendations from the workshop will be finalised by the Environmental Risk Assessment Working Party by Q3, for submission to CVMP and decision on the need for further environmental risk-assessment guidance with regard to aquaculture.
Contribute to minimising the need for testing of veterinary medicinal products in animals	Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas	50%	The VICH international guideline GL50 'Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use' was under revision in the first half of the year, with a deadline for comments by 1 August 2016. The draft VICH international guideline GL55 'Harmonisation of criteria to waive target animal batch safety testing for live

Objective	Activity	% complete	Achievements / results
			vaccines for veterinary use' was published for comments on 26 February 2016, with a deadline of 1 August 2016.
	Improve the guidance available on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches	50%	A reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs was adopted by the CVMP in Q2, and published for six months' consultation, ending on 31 October 2016. A guideline for individual laboratories for transfer of quality-control methods validated in collaborative trials with a view to implementing 3Rs was developed and finalised in the first half of the year. It is expected to be adopted by the CVMP and CHMP in July 2016 for a six-month consultation.

3. Horizontal activities and other areas

3.1. Committees and working parties

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Number of meetings	238	222	187	187	484	484	0	0%
Number of teleconference meetings[1]	2,665	2,341	1,549	1,434	5,000	5,000	0	0%
Number of delegates	4,277	4,240	3,686	3,548	9,000	9,000	0	0%

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

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of delegate satisfaction with the service level provided by the secretariat	90%	n/a	-	-	-
Percentage of up-to-date electronic declarations of interests submitted by committee members and experts prior to participating in a committee, SAG or other meeting	100%	98%	99%	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%	100%	-*
Percentage of ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	90%	100%	100%	88%	-*

* New performance indicators introduced in 2014.

Achievements

Objective	Activity	% complete	Achievements/results
Improve collaboration and communication between committees, working groups and SAGs to increase quality, efficiency and consistency of outputs	Analyse involvement of scientific advisory groups in evaluation activities to identify gaps and improve guidance	20%	A monitoring mechanism has been implemented and the data is being collected regularly, for analysis later in the year.
	Develop and embed in the Agency the concept of therapeutic-area-specific communities (starting with the Oncology community) to facilitate knowledge exchange and create knowledge development on therapeutic-area aspects within the Agency	40%	A pilot for the oncology community was completed in May 2016 and is now transformed into an established community, continuing the ongoing activities and further developing active cooperation in priority areas (PRIME, CMA, AA). It was decided to expand the initiative to other therapeutic areas, developing other communities.
Provide up-to-date, timely, state-of-the-art guidance documents on	Explore opportunities for collaboration with HTA organisations on the development and revision of methodological and disease-specific guidelines	0%	Activity not progressed due to lack of capacity/interest from EUnetHTA.

Objective	Activity	% complete	Achievements / results
relevant topics of medicines' development	Develop scientific guidance for the development of medicines in the elderly	75%	Six-month consultation on the frailty guideline closed at the end of May 2016.
	Support the finalisation of the revised dementia guideline by the Central Nervous System Working Party	100%	The draft guideline was published for public consultation in February 2016. The consultation will end in July and, following the review of the comments, the final guideline is expected to be released in 2017.
	Provide administrative and scientific support to the drafting/revision of BSWP guidelines on adjustment for baseline covariates, multiplicity and the investigation of subgroups in clinical trials	60%	A guideline on adjustment for baseline covariates in clinical trials was published in January 2016. A guideline on multiplicity issues in clinical trials, questions and answers on data-monitoring committees and a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development were drafted and under internal review in the first half of the year. A guideline on the investigation of subgroups in clinical trials was being finalised after comments from the public consultation.
	Draft a paper to summarise progress and to suggest new areas of guidance/training on the use of modelling and simulation methodology	50%	A draft guideline to support and guide the use of innovative modelling and simulation approaches was being finalised in the first half of 2016. It is expected to be published for a six-month consultation period in July 2016.
	Draft a paper to summarise progress and to suggest new areas of guidance/training on the use of extrapolation methodology	95%	A draft reflection paper on extrapolation of efficacy and safety in paediatric medicine development was published in April 2016. A regulators workshop was held, as well as a stakeholders workshop, in May 2016. The reflection paper is being updated in line with the outcome of the workshop.

3.2. Inspections and compliance

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
GMP inspections	374	350	235	259	450	525	+75	+17%
GLP inspections	0	1	0	0	1	0	-1	-100%
GCP inspections	56	35	33	42	70	120	+50	+71%
Pharmacovigilance inspections	3	10	10	5	16	10	-6	-38%
Notifications of suspected quality defects	90	91	74	90	180	180	0	0%
Other GMP inspections-related notifications[1]	36	8	-	-	20	60	+40	+200%
Number of medicinal products included in the sampling and testing programme	48	52	5	10	50	48	-2	-4%
Standard certificate requests	2,042	1,581	1,663	1,729	3,100	3,369	+269	+9%
Urgent certificate requests	273	447	285	159	750	450	-300	-40%
Parallel distribution initial notifications received	1,629	1,423	1,226	1,268	2,600	3,100	+500	+19%
Parallel distribution notifications of change received	1,211	1,054	744[2]	1,504	1,600	2,300	+700	+44%
Parallel distribution notifications of bulk change received	4	8	-	-	12	10	-2	-17%
Parallel distribution annual updates received[3]	2,202	2,064	1,274	n/a	3,600	4,400	+800	+22%

[1] Other GMP inspections-related notifications previously included under suspected quality defects.
[2] Sharp decrease due to introduction of annual updates.
[3] Parallel distribution annual updates introduced in May 2013.

Performance indicators

Performance indicators related to core business		Target 2016	Outcome at the end of			
			Q2 2016	Q2 2015	Q2 2014	Q2 2013
	Percentage of inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%
	Percentage of standard certificates issued within the established timelines	90%	85%	82%	0.5%	28%
	Average days to issue standard certificate	10	7.9	8	17	12.3
	Percentage of urgent certificates issued within the established timelines	100%	100%	100%	100%	100%
	Percentage of parallel distribution notifications checked for compliance within the established timeline	90%	98%	99%	97%	99.8%
	Number of training activities organised in the area of inspections (minimum number)	4	1	2	2	n/a
	Additional GCP inspections addressed through information exchange on inspections carried out by international partners	35%	31%	37%	29%	-
	Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	10%	8%	10%	0.4%	-
	Percentage of outcome reports of the sampling and testing programme for centrally authorised products followed up with the MAH within one month of receipt	100%	100%	100%	100%	100%

Achievements

Objective	Activity	% complete	Achievements/results
Increase efficiency, consistency, quality and coverage of inspections through enhanced	Continue practical implementation of the risk-based inspections programme for third-country manufacturing plants of centrally authorised products, focusing EU inspectional resources on sites of highest risk	90%	Risk-based approach to inspections planning for third-country manufacturing plants of centrally authorised products is fully implemented since Q3 2014 and routinely used by EMA.

Objective	Activity	% complete	Achievements / results
international cooperation and reliance on inspections by trusted authorities	Identify (2016) and develop (2016-2017) compliance and inspections activities in areas of particular interest, based on mutual reliance with trusted international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan)	50%	Within the EMA-FDA GCP initiative, regular teleconferences took place throughout the first half of the year. Three joint EMA-FDA inspections and four observational inspections were coordinated. Inspection coverage of pivotal clinical trials submitted in marketing authorisation applications was improved by 31% in the first half of 2016. A number of teleconferences took place and the exchange of information on product-specific issues increased as part of the EMA/MSs-FDA bioequivalence initiative. Discussions with the WHO took place on potential collaboration on training activities on GCP inspections for bioequivalence studies. In April 2016, the first ad hoc pharmacovigilance inspections information exchange with Swissmedic took place under the confidentiality arrangement.
	Deliver training and capacity-building activities for inspectors and assessors on inspection-related activities	50%	The Agency participated in two capacity-building events in India. An online GCP training course (one webinar for EU and one webinar for non-EU participants) took place in May 2016. In addition, preparations for annual GCP, GVP and BE inspection workshops (Q4) took place. A training course on advanced quality risk management for GMP inspectors (September 2016) and a GCP training course in China, as part of the APEC training programme on multi-regional clinical trials, were being prepared in the first part of 2016.
	Develop the plan to further extend cooperation with Member States in coordinating third-country inspections	35%	Collaboration with Member States on coordinating third-country inspections and the GMDP IWG continued in the first half of the year. Instructions and rules on data entry into the EudraGMDP about the planned third-country inspections were

Objective	Activity	% complete	Achievements / results
			agreed, as was a document on cooperation between EMA, EEA NCAs and EDQM on inspection planning.
	Continue work to establish a mutual reliance framework with FDA to increase the scope of EU international inspections activities	50%	In the first half of 2016, the Agency continued to support the work of the mutual reliance initiative between EU and FDA, co-chairing the task force.
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects	Implement process improvements on the handling of quality defects and non-compliance issues	50%	A new form for reporting quality defects/suspected falsified medicinal products was being developed during Q1-Q2 2016. Two SOPs are also currently under revision.
	Continue researching the root causes of quality defects	50%	Discussion with FDA on implementation of the MedDRA catalogue continued in the first part of the year. At the EU level, agreement was reached on the terms used, and these will be implemented in the revised reporting form (see activity above). This will allow analysis of root causes for quality defects.

In addition to the above activities, work on preparing a pilot phase with FDA on sharing pharmacovigilance inspections information started in 2016, with the drafting of a document that outlines the aims and objectives of the EMA-FDA pharmacovigilance inspection initiative. Also, EMA is working with the Member States on implementing the actions identified in the Network strategy regarding supply issues and availability of medicines.

3.3. Partners and stakeholders

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast			
					Initial	Revised	Change	
Requests for SME qualification	357	499	270	236	650	650	0	0%
SME status renewal requests	260	139	103	119	1,400	1,400	0	0%
Requests for access to documents	418	333	152	176	500	750	+250	+50%

Procedure		2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
	Documents released following requests for access to documents	1,179	1,557	534	-	2,300	2,300	0	0%
	Requests for information	2,441	2,338	2,313	3,031	4,500	4,500	0	0%
	Number of patients involved in EMA activities	302				650	650	0	0%

Performance indicators

Performance indicators related to core business		Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
	Satisfaction level of patient and consumers' organisations	80%	n/a	n/a		n/a
	Satisfaction level of SMEs	80%	93%	92%	-	-
	Percentage of responses to ATD requests provided within set timelines	90%	90%	93%	-	-
	Percentage of responses to RFI requests provided within set timelines	97%	97%	99%	-	-
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	70%	68%			

Achievements

Objective	Activity	% complete	Achievements/results
Enhance cooperation within the European medicines regulatory network	Develop training courses to be provided through the Network Training Centre	49%	During the first six months of 2016, the EU Network Training Centre (EU NTC) provided 25 training courses.
	Conduct horizon-scanning to identify emerging trends at an early stage and to ensure appropriate expertise is available and improve regulatory preparedness, including through supporting the work undertaken by the Innovation Network and EU Network Training Centre	15%	An awareness session was organised with the NCAs and the trends from the ITF were analysed in the first half of 2016. Ad hoc learnings are being used to identify opportunities for increasing effectiveness of the support provided to the companies. Development of a more structured approach to

Objective	Activity	% complete	Achievements / results
			horizon-scanning was started.
	Complete the data-gathering initiative for fee-generating activities (2016) and non-fee generating activities (2016-2017)	50%	All fee-generating procedures, as well as major non-fee generating activities (PDCO, COMP, working parties), have been launched during Q1 and Q2.
Further strengthen the Agency's transparency and open-data commitments	Implement necessary processes for clinical data publication, including processes for document receipt, redaction consultation and conclusion, public access process and others	70%	External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use was published in March.
	Initiate reflection on providing access to individual patient data	5%	During the first half of the year, the Agency provided input to initiatives on collecting individual patient data, which will contribute to the reflection on providing access to individual patient data.
	Publish for public consultation the transparency policy	10%	A new approach towards future transparency at EMA, taking into account identified drivers for change since 2009 and transparency initiatives undertaken by other regulatory authorities and other EU agencies, was being developed during the first half of 2016.
	Develop principles for public consultation of EMA core scientific and corporate documents, and implement them in a guidance document	60%	Draft principles for public and targeted consultation of EMA core and scientific documents were prepared in Q1-Q2 2016.
	Publish for public consultation the revised policy on access to documents	75%	The revised policy was drafted and discussed by management in the first half of 2016. The policy is expected to be finalised for the December Management Board meeting.
	Finalise and publish the policy on handling falsified data/information on medicines		It was decided to include the issue of handling falsified data in the whistle-blower policy.
	Publish a report on coordination of safety announcements within the Network, and revise EU guidance on safety communication	50%	A draft report is being prepared.
Provide stakeholders and partners with consistent,	Develop a crisis communication strategy	25%	An internal draft version of the crisis communication strategy was prepared in the first half of 2016.

Objective	Activity	% complete	Achievements / results
high-quality, timely, targeted and accessible information on the Agency's work, outputs and medicinal products	Develop a framework for communicating the scientific output of EMA scientific committees	25%	In the first half of the year, all committees were interviewed and a mapping exercise was completed. The results of both the interviews and the mapping exercise are now being analysed, with a view to providing improvement recommendations.
	Publish product-related communication guidance on what and when EMA publishes information on products	100%	The guidance was published in May 2016.
	Expand user-testing by patients for all product-related communications that include patients as a target audience	10%	Based on the feedback received from stakeholders, the Agency initiated a reflection on how to user-test various communication products targeting the general public.
Strengthen stakeholder relations, focusing on patients and consumers, healthcare professionals, industry associations and academia	Adopt (2016) and implement (2017) a framework for collaboration with academia	50%	Public consultation on the proposal of a framework for collaboration with academia was conducted. The draft framework was discussed at a Scientific Coordination Board meeting and the HCPWP meeting with academia in June.
	Implement a framework for interacting with industry stakeholders	70%	Eligibility criteria were adopted by the Management Board in June 2016. The review of the eligible organisations is expected to be completed by January 2017.
	Publish annual reports on EMA's interaction with industry associations	100%	The 2015 annual report was presented at the June Management Board meeting and subsequently published on the Agency's website.
	Publish annual reports on EMA's interaction with patients, consumers, healthcare professionals and their organisations	100%	The 2015 annual report was presented at the June Management Board meeting and subsequently published on the Agency's website.
	Conduct a joint PCWP/HCPWP workshop on the use of social media to further engage with patients, consumers and healthcare professionals	50%	Preparations for a workshop took place in the first half of the year. The workshop was scheduled for 19 September 2016.
	Publish a 10-year report on PCWP operations	50%	A dedicated workshop to mark 10 years of the PCWP took place on 14 June 2016.
	Explore processes to capture patients' input on the value of	75%	An article on incorporating patient preferences into drug

Objective	Activity	% complete	Achievements / results
	evidence during benefit-risk evaluation, based on the outcome of the pilot phase of patients' involvement in benefit-risk assessments		development and regulatory decision-making was published in May 2016. A study to explore the process to capture patient input on the value of evidence during benefit-risk evaluations was completed in June. An article on the study is expected to be published in Q3 2016.
	Develop (2016) and implement (2017) recommendations to promote GPs' interactions with EMA	50%	A workshop with GPs was held in April, and this identified areas for mutually beneficial collaboration between GPs and EMA. A report with the outcomes of the workshop was published in June.
	Implement a revised framework for EMA interaction with patients	70%	A study to explore the process for capturing patient input on the value of evidence during benefit-risk evaluations was completed in June. An article on the study is expected to be published in Q3 2016. Training of patients on EMA activities continued in the first half of the year.
Further develop support to, and strengthen stakeholder relations with, SMEs	Develop an action plan arising from the 10-year report on the implementation of SME Regulation	25%	Development of the action plan started in Q1-Q2 2016, and is expected to be completed before the end of the year.
	Enhance communication and outreach to SMEs, to increase regulatory awareness and promote the use of new approaches and tools in development	50%	An SME workshop on statistical perspectives in regulatory clinical developments was held on 5 February 2016. A second SME workshop on clinical trials is planned for early October. Regular communication through mailings and quarterly newsletters to SMEs continued in the first half of the year.
	Deliver high-quality guidance and systems for optimal use of available regulatory tools for SMEs (EU e-SME application) to facilitate efficient and effective access to support measures	50%	In the first half of 2016, SME webpages were revised to make them more user-friendly and facilitate access to support measures. An SME user guide is being prepared for publication on the website. In addition, SOPs on conditional fee exemption, maintenance and renewal, as well as the e-SME declaration, are being revised.

Objective	Activity	% complete	Achievements / results
	Develop a plan for further development of the network of SME and innovation support structures of EU agencies and organisations, including greater work-sharing and exchange of best practices with bodies offering support to SMEs in the national, European and international context	50%	In Q1-Q2 2016, a meeting to share best practices with the EU agencies' SME offices took place in Brussels. Regular interactions with the Research Executive Agency on the SME definition, as well as interactions with DG Research on queries relating to Horizon 2020, also took place. The plan for further development of the network of SME and innovation support structures of EU agencies and organisations is under development.

3.4. International activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast		
					Initial	Revised	Change
n/a							

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
n/a					

Achievements

Objective	Activity	% complete	Achievements / results
Ensure best use of	Enhance cooperation between international regulators in all	50%	Alongside regular cluster activities with non-EU regulators,

Objective	Activity	% complete	Achievements / results
resources through promoting mutual reliance and work-sharing	therapeutic areas, including paediatric medicines, biosimilars, orphan medicines, veterinary medicines, generics and medicinal products derived from blood		cooperation with international regulators continued to expand in all therapeutic areas, including paediatric medicines, biosimilars, orphan medicines, veterinary medicines, generics and medicinal products derived from blood. In the first half of 2016, the International API programme and the pharmacovigilance cluster to include Japanese regulators were expanded. A strategic review of paediatric approaches with FDA was being planned and PSAIBs were published in the context of the IPRF Biosimilars working group. A patient cluster with FDA was also established in the first part of the year.
	Implement and review the IGDRP information-sharing pilot to the centralised procedure	50%	In the first half of the year, no applications were received as part of the IDGRP information-sharing pilot. To raise awareness of the data-sharing pilot among generic-medicines applicants, the eligibility outcome letter was amended to include a statement on the data-sharing pilot.
	Establish additional collaborations with FDA on patient engagement and pharmaceutical quality	70%	A meeting with FDA was held in January to prepare for a quality fellowship. It was agreed to build a working platform for cooperation with FDA that is likely to be a quality cluster, with a main focus on innovative technologies.
	Optimise Article 58 scientific opinion activities, to include enhancing collaboration with the WHO and concerned regulators and developing additional communication tools		The Article 58 procedure was presented at the DIA Euromeeting 2016 in Hamburg, in April, and a revised infographic describing the procedure was published. A study looking at stakeholder awareness, experience and views on the Article 58 procedure was published on the EMA website in April 2016. An action plan for increasing perception and use of Article 58 was drafted in the first half of the year, and is currently under internal review. The Umbipro CHMP opinion was adopted in April, and Pyramax

Objective	Activity	% complete	Achievements / results
			(antimalarial) was the first Article 58 product included in the WHO-EMA collaborative registration pilot with low- and middle-income countries in Africa.
	Update existing guidance on the Article 58 scientific opinion procedure	75%	A draft guideline on EMA procedural advice for medicinal products intended exclusively for markets outside the European Union under Article 58 of Regulation (EC) No 726/2004 was prepared in Q1 and Q2. It will be circulated for internal comments in Q3 2016.
	Explore mechanisms to enhance involvement of non-EU regulators in EMA scientific reviews, to facilitate work-sharing		Assessment reports for 4 products (3 CAPs and 1 Art. 58) were shared with African regulators in Q1-Q2 2016, as part of the pilot with WHO for collaborative registration – where the assessment and inspection work carried out by the EU assessors and inspectors is available to regulators in low- and medium-income countries, while allowing these regulators to retain their regulatory responsibilities. Discussions on improving the pilot to benefit further patients in African countries continue. EMA also took active part in drafting a new WHO guideline on good regulatory practices (GRP), which should be finalised by the WHO in 2017. The assessment report for a centralised product was shared with regulators in Israel, who also participated as observers for the first time in part of the May CHMP meeting during the discussion on the list of questions. A template intended to help companies when giving consent to EMA to share assessment and inspection documents with regulators outside the EU has been published on the EMA public website.
	Provide input to activities aimed at greater mutual reliance — such as the mutual reliance initiative with FDA and ICMRA GMP		An FDA MRI procedure based on observation of the activities of the Joint Audit Programme was completed in the first half of

Objective	Activity	% complete	Achievements / results
	— and exploring mechanisms for confidential exchange of trade secret information		2016. The FDA template for sharing trade secret information is being reviewed by the Commission. The ICMRA GMP pilot was also launched.
Promote convergence of global standards and contribution to international fora	Provide assistance to candidate countries, to align their standards and practices with those established in the European Union and to further foster their integration process		Following the IPA meeting in Copenhagen in April 2016, preparations are underway for EMA to organise activities for beneficiaries under the IPA II programme.
	Conduct gap analysis of existing regulatory frameworks in paediatrics and dementia, and organise workshops to improve understanding of the frameworks and facilitate development of medicines in these areas		A paper outlining the US and EU frameworks for paediatric development was submitted for publication and planning for a September FDA-EMA workshop was completed. Comparative work on FDA and EMA guidelines on Alzheimer's disease was initiated.
	Support relevant external activities in dementia/Alzheimer's disease with international partner agencies and intergovernmental initiatives	80%	A joint presentation with FDA Neurology division, and also on behalf of Health Canada and PMDA, on the update of the multilateral cooperation workstream activities was given at the integrated development initiative meeting facilitated by OECD and hosted by BfArM in Bonn, in June 2016.
Assure product supply chain and data integrity	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries		In the first half of the year, a mechanism to improve cooperation with Indian and Chinese regulators on observing GMP inspections was agreed and implemented.
	Develop training and communication materials on the importance of data integrity, in collaboration with other regulators, such as FDA	50%	Preparations for joint training activity with FDA on data integrity took place in the first half of the year. The training is scheduled to take place in October and November in China.
	Contribute to ICH activities on starting materials and lifecycle management	80%	In the first half of the year, a revised set of Q&As (ICH Q11) on starting materials was agreed for comment by constituents. Adoption for public consultation is expected in November 2016. Drafting of ICH Q12 on lifecycle management continued in Q1-Q2 2016 and consultation is expected in June 2017.

Objective	Activity	% complete	Achievements / results
	Promote increased international cooperation in the area of supply chain security, in particular through efforts to coordinate and integrate initiatives at the level of ICMRA		A draft paper aimed at promoting alignment and interconnectivity of track and trace systems globally was developed by a drafting group led by EMA. The paper was presented to the ICMRA management committee in June 2016.
Support training and capacity-building and promote the EU regulatory model	Increase involvement of non-EU regulators (including candidate countries) in other training activities and the work of the EU Network Training Centre		Non-EU regulators have been invited to and have participated in selected NTC events and other training activities throughout the first half of 2016. During the first six months of 2016, EMA sent out invitations to international partners for 8 training events (remote and in-person training), with over 30 international participants taking part.
	Identify training priorities and explore how to address these with key regulators outside the EU	50%	In the first half of the year, India and China working groups on pharmaceuticals identified GMP/GCP training requirements for Indian and Chinese regulators.
	Increase involvement of experts and observers from concerned regulators in Article 58 activities	70%	In this reporting period, the Agency engaged with WHO and DG Sante to address operational and regulatory issues, such as expert nomination and the eligibility process. An action plan for increasing perception and use of Article 58 was drafted in the first half of the year, and is currently under internal review.

3.5. Data-management support

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast			
					Initial	Revised	Change	
Number of Telematics information services provided by EMA	21	-	-	-	23	21	-2	-9%
Number of ongoing Telematics IT projects where EMA	7	-	-	-	17	7	-10	-59%

Procedure		2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
	is the delivery organisation								
	Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	5	-	-	-	6	5	-1	-17%

Performance indicators

Performance indicators related to core business		Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
	Satisfaction of external customers of Telematics information services provided by EMA (% satisfied or very satisfied)	80%	90.4%	-	-	-
	Satisfaction of EMA internal customers of information services (% satisfied or very satisfied)	80%	90.4%	-	-	-

Achievements

Objective	Activity	% complete	Achievements/results
Deliver information technology solutions required by EU law	Deliver information systems according to the EU Telematics roadmap	40%	The PSUR repository was delivered according to plan. Clinical trial systems and master data services are in development and broadly on track. EudraVigilance, and consequently the audit, are delayed, as was highlighted to the Management Board in their June meeting.
	Implement the ISO IDMP roadmap with EU NCAs and industry	75%	Over the first half of the year, extensive work was undertaken to publish versions 1 and 2 of the substance technical specifications and comments on the medicinal product and pharmaceutical product technical specifications were addressed. Product technical specifications are expected to be approved for publication in November 2016, while the substance technical specification is likely to be published in Q2-Q3 2017.

Objective	Activity	% complete	Achievements / results
			In addition, work on the new version of ISO IDMP standards continued during Q1-Q2 2016, and the new standard is expected to be published in late 2017.
	Develop and implement common policies, procedures and standards to maximise the sharing and optimise investment in data	25%	During the first part of the year a number of documents (data models, application programming interface specifications, target operating model, use cases, etc.) were developed and agreed internally, as well as adopted and published externally for implementation of RMS and OMS. Work on EU implementation guides in collaboration with our stakeholders continued in the first half of the year, and is expected to be finalised in the first half of 2017.
	Implement effective communication systems to support the Network's readiness in using and integrating Telematics systems	75%	During the first half of 2016, the EU Telematics website was revamped, including also a dedicated ISO IDMP/SPOR page, in order to strengthen communication with stakeholders. A plan for organising webinars and workshops for the Network was also agreed in March and is expected to be completed by the end of the year. Monthly bulletins have been published since October 2015, providing the Network an overview of Telematics news. Industry's participation in EU Telematics at a strategic level was agreed in February, with two meetings per year to take place with the pharmaceutical industry associations. Further streamlining of the Telematics maintenance structure and optimisation of the Telematics governance structure continues.
Share information on medicines	Implement information provision and analytics information services to increase value of information through web access to information, business intelligence and analytics	35%	During the first half of 2016, an internal reflection document on data analysis with a vision for management reporting (e.g. dashboards on budget, FTEs utilisation) and scientific data analytics (e.g. big data, real-world evidence) was agreed. Operational tools such as the BIACC (Business Intelligence & Analytics Competence Centre) and the RACI were established

Objective	Activity	% complete	Achievements / results
			at the end of Q2 2016. In addition, a first draft for the Data Warehouse and Business Intelligence target architecture was presented to the Architecture Board and was on target for approval by the end of September.
Establish and improve EMA information services	Establish a set of standard information services to support efficiency and effectiveness of scientific and other core activities	15%	Internal RMS release 1 went live in May and delivered the infrastructure that will support the subsequent SPOR projects as well as the capability to publish lists.
	Develop and start implementing improvements in the management of electronic documents and records	50%	New strategy for record management and archiving, as well as a records management target operating model, were created in the first half of 2016. Retention policies for financial records were also reviewed in Q1-Q2. A review of the electronic content management tool available in house, as well as assessment and selection of a new tool, is planned to be completed by the end of the year.
	Improve EMA's technology landscape by means of enterprise architecture	50%	Simplifications of the application landscape were identified and agreed with the business in the first half of 2016. Activities to decommission obsolete applications were started.
	Develop and implement an information security management system to protect data assets and strengthen information security	20%	In Q1-Q2 2016, an information classification scheme methodology was developed and is expected to be approved by EXB in October 2016.

4. Support and governance activities

Workload indicators

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Requests for interviews and comments by media representatives	1,110	1,080	-	-	2,200	2,200	0	0%
Number of press releases and news items published	88	102	-	-	200	200	0	0%

Procedure	2016 Q1–Q2	2015 Q1–Q2	2014 Q1–Q2	2013 Q1–Q2	2016 annual forecast Initial	Revised	Change	
Number of reports, brochures, leaflets produced	5	7	-	-	6	6	0	0%
Number of documents published on EMA website	4,416	-	-	-	10,000	10,000	0	0%
Number of pages published and updated on EMA website	2,824	-	-	-	5,000	5,000	0	0%

Performance indicators

Performance indicators related to core business	Target 2016	Outcome at the end of Q2 2016	Q2 2015	Q2 2014	Q2 2013
Percentage of posts on the Agency establishment plan filled	97%	98%	97%	97%	93%
Percentage of revenue appropriations implemented	97%[1]	55%[2]	47%	44.3%	47.5%
Percentage of expenditure appropriations implemented	97%[1]	73%[2]	67%	65.5%	71.7%
Percentage of payments against appropriations carried over from year N-1	97%	83%[2]	73%	86.3%	79.9%
Percentage of payments made within 30 days' time	98%	98.98%[2]	100%	97.4%	-[3]
Satisfaction level of partners/stakeholders with EMA communications	n/a	n/a	84% / 87%	-	-
Key messages included in media articles generated by EMA press releases:					
At least one key message	95%	100%	100%	-	-
At least two key messages	70%	32%	100%	-	-
Quote included	60%	60%	n/a[4]	-	-
Average rating of pages on corporate website during the year	3	3.6	-	-	-
Availability of Telematics IT systems (% of time)	98%	99.8%	100%[5]	99.5%[5]	99.4%[5]

Performance indicators related to core business	Target 2016	Outcome at the end of			
		Q2 2016	Q2 2015	Q2 2014	Q2 2013
Availability of corporate IT systems (% of time)	98%	99.9%	-[5]	-[5]	-[5]
Availability of corporate website (% of time)	98%	99.9%	-	-	-

[1] Annual target to be reached at year-end.
[2] Results at the end of July.
[3] 2013 results not comparable, due to change in indicator (30 day vs 45 day timeline in 2013).
[4] No quotes were included in press releases.
[5] In previous years, one combined performance on Telematics and corporate IT systems availability against Agency working hours was reported.

Achievements

Objective	Activity	% complete	Achievements/results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Develop the Agency's multiannual programming, to implement the Network strategy 2016-2020	100%	The EMA multiannual work programme was adopted by the Management Board on 16 June 2016. It follows the structure of the Network strategy and translates the strategy into more specific medium-term objectives and key initiatives to deliver the objectives. The multiannual work programme is expected to be reviewed annually, to ensure it is up to date and reflects all key priorities and developments.
	Conduct self-assessment of the Agency's quality management system against the new ISO 9001:2015 standard	0%	The activity is planned to start in the second half of the year.
	Develop a corporate communication strategy	100%	A framework strategy for external communications (previously 'corporate communication strategy') was developed in the first half of 2016 and was endorsed by the Management Board at its June meeting. A communications plan for 2016 was adopted by EXB in May 2016.
	Develop a social media strategy	25%	A reflection paper setting out the different options for further EMA engagement through social media was developed in Q1-Q2 2016.

Objective	Activity	% complete	Achievements / results
Maintain high level of independence, integrity and transparency in all aspects of the Agency's work	Implement the conflicts-of-interests policy for Management Board members and EMA employees	100% 75%	The 'Policy on competing interests for Management Board members' was adopted in December 2015 and came into effect in May 2016. Guiding principles for the revision of the decision on the rules concerning the handling of declared interests for the Agency's staff were agreed at the March Management Board meeting, and a revised decision on the rules concerning the handling of declared interests of EMA staff members was prepared for adoption at the October Management Board meeting.
	Conduct annual reviews of the Agency's handling of independence	75%	During the first half of 2016, the Agency conducted the annual assessment of handling of independence and prepared a report for discussion at the Management Board in October.
Align the Agency with the highest European standards in environmental performance	Prepare and implement an action plan to register the Agency for EMAS certification	25%	Preparation for EMAS certification was initiated with the procurement of an environmental consultant to verify the Agency's strategy, policy and action plan. The Green group created in 2015 launched its first action in January, to improve the Agency's waste-management system by including food waste.

In addition to the above activities, in the first half of the year, the first draft of standards for EMA and Telematics websites, templates and online style guide was completed, and internal discussions on development of tools and features to enhance the current corporate website (e.g. tools for search-engine optimisation, analytics and accessibility) started.

Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AA	accelerated assessment
ADAPT SMART	accelerated development of appropriate patient therapies: a sustainable, multi-stakeholder approach from research to treatment-outcomes; a European public-private collaboration
ADR	adverse drug reaction
ADVANCE	accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	ad hoc expert group on veterinary novel therapies
AER	adverse event report
Agency	European Medicines Agency
APEC	Asia-Pacific Economic Cooperation
API	active pharmaceutical ingredient
Art	Article
ATD	access to documents
ATMP	advanced-therapy medicinal product
BE	bioequivalence
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
BIACC	Business Intelligence & Analytics Competence Centre
BSWP	Biostatistics Working Party
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CMA	conditional marketing authorisation
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CPAS	advisory group on classification of post-authorisation studies
CPTR	Critical Path to TB Drug Regimens initiative
CVMP	Committee for Medicinal Products for Veterinary Use
DCDA	defined course dose for animals
DDDA	defined daily dose for animals
DG	Directorate-General of the European Commission
DIA	Drug Information Association
DoI	declaration of interests
EC	European Commission
EC C3	Directorate C3 of the European Commission
ECD	Eudra Common Directory
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECNP	European College of Neuropsychopharmacology
eCTD	electronic common technical document
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMAS	EU Eco-Management and Audit Scheme
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
EPL	EMA product lead

Term / abbreviation	Definition
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and development practice
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EudraLex	EU legislation; collection of rules and regulations governing medicinal products in the European Union
EUnetHTA	European network for Health Technology Assessment
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EWP	Efficacy Working Party
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
FTE	full-time equivalent
GCP	good clinical practice
GL	guideline
GLP	good laboratory practice
GMO	genetically modified organism
GMDP	good manufacturing and development practice
GMP	good manufacturing practice
GP	general practitioner
GRP	good regulatory practice
GVP	good pharmacovigilance practice
HCPWP	Healthcare Professionals Working Party
HIV	human immunodeficiency virus
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	individual case-safety report
IDMP	Identification of Medicinal Products
IDWP	Infectious Diseases Working Party
IFAH Europe	International Federation for Animal Health Europe
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
I-MOVE	Influenza Monitoring of Vaccine Effectiveness network
IPA	informal network of EU agencies working with pre-accession
IPRF	International Pharmaceutical Regulators Forum
ITF	Innovation Task Force
ISO	International Organisation for Standardisation
IWG	Inspectors Working Group
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEG 3Rs	Joint CVMP/CHMP Ad-hoc Expert Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products
JIRA	bug-tracking, issue-tracking and project-management software application
KPI	key performance indicator
LMIC	low and middle-income countries
MA	marketing authorisation
MAA	marketing-authorisation application
MAH	marketing-authorisation holder
Management Board (MB)	Management Board of the EMA
MedDRA	Medical Dictionary for Regulatory Activities
Member State (MS)	Member State of the European Union
MHRA	Medicines and Healthcare products Regulatory Agency, UK
MLM	medical literature monitoring

Term / abbreviation	Definition
MRI	mutual reliance initiative
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NTC	EU Network Training Centre
NUI	non-urgent information
OECD	Organisation for Economic Cooperation and Development
PAES	post-authorisation efficacy study
PAM	post-authorisation measure
PASIB	public assessment summary information for biosimilar
PASS	post-authorisation safety study
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority Medicine; a scheme to foster the development of medicines with high public-health potential
PREDICT-TB	Model-based preclinical development of anti-tuberculosis drug combinations, IMI project
PrEP	pre-exposure prophylaxis
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
QWP	Quality Working Party
R&D	research and development
RA	rapid alert
RACI	responsible, accountable, consulted, informed
RFI	request for information
RMP	risk-management plan
RMS	referentials management service
SA	scientific advice
SAG	Scientific Advisory Group
SAGE	Strategic Advisory Group of Experts on Immunization (WHO)
SAWP	Scientific Advice Working Party
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	small and medium-sized enterprise
SPOR	substances, products, organisations, referentials
SmPC	summary of product characteristics
SOP	standard operating procedure
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
SWP	Safety Working Party
SWP-vet	Veterinary Safety Working Party
TIGRE	Team of International Global Rare Disease Experts initiative
VE	Vaccines Europe
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WHO	World Health Organization
WIN	working instruction