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Mid-year report 2015

January - June 2015

Prepared by the Deputy Executive Director of the European Medicines Agency (EMA) for presentation to the Agency's Management Board on 2 October 2015.

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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 2015 and thus reflects the situation as of 30 June 2014. Further developments have taken place since, that have not been included in this document.

Assessment activities for human medicines

- **Scientific advice and protocol assistance** requests are in line with the annual forecasts, and slightly above the 2014 midyear results.
- Higher than expected number of **protocol assistance requests** could be related to Horizon 2020 requirement for a product to be eligible for funding. The activity is expected to level out in the 2nd half of the year.
- Number of **orphan designation applications** reached 120, a slightly lower result than in 2014.
- **Paediatric procedure applications** remained at the 2014 level, and are in line with the expectations for 2015.
- **Requests for ATMP classification** reached 13 in Q1-Q2 2015, remaining on the same level as the year before.
- **45 initial evaluation applications** were received in the first half of 2015 – slightly below the expectation for 2015, yet remaining on a similar level as in 2014.
  - As expected in the 2015 forecasts, new **orphan medicinal product applications** saw a slight increase as compared to 2014, while the **non-orphan product applications** received by the end of Q2 2015 were below the expectation and last year's result.
  - **Similar biological medicinal product applications** and **hybrid and abridged applications** have remained at the same low levels as before.
  - **Generic products** still remain at the slightly higher level of applications.
- **Variations applications** saw a slight increase as compared to 2014 results, yet are within expectations for 2015. **Type IA** and **type II variations** received higher number of applications than expected in the first half of the year.
- Number of **referrals** received in the first 6 months of 2015 has been **significantly lower** than expected, and the annual forecast has been revised accordingly.
- Number of both, the **reviewed and validated signals** is higher than expected for 2015, and also exceeds the 2014 results, reaching 1,354 reviewed signals and 29 validated signals.
- Number of **PSURs received** has fallen slightly, if compared to 2014, but remains in line with the forecasts for 2015. **115 PSUSAs** were received in Q1-Q2 2015.
- Number of **emerging safety issues received** reached the annual forecast by midyear. The annual forecast has therefore been adjusted accordingly.

- Number of **new herbal monographs** stayed at the same level as in 2014, while **revised herbal monographs** were lower in relation to both, expectation for 2015 and the results in Q1-Q2 2014.
- Main **performance indicators** related to the assessment activities of human medicines have been met.
  - **6% increase** in **scientific advice requests** was observed in the first half of 2015, with **34%** of the requests for scientific advice originating **from small and medium enterprises**.
  - **Average clock stop** for new active substances and biosimilars was 142 days, vs the expectation of 180 days.

Assessment activities for veterinary medicines

- **Scientific advice requests** for veterinary medicines remained at the same level as in 2014 – slightly below the expectation for 2015.
- Requests for **MUMS classification** increased as compared to 2014 results, reaching 14 requests in Q1-Q2 2015.
- 3 **initial evaluation applications** were received in the first half of the year, significantly less than in the same period last year and below the expectation for 2015. The annual forecast has been reduced to reflect this lower level of activity.
- **New MRL applications** and **MRL extension and modification applications** remained at the same level as in the previous years.
- **Variations applications** for veterinary medicines continue to increase; first half of 2015 saw an increase both in relation to the forecasts for the year and as compared with the results in 2014.
- **Referral procedures** remained at the same low level as in 2014, leading to slightly decreased annual forecast.
- Number of **PSURs received** remained in line with the forecasts – and on similar level as 2014, while the number of **adverse event reports** continues to increase, exceeding also the mid-year expectation for 2015.
- Main **performance indicators** related to the assessment activities of veterinary medicines have been met.

Inspections and compliance

- 10 **pharmacovigilance inspections** were requested in the first half of 2015, remaining at the same level as 2014.
- Number of **GMP inspections** increased significantly as compared to 2014 (350 vs 235), almost reaching the annual forecast for 2015.
- **GCP inspections** remained at the same level as the year before and in line with the 2015 forecasts.
- **Additional 37% GCP inspections** were addressed through information exchange with international partners.
- 1 **GLP inspection** was requested in Q1-Q2 2015.

- Number of **notifications of suspected quality defects** increased, returning to the 2013 levels, and leading to a higher revised annual forecast.
- 1,581 **standard certificate requests** were received in the first half of 2015, slightly lower than in 2014. The **average days to issue a standard certificate** have been reduced to **8 days**.
- **Urgent certificates** continue to grow in popularity. **447 requests** were received by the end of Q2 2015 (56% increase over 2014), reaching the annual forecast.
- Number of **parallel distribution initial notifications** increased slightly in the first 6 months of 2015, yet the annual forecast remains unchanged.
- Due to increase in safety updates **parallel distribution notifications of change** reached annual forecast in the first half of 2015, leading to an upward-revised forecast.
- **2,064 parallel distribution annual updates** were received in Q1-Q2 2015, a 62% increase from 2014. With 80% of annual forecast reached, it has been revised upwards to reflect the popularity of the annual updates.

Key achievements

- Celebrating the 20th anniversary of the Agency and in recognition of the 50th anniversary of pharmaceutical legislation in Europe, the 20th anniversary scientific conference was held on 18 March 2015. EMA 20th anniversary booklet, capturing the important progress in regulatory science and societal changes in the field of medicines regulation, as well as achievements of EMA in fulfilling its mission over the past two decades, was published and presented at the conference.
- Following the first in-depth meeting with HTAs in December 2014, a report on the initial experience with the adaptive pathways project and the next steps to take, was finalised and sent to HTAs in March 2015.
- Analysis of experience with the conditional marketing authorisation was presented to the EC expert group STAMP in January and May. CHMP draft guideline on conditional marketing authorisation was updated in the first half of the year and is expected to be adopted for public consultation at the CHMP July meeting
- Analysis of the accelerated approval concept was completed in Q1 2015 and the revised guidance and templates were presented to the committees in May and June.
- ADVENT group held its first plenary meeting in January 2015. CVMP endorsed ADVENT work plan 2015 and agreed the priority topics for which guidance will be developed by ADVENT group in the first half of the year.

- Draft EU Network strategy was adopted in March for 3 month public consultation, ending 30 June 2015.
- Following consultation with national competent authorities and stakeholders, an EU Telematics strategy and implementation roadmap 2015-2017 was adopted by the EU Telematics Management Board in June 2015 and scheduled for endorsed by HMA and the EMA Management Board in summer 2015.
- The interim platform for the Network training centre was launched in January.

- The multinational team concept in relation to veterinary medicines assessment was presented to HMA. The concept was extended to scientific advice procedures for human and veterinary products.
- The pilot project gathering data on scientific advice/protocol assistance started in January and will conclude in September.

- Literature monitoring service to be launched on July 1st for 50 active substances. Further expansion to 300 substances and herbal medicines is planned in September.
- Draft strategy on the methods and approach for measuring pharmacovigilance impact was prepared in the 1st half of 2015, and presented to the PRAC in June. Drafting of the report started, following the endorsement of PRAC.
- Strategy for developing an EU collaborative framework for patient registries was agreed by the task force in June 2015. The pilot is expected to start in Q4 2015.
- The finalised code of conduct for vaccine benefit risk studies was published on ADVANCE project website in May 2015.
- Data collection related to the indicators of the pharmacovigilance system for the EC's report on EMA and Member States' tasks in pharmacovigilance started in March 2015.

- The PSUR repository went live on 26/01/15 and the audit started as originally planned. The audit was concluded successfully and, following PRAC's positive endorsement, the Management Board confirmed full functionality of the repository in June. A pilot on centrally and nationally authorised products is underway. Work on the next planned releases is ongoing.
- As part of the Clinical trials programme delivery, business analysis and business requirement gathering for both, EU portal and database, and safety reporting projects was carried out over the first half of 2015.
- The first EU veterinary medicinal product database was delivered in Q1 2015.
- The previous pandemic preparedness plan was reviewed and transformed into a wider ranging preparedness plan for emerging health threats. Implementation work will continue in the second half of the year.
- The procedural/regulatory guidance for pandemic vaccines was adopted by CHMP/CMDh in May 2015.
- As part of initiative to improve collaboration and communication between committees, common templates and streamlined process for delivering committee work plans was implemented in Q1, further strengthening interactions between the committees.
- As part of the work to continuously improve the way scientific opinions are delivered, effects table has been included in the assessment reports of all applications for marketing authorisation and extension of indication since February 2015.
- The revised policy on handling of conflicts of interests of scientific committees' members and experts entered into force on 30 January 2015. A revised EMA breach of trust procedure on conflicts of interests for scientific committee members was also adopted and published in May 2015.

- Working to increase patient involvement and obtaining real-life data, the first focus group was convened in Q2 2015 in collaboration with Melanoma Patient Network Europe and Myeloma Patients Europe, and discussed patient preferences based on a fictitious case study. Reports to CHMP and other fora were made and additional focus groups are planned to elaborate the methodology.
- In the area of transparency and in preparation for the publication of clinical data reports, a draft guidance on anonymisation of individuals in clinical reports was prepared in the first half of the year, and targeted consultation with academics, pharmaceutical industry, NGOs and patients' organisations started in June.

- As part of the activities to increase the quality and consistency of the product information provided to stakeholders, roll-out of the new labelling process started in May and is expected to be completed by the end of the year.
- EC/EMA – Swissmedic confidentiality arrangement on exchange of non-public information relating to medicines for human and veterinary use was finalised in the first half of 2015, and is expected to be signed and come into force in July 2015.
- EC/EMA – WHO confidentiality arrangement on exchange of non-public information relating to medicines for human use was finalised in the first half of the year, and is expected to be signed in Q3.
- The IGDRP pilot for sharing generic medicines' assessment reports was extended to centralised products in January 2015. A call for expression of interest for the applicants was launched in January. 3 companies have expressed their interest to participate in the pilot.
- WHO-nominated experts/observers from Ghana and Tanzania participated in the Article 58 procedure for malaria vaccine Mosquirix. In addition, EMA together with the EC and Bill & Melinda Gates Foundation, with the support of external consultants, carried out a strategic review of the use, role and vision of its Article 58 scientific opinion.

Detailed mid-year report

Explanation of symbols used in this document

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 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 percentage, 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, decrease in received and validated signals will be marked amber or red, yet this could be regarded as 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: result below the target will be marked green or blue while result 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, 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 2015 for the first time, data on previous year's results is not provided.

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Scientific advice/protocol assistance pre-submission meetings	75	-	-	-	165	165	0	0%
Scientific advice and protocol assistance requests, of which:	243 (291)*	216 (275)*	237	258	493	493	0	0%
Parallel scientific advice with international regulators	2	1	3	2	6	4	-2	-33%
Joint scientific advice with HTA bodies	21	6	1	3	12	30	+18	+150%
Protocol assistance requests	82	-**	-	-	116	129	+13	+11%
Novel technologies qualification advice/opinions	7	-	-	-	23	17	-6	-26%
Scientific advice finalised	199	-	-	-	464	431	-33	-7%
Protocol assistance finalised	86	-	-	-	102	162	+60	+59%
Orphan medicines application pre-submission meetings	100	-	-	-	190	200	+10	+5%
Orphan medicines applications, of which:	120	138	106	103	260	240	-20	-8%
Parallel orphan applications with international regulators	48	47	25	22	120	96	-24	-20%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	229	234	215	212	480	480	0	0%
Finalised procedures for compliance check on PIPs	35	-	-	-	72	72	0	0%
Requests for classification of ATMPs	13	13	12	11	25	28	+3	+12%
Innovation Task Force briefing-meeting requests	36	12	-	-	35	42	+7	+20%
Innovation Task Force Art 57 CHMP opinion requests	1	4	-	-	8	2	-6	-75%

* Since 2014 scientific advice and protocol assistance are split in pre-authorisation and post-authorisation. Total number of SA and PA requests in Jan-Jun 2015 was 291, with 243 of the requests received in pre-authorisation phase

** In previous years reflected only in total number of scientific advice and protocol assistance; separate indicator introduced in work programme 2015

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Scientific procedures completed within regulatory timeframes*	100%	100%	99%	99%
Increase in scientific-advice requests	10%	6%	16%	-
SME requests for scientific advice (percentage of total SA requests)	20%	34%	-	-
Percentage of initial evaluation applications (for new active substances and biosimilars) that have received scientific advice	76%	77%	-	-
Percentage of applications designated as orphan medicines	75%	67%	-	-
Number of confirmation of applicability of paediatric class waivers	45	24	-	-

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

Achievements

Objective	Activity	Achievements / results
Promote more active use of scientific advice and other pre-application support, including early and iterative dialogue with pharmaceutical sponsors	Launch a scheme to facilitate interaction and early dialogue with sponsors throughout the medicines lifecycle	Development of the single interface for sponsors and developers to improve access to scientific and regulatory guidance has been delayed and will progress further in line with the corporate website project implementation.
	Organize a workshop on significant benefit	Draft agenda for the workshop was prepared in Q2 2015. Further preparations will be carried out to deliver the workshop in December 2015.
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product life-cycle	Finalize guidance to applicants to facilitate access to parallel SA HTA procedure	Further analysis of the comments received earlier on the draft guideline was conducted in the first half of 2015, to consider the experience gained from the pilot. An interim revision of the HTA EMA parallel advice best practice guide, response to the comments and a report on the pilot will be delivered in the second half of 2015.
	Review existing guidance on parallel scientific advice with the FDA	The guidance was reviewed, finding that no changes need to be introduced.
	Develop guidance for the qualification of novel methodologies, in collaboration with IMI, EFPIA and FDA	Common letter of intent with IMI, EFPIA and FDA was finalised and published on EMA website in January.
Facilitate research and development of new	Complete the adaptive pathways pilot project and review outcomes of the pilot	Following the first in-depth meeting with HTAs in December 2014, a report on the

Objective	Activity	Achievements/results
medicinal products		initial experience with the adaptive pathways project and the next steps was finalised and sent to HTAs in March 2015.
	Provide scientific and regulatory input to the European Commission on specific borderline products	Presentation on the EMA scientific and regulatory issues/experience with borderline products was given at the DG Research workshop on Key Enabling Technologies in May.
	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	Work on new process and criteria for proposing research topics, as well as criteria to define level of EMA involvement in various research projects started in Q1 2015 and is expected to be finalised in Q3. No research topics were submitted in the first half of the year.
Support development and availability of medicines for specific target groups	Develop and implement EMA Gender strategy	Presentation on the EMA actions regarding Gender strategy was given at EUGenMed conference in Q2 2015.
	Implement EMA Geriatric medicines strategy	Frailty guideline draft was discussed at CHMP organisational Matters group and concerned working parties in March. It is expected to be discussed at the Guideline coordination group and released for public consultation in October. The first draft of the geriatric GVP was finalised in Q2 2015.

1.2. Initial evaluation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Initial evaluation applications, of which:	45	43	36	52	114	112	-2	-2%
New non-orphan medicinal products	14	20	24	25	48	40	-8	-17%
New orphan medicinal products	12	9	5	8	24	24	0	0%
Similar biological products	3	2	1	6	8	9	+1	+13%
Generic products	11	7	2	11	24	26	+2	+8%
Hybrid and abridged applications	5	4	3	2	8	12	+4	+50%

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Scientific opinions for non-EU markets (Art 58)	0	1	0	0	1	1	0	0%
Paediatric-use marketing authorisations	0	0	1	0	1	0	-1	-100 %

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of applications evaluated within legal timeframes*	100%	100%	100%	99%
Average assessment time for new active substances and biosimilars (days)	205	205	-	-
Average clock-stop for new active substances and biosimilars (days)	180	142	-	-

* Includes marketing authorisation and plasma master file applications

Achievements

Objective	Activity	Achievements/results
Provide high quality, robust, scientifically sound and consistent scientific opinions to the EC	Embed the use of Effects table in all assessment reports	Effects table has been included in the assessment reports of all applications for marketing authorisation and extension of indication since February 2015.
	Implement guidance to support a consistent approach for imposed PASS/PAES	The initial list of items for monitoring as part of the pharmacovigilance indicators was developed at the beginning of 2015. Additional items for monitoring will be developed later in the year. The oversight structure for the post-authorisation studies is expected to be established later in the year.
Provide high quality, evidence-based and consistent product information that meets stakeholders' needs	Implement an improved process for the review of the product information	Roll-out of the new labelling process started in May and is expected to be completed by the end of the year.
	Initiate discussions with HTA bodies on labelling usability	Development of the principles started in March and discussions were initiated at EMA/EUnetHTA meeting in May. The principles are expected to be completed by Q4 2015.
	Strengthen existing guidance on labelling and promote the use of the guidance and advisory groups to support labelling	Guidance on labelling was updated in the first part of the year, and Q&As with updated guidance on specific SmPC

Objective	Activity	Achievements / results
	discussions during product evaluation	guideline topics published. Regular webinars to provide training for the assessors on SmPC-related matters are held.
Increase patient involvement in benefit/risk evaluation of medicines	Prepare 1-year analysis report on patient involvement in benefit/risk evaluation in CHMP	Due to insufficient number of cases of patient involvement in benefit/risk evaluation at CHMP since September 2014, analysis and the report has been postponed to 2016.
	Develop recommendations on the feasibility of convening focus groups in specific disease areas to obtain real-life data	The first focus group was held in Q2 2015 in collaboration with Melanoma Patient Network Europe and Myeloma Patients Europe, and discussed patient preferences based on a fictitious case study. Reports to CHMP and other fora were made and additional focus groups are planned to elaborate the methodology.
	Analyse the applicability of methods, including visualisation and patient values, for benefit risk assessment (2015) and publish an interim report (2016)	Survey on the necessary guidance and systems to support efficient and effective conduct of pharmacovigilance was launched in June 2015 among the participants of a PROTECT symposium held in February. The results are expected in July. Work on the report will commence in Q3 2015.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within the existing legal frameworks, including through collaboration with international partners	Deliver analysis of the use of conditional marketing authorisation concept and review changes needed regarding tools or training	Analysis of experience with the conditional marketing authorisation was presented to the EC expert group STAMP in January and, following its update, in May. Discussions with CHMP sponsors took place throughout the first half of the year, and the analysis was presented in the committee meetings in Q2 2015. CHMP draft guideline on conditional marketing authorisation was updated in the first half of the year and is expected to be adopted for public consultation at the CHMP July meeting.
	Deliver analysis of accelerated approval concept and review changes needed regarding tools and training	Analysis of the accelerated approval concept was completed in Q1 2015 and the revised guidance and templates were presented to the committees in May and June. These are expected to be released for public consultation in Q3 2015.
	Provide guidance on optimal use of the full range of available regulatory tools to	The previous pandemic preparedness plan was reviewed and transformed into a

Objective	Activity	Achievements/results
	address emerging public health threats	wider ranging preparedness plan for emerging health threats. The new plan was completed towards the end of Q2, and the composition of the internal task force was revisited and key documents updated. Implementation work will continue in the second half of the year.
	Explore with HTA bodies the opportunity for information exchange on assessments around time of licensing to support rapid relative effectiveness assessments	Following the discussions at the EMA/EUnetHTA meeting in May, the draft agreements for information exchange on assessments were sent to the EC for comments. Following the feedback, the proposal will be developed further.
Enrich the tools available to the European regulatory network to support a robust benefit-risk evaluation of human medicines throughout their lifecycle	Explore approaches and scenarios for use of individual patient data (IPD) to enhance committees' scientific assessment	Discussions with the EC began in Q2 in order to clarify the scope of this activity.

1.3. Post-authorisation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Variations applications, of which:	2,941	2,553	2,675	2,693	5,605	5,602	-3	0%
Type IA variations	1,483	1,253	1,480	1,478	2,665	2,750	+85	+3 %
Type IB variations	896	805	817	739	1,960	1,820	-140	-7%
Type II variations	562	485	370	468	980	1,032	+52	+5 %
Line extensions of marketing authorisations	8	10	8	8	18	19	+1	+6 %
Post-authorisation scientific advice requests	48	59*	n/a*	n/a	105	105	0	0%

* Separation between pre- and post-authorisation scientific advice introduced in 2014. Previous data included in the pre-authorisation scientific advice volumes

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%
Percentage of risk management plans peer-reviewed within the assessment process of variations and line extensions	100%	100%	100%	100%

Achievements

Objective	Activity	Achievements / results
Provide high quality, efficient and consistent scientific assessment of post-authorisation changes to marketing authorisations	Develop agreed high quality standards to support review PASS protocols	New process for review of non-imposed PASS protocols through scientific advice working party was developed in the first half of the year, including aspects of risk management in the scientific advice process.
Further promote use of scientific advice throughout the lifecycle of the product, including further development of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)	Implement a pilot process for review of non-imposed PASS protocols through scientific advice procedures	Joint Scientific advice working party members were nominated in June. The process for review of non-imposed PASS protocols has been developed and the pilot will commence in July 2015.
Improve the knowledge of the impact of medicines' use on environment	Update review of environmental risk assessment in submitted dossiers	The updated risk-based approach in relation to environmental risk assessment was implemented in the first half of 2015. Training on identifying environmental risk assessment issues and application of the risk-based approach in the process of assessment work was given to the EPLs in May.

1.4. Referrals

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	3	13*	25	22	15	8	-7	-

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
								47%
Non-pharmacovigilance referrals started	4	-**	-	-	13	8	-5	-38%

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

Performance indicators

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

Achievements

Objective	Activity	Achievements/results
n/a		

1.5. Pharmacovigilance activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Total adverse drug reaction reports, of which:	663,395	-	-	-	1,215,893	1,215,893	0	0%
Adverse drug reaction (ADR) reports for CAPs	458,494	-	-	-	763,534	763,534	0	0%
Number of signals peer-reviewed signals by EMA	1,354	1,095	1,400	1,106	2,000	2,000	0	0%
Number of signals validated by EMA	29	11	22	26	40	40	0	0%
PSURs received	275	302	256	288	566	566	0	0%
PSUSAs received	115	-	-	-	210	210	0	0%
Number of imposed PASS/PAES	13	21*	-	-	51	51	0	0%
Number of emerging safety issues received	19	-	-	-	20	35	15	+75%
Number of notifications of withdrawn products received	83	-	-	-	150	160	10	+7%

* New procedures established in 2014.

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of reaction monitoring reports supplied to the lead Member State monthly	100%	100%	100%	100%
Percentage of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%
Cumulative number of products on the list of products subject to additional monitoring	270	231	-	-

Achievements

Objective	Activity	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	Publish the report on the impact of the EU PROTECT project on medicines development, regulation and pharmacovigilance	Survey on the necessary guidance and systems to support efficient and effective conduct of pharmacovigilance was launched in June 2015 among the participants of a PROTECT symposium held in February. The results are expected in July. Work on the report will commence in Q3 2015.
	Launch literature monitoring service	Contract with the service provider was signed in May and the service will be launched on July 1st for 50 active substances. Further expansion to 300 substances and herbal medicines is planned in September.
	Publish Good practice guide on coding & reporting and on risk minimisation & prevention of medication errors	Following the 2 month consultation held in April-May 2015, the comments received are now being reviewed. Both good practice guides are expected to be finalised in Q4 2015.
	Develop, test and validate a Standardised MedDRA Query (SMQ) on medication errors to facilitate ICSR data retrieval as a first step in investigating drug safety issues	Council for International Organisations of Medical Sciences (CIOMS) working group developed and tested the draft SMQ in May 2015. SMQ is expected to be finalised in Q4, following the review of MedDRA Maintenance and Support Services Organisation.
	Prepare (2015) and publish (2016) a report on methods and approach for measuring pharmacovigilance impact	Draft strategy on the methods and approach for measuring pharmacovigilance impact was prepared in the 1st half of 2015, and presented to the PRAC in June. Drafting of the report started, following

Objective	Activity	Achievements / results
		the endorsement of PRAC.
	Finalise remaining GVP modules	Work on GVP modules XII (Safety related action on authorised medicinal products) and XIV (International cooperation) continued in the 1st half of the year. These are expected to be released for public consultation in Q3 and Q4 2015, respectively. GVP module XVI was amended in April.
	Publish draft code of conduct (2015) and governance proposals (2016) for vaccine benefit risk studies from the ADVANCE project	The finalised code of conduct for vaccine benefit risk studies was published on ADVANCE project website in May 2015. A lighter version of the document will be prepared in Q3 2015.
	Conduct pilot studies, based on common protocols, with a small number of Member States in the context of PRAC safety assessments (2015). Develop recommendations for a sustainable process, based on the experience gained (2016)	The overall approach to conducting pilot studies related to clinical use of medicines in Member States was agreed at PRAC in Q1 2015 and preparing draft protocols to support the conduct of pilot studies was started. The protocols are expected to be finalised in September 2015.
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through use of high quality data, information and knowledge	Deliver a PCWP/HCPWP workshop on risk minimisation tools	In the first half of 2015, the agenda of the workshop was prepared and speakers identified. The workshop is scheduled to take place in September.
	Define the scope and process of best evidence generation in the context of PRAC	The overarching approach on best evidence generation for pharmacovigilance issues was agreed with PRAC in Q2 2015. Strategy document outlining the scope and process for best evidence generation is foreseen to be finalised in Q4 2015.
	Establish a new framework procedure for the external procurement of effectiveness and pharmacoepidemiology studies on medicines	The framework contract tender for effectiveness and pharmacoepidemiology studies was finalised in April, and the contracts with the external centres are expected to be finalised by September 2015.
	Amend eRMR to include products that are subject to additional monitoring	Amendments to eRMR to include products subject to additional monitoring have been fully implemented since June 2014.
	Initiate a pilot on EU collaborative framework for Patient registries	The EU Joint Action methodological guideline was presented to the cross-committee task force in January 2015, and was being improved in the first half of 2015 to consider the comments received. Strategy for developing an EU

Objective	Activity	Achievements/results
		collaborative framework for patient registries was agreed by the task force in June 2015. The pilot is expected to start in Q4 2015.
	Analyse in collaboration with the Member States the need to update relevant guidance for the industry to reflect the use of social media and other tools in ADR reporting, considering output from the WebRADR project	Analysis of the need to update relevant guidance continued in the first half of the year, including discussion of the legal aspects relating to the use of social media and other tools in ADR reporting.
	Investigate compatibility of Applications for patient reporting developed at national level (WebRADR project) with subsequent reporting from Member States to EudraVigilance	In Q1 2015 EMA initiated work on analysing the outcome of the survey which will be used by the Member States (and EMA) to draft best practice guidances.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish report on EMA pharmacovigilance activities*	Data collection related to the indicators of the EMA pharmacovigilance system for the EC's report on EMA and Member States tasks in pharmacovigilance started in March 2015.
	Publish final report on the IMI PROTECT study of consumer reporting during pregnancy, including recommendations for action	-
	Deliver analysis from the pilot-phase conducted in 2014 on publication of Risk Management Plan summaries for newly centrally-authorised products	The pilot phase was completed in March 2015, and the results were analysed in Q2. The report is expected to be finalised in Q3 2015.

* In 2015, if reporting aligned with MS reporting. If not, report will be published in 2016

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

1.6. Other specialised areas and activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Herbal monographs, new*	6	7	4	9	15	15	0	0%
Herbal monographs, revised	1	3	4	0	10	5	-5	-

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
								50%
List entries	0	0	0	0	1	1	0	0%

* 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 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
n/a				

Achievements

Objective	Activity	Achievements/results
Implement the new Clinical Trials Regulation (EU) No 536/2014	Deliver Clinical Trials programme	Business analysis and business requirement gathering for both, EU portal and database, and safety reporting projects was carried out over the first half of 2015. Further work on the EU portal and database will be done after the decision on the workflow/case management tool is made.
Assure quality of data and appropriate protection of participants of clinical trials through risk proportionate approaches to the design and management of clinical trials, especially those conducted outside EU/EEA	Implement a standardised set of information on clinical trials to be included in applications, CHMP assessment reports and EPARs	Day 210 assessment report template was amended in the first half of 2015, to refer to GCP/GLP inspections information to be included in the report. The amended template was adopted at the June CHMP meeting.
	Implement framework for ethics experts to advise CHMP	The draft mandate of the Ethics advisory group was amended in May 2015, addressing the comments received earlier from the CHMP. In the 2nd half of the year further discussions with CHMP will be held and the criteria for the selection of the members of the Ethics advisory group will be agreed.
Facilitate development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	Deliver workshops on pharmacokinetics / pharmacodynamics of antibacterial agents and bacteriophages	The workshop was held in June 2015.
	Review the guideline for development of new tuberculosis medicines	Public consultation of the concept paper for the guideline ended in February 2015. The comments received are now being reviewed and considered for the drafting

Objective	Activity	Achievements/results
		of the guideline, which is expected to begin towards the end of 2015.
Support high level of coordinated cross-European preparedness to act upon public health threats	Finalise guideline on clinical/non-clinical development of influenza vaccines	Consultation on the guideline finished on 31 January. The comments received were discussed at the Vaccines working party and agreement on how to address them was reached in May. The guideline is expected to be completed by the end of the year.
	Finalise procedural/regulatory guidance for pandemic vaccines	The guidance was adopted by CHMP/CMDh in May 2015.
Facilitate availability of herbal medicines in the European Union	Identify remaining herbal substances requiring EU harmonisation and develop strategies/guidance to maintain up-to-date consistent standards (monograph/ guideline revisions)	2 new substances identified by the NCAs were added to the priority list for assessment in the first half of the year. Another two substances are planned to be proposed in July for adoption later in the year. Based on a survey conducted at the beginning of the year on registered/authorised herbal medicinal products in the Member States, marketed substances not yet considered for HMPC assessment were extracted. Revision of guideline on the reasons and timelines for revision of final Community herbal monographs and Community list entries and of the procedure for the systematic review of Community herbal monographs and supporting documents continued in the first half of 2015.
	Assess combination products and herbal substances originating from non-European traditional systems	Working party discussions on setting European standards for herbal combination products, including solutions for tea combinations, took place throughout the first half of the year and are expected to continue in the second half of 2015. A meeting of the EU – India joint working group was held in Delhi in May, leading to an agreement to invite an Indian expert to attend an HMPC meeting at the end of 2015 or beginning 2016. Work on 6 Indian plants has so far led to public statement. One major traditional Chinese medicinal plant was discussed twice in the first half of 2015. Publication of the draft is expected in early 2016.

2. Evaluation activities for veterinary medicines

2.1. Pre-authorisation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	2	1*	-	-	4	4	0	0%
Scientific advice requests received	10	11	19	15	30	28	-2	-7%
Requests for classification as MUMS/limited market	14	9	13	12	25	23	-2	-8%

* ITF procedure made available to veterinary products in 2013

Performance indicators

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

Achievements

Objective	Activity	Achievements/results
Provide support and incentives to development of new medicines for MUMS/limited markets	Inform companies of expiry of MUMS status of their products and possibilities for requesting extension, and review products currently classified as MUMS/limited markets whose status expires in 2015	The MUMS status of 12 products was identified to expire in 2015. 5 reminder letters of the approaching expiry of MUMS status were sent to the relevant companies in February, 6 months before status expiry (remaining 7 letters were already sent in 2014). No applicants have requested reclassification in the first half of 2015.
	Publish annual report on MUMS/limited market activities	The annual report on MUMS/limited market activities was adopted at CVMP in February and published, following its adoption at the EMA Management Board in March.
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international	Review the procedures for scientific advice to identify areas for improvement, considering the views of recipients regarding the usefulness and quality of the advice received	Work is planned to begin in 2nd half of 2015.
	Inform applicants of the possibility to apply for parallel scientific advice with the FDA,	As part of the regular process of providing scientific advice, the applicants are

Objective	Activity	Achievements/results
partners	as part of pre-submission advice	continuously informed on a bilateral basis of the possibility to receive parallel scientific advice with FDA Center for Veterinary Medicine.
Promote innovation and use of new approaches in development of veterinary medicines	Establish and start operation of the ADVENT group	Following the establishment of the ADVENT group, it held its first plenary meeting in January 2015. At its March meeting CVMP endorsed ADVENT work plan 2015 and agreed the priority topics for which guidance will be developed by ADVENT group.
	Inform industry through presentations and as part of existing pre-authorisation procedures of the possibility to access the Agency's Innovation Task Force	Innovation task Force was presented as part of the presentation on support to novel therapies, at the CVMP interested parties meeting in March and SME meeting in April 2015. ITF was also continuously promoted on bilateral basis in the pre-submission meetings and in response to individual queries. Website landing pages for ITF will be created in 2nd half of the year, to specifically refer to support for novel therapies.

2.2. Initial evaluation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Initial evaluation applications	3	7	11	3	20	14	-6	-30%
New MRL applications	2	3	3	0	5	2	-3	-60%
MRL extension and modification applications	1	1	3	2	2	2	0	0%
MRL extrapolations	0	2	0	0	1	1	0	0%
Art 9, Biocides	0	0	0	0	2	2	0	0%
Review of draft Codex MRLs	0	0	0	6	0	0	0	0%

Performance indicators

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

Achievements

Objective	Activity	Achievements/results
Provide high quality and consistent scientific opinions to EC	Put in place the arrangements necessary to facilitate multinational national assessment teams and update the register of expertise of CVMP members and experts	The multinational team concept was presented to HMA in Q1. The EMA MB amended fee-related documents to allow remuneration of multinational teams at its March meeting. 4 requests to set up multinational assessment teams were received by the end of Q2.
	Update assessment report templates to provide new guidance on the principles for preparing veterinary medicines' assessment reports and further embed benefit-risk methodology in the veterinary medicines assessment process	The guideline and scientific overview template for pharmaceuticals were discussed and revised in working parties in the first half of the year. The draft will be discussed at CVMP in 2nd half of 2015.
	Provide assessor training to ensure consistent use of the above-mentioned assessment methodology	Assessor training will be provided once the assessment report templates and guidelines are updated.
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	Provide technical support to the European Commission in drafting the implementing acts specified in Regulation (EC) No 470/2009	A request from the EC on one implementing measure was received in Q2. A first revised draft of implementation act was prepared for circulation to the July CVMP. It is expected to be sent to the Commission after adoption at the September CVMP.
	Provide technical support to the European Commission as part of the development of a Commission strategy for managing risks to the environment related to the use of medicines (both human and veterinary)	No requests for support were received in the first half of 2015.

2.3. Post-authorisation activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Variations applications, of which:	215	146	105	116	305	343	+33	+11 %
Type IA variations	115	72	44	38	150	175	+25	+17 %
Type IB variations	72	54	46	35	110	120	+10	+9 %
Type II variations	28	20	15	30	45	45	0	0%
Line extensions of marketing authorisations	2	2	3	4	5	3	-2	-40%

Performance indicators

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

Achievements

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

2.4. Referrals

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated*	3	4	9	4	12	10	-2	-17%

* 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 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%

Achievements

Objective	Activity	Achievements / results
n/a		

2.5. Pharmacovigilance activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	73	80	80	67	150	150	0	0%
Total adverse-event reports, of which:	15,383	13,000	10,139	10,047	22,500	22,500	0	0%
Adverse-event reports (AERs) for CAPs	6,949	5,282	3,731	2,440	8,000	8,000	0	0%

Performance indicators

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

Achievements

Objective	Activity	Achievements / results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high	Publish reflection papers on integration of signal detection and PSUR assessments, and promotion of pharmacovigilance reporting	A reflection paper on promotion of pharmacovigilance reporting was adopted by CVMP and published on EMA website in March. Drafting the concept paper for the revision of recommendation for the basic

Objective	Activity	Achievements/results
quality processes		surveillance of Eudravigilance veterinary data started in Q2 and is expected to be adopted for public consultation at the end of Q3 2015. The recommendation will cover topics of integration of signal detection and PSUR assessments.
	Develop a scheme for categorising products in the product database to further facilitate cross-EU pharmacovigilance	Categorisation of veterinary products will begin after analysis on ways to integrate veterinary product data in SPOR is completed.
	Revise the process for CAPs and develop a new one for NAPs for surveillance of EVVet data	Draft recommendation on pharmacovigilance surveillance and signal detection of veterinary products (both, CAPs and NAPs) was adopted by CVMP and HMA in Q2 2015. Drafting a concept paper for the revision of the recommendation for the basic surveillance of EudraVigilance veterinary data began in Q2. It is expected to be finalised by Q4 2015.
	Implement parts of the veterinary EU Telematics strategy covering pharmacovigilance elements not dependent on the new legislative proposal, including product data, data warehouse and others	The first EU veterinary medicinal product database was delivered in Q1 2015. Further work on data warehouse or other components will begin after analysis on ways to integrate veterinary product data in SPOR is completed.
	Publish reflection paper on causality assessment	Drafting of the reflection paper continued throughout the first half of the year. Adoption is expected in Q3-Q4 2015.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish the veterinary pharmacovigilance annual bulletin	The veterinary pharmacovigilance bulletin was published, following its adoption by CVMP in March.

2.6. Other specialised areas and activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
n/a								

Performance indicators

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

Achievements

Objective	Activity	Achievements/results
Support increased availability of veterinary medicines	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation	In the first half of 2015 EMA provided support to the EC during the Council Working Party meetings with answers to the questions relating to the new veterinary legislation proposal.
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Clarify the regulatory requirement for the development of new veterinary antimicrobials by providing further guidance/advice to applicants	In February CVMP adopted for consultation a Revised guidance for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and a new Draft guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals. The comments received will be incorporated in the 2nd half of 2015 and both guidelines are expected to be finalised in 2016.
	Prepare with the Commission workshop for stakeholders on advice provided by the EMA on assessment and control of the risks to man that may arise from the use of antimicrobials in animals	Work on preparing and delivering the workshop will commence in the second half of the year.
	Complete a pilot survey of antimicrobial consumption in pigs	Pilot survey was completed in January and work on the report on the pilot started in Q2. The report will be published in Q3. The methodology to measure use of antimicrobials was updated in March, based on the experience gained. The methodology will be finalised after the review of an advisory expert group in the 2nd half of 2015. In order to establish technical units of measurements (DDDA and DCDA) for veterinary antimicrobials, the working group calculated preliminary technical units of measurement in the first half of 2015.

Objective	Activity	Achievements / results
	Contribute to TATFAR recommendations related to veterinary medicines	In the first half of 2015 EMA contributed to producing the inventory of knowledge gaps in the transfer of resistance from animals to man and coordinated the work on TATFAR recommendation 18, including organised two teleconferences for the implementers in March and May.
	Produce first drafts of reflection papers on extended-spectrum penicillins and on benefit risk assessment in the case of veterinary antimicrobials	A guideline on benefit risk assessment in the case of veterinary antimicrobials was published in Q1 2015 for 6 month consultation. The guideline is expected to be finalised in 2016. Draft concept paper on extended-spectrum penicillins was prepared and will be published for consultation in Q3 2015.
Promote uptake of harmonised standards at international level	Contribute to development of the VICH Strategy (phase IV)	Drafting of the VICH Strategy (Phase IV) continued in the first half of the year. The strategy is expected to be adopted at the VICH Steering Committee meeting in Japan in Q4 2015. In April CVMP endorsed a document on generation studies to be proposed for international harmonisation.
	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	In the first half of 2015 EMA provided training at a VICH Outreach forum Training in Tanzania in June.
Contribute to minimising the need for testing of veterinary medicinal products in animals	Contribute to development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch testing of veterinary vaccines	Work on the guidance continued in the first half of 2015. A revised draft guidance was circulated at IWP in March and CVMP in April.

In addition to the activities outlined in the Agency's work programme, in Q1 2015 the EC requested a joint EFSA-EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU and the resulting impacts on food safety. Draft work plan was prepared with EFSA in the first half of the year.

3. Horizontal activities and other areas

3.1. Committees and working parties

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Number of meetings	222	187	187	221	477	437	-40	-8%
Number of teleconference meetings*	2,341	1,549	1,434	440**	3,600	4,300	+700	+19%
Number of delegates	4,240	3,686	3,548	4,035	8,900	8,300	-600	-7%

* Total audio, video and web-conference meetings
** No data on audio conferences available for data protection reasons

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of delegate satisfaction with the service level provided by the secretariat	80%	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%	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%	-**
Percentage of ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	80%	100%	88%	-**

* The survey was launched in June and the results are expected in Q3.
** New performance indicators introduced in 2014

Achievements

Objective	Activity	Achievements / results
Improve collaboration and communication between committees to increase quality, efficiency and consistency of opinions	Implement harmonised product evaluation and post-authorisation processes for human medicines committees	Implementation of harmonised processes for product evaluation and post-authorisation processes continues throughout 2015 as a follow-up from the cross-agency efficiency improvement programme that was concluded in 2014. Common templates and streamlined

Objective	Activity	Achievements/results
		process for delivering committee work plans was implemented in Q1, further strengthening interactions between the committees.
Provide up-to-date, timely state-of-art guidance documents on relevant topics of medicines' development	Improve planning and delivery of working parties guidance documents	Work to review the functioning and outputs of the Agency's Working Parties and Scientific Advisory Groups, including guidance documents, started in Q1 2015 with the review of the WPs/SAGs architecture, governance and operations.

3.2. Inspections and compliance

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
GMP inspections	350	235	259	196	390	425	+35	+9 %
GLP inspections	1	0	0	0	1	1	0	0%
GCP inspections	35	33	42	34	70	70	0	0%
Pharmacovigilance inspections	10	10	5	8	15	15	0	0%
Notifications of suspected quality defects	91	74	90	82	140	180	+40	+29 %
Other GMP inspections related notifications*	8	-	-	-	20	20	0	0%
Number of medicinal products included in the sampling and testing programme	52	5	10	5	45	52	+7	+16 %
Standard certificate requests	1,581	1,663	1,729	1,604	3,300	3,000	-300	-9%
Urgent certificate requests	447	285	159	-	450	700	+250	+56 %
Parallel distribution initial notifications received	1,423	1,226	1,268	1,199	2,550	2,600	+50	+2 %
Parallel distribution notifications of change received	1,054	744**	1,504	1,675	1,100	1,500	+400	+36 %
Parallel distribution notifications of bulk change received	8	-	-	-	10	10	0	0%
Parallel distribution annual updates received***	2,064	1,274	n/a	n/a	2,600	3,000	+800	+31 %

* Other GMP inspections related notifications previously included under suspected quality defects
** Sharp decrease due to introduction of annual updates
*** Parallel distribution annual updates introduced in May 2013

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of inspections conducted within established regulatory timeframes	100%	100%	100%	100%
Percentage of standard certificates issued within the established timelines	90%	82%	0.5%	28%
Average days to issue standard certificate	10	8	17	12.3
Percentage of urgent certificates issued within the established timelines	100%	100%	100%	100%
Percentage of parallel distribution notifications checked for compliance within the established timeline	90%	99%	97%	99.8%
Number of training activities organised in the area of inspections	4	2	2	n/a
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	25%	37%	29%	-
Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	10%	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%

Achievements

Objective	Activity	Achievements / results
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	Launch implementation of the risk-based inspections programme for 3rd country manufacturing plants of centrally authorised products, focusing EU inspectional resources to sites of highest risk	Risk-based approach to inspections has been fully implemented since Q3 2014, with the inspections programmes for each year prepared, considering the risk-based aspects.
	Identify and develop compliance and inspections activities in areas of particular interest, based on mutual reliance with trusted international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan)	Two teleconferences with FDA and WHO on the bio-equivalence initiative were held in the first half of 2015. Other compliance and inspections activities are being discussed via regular and ad hoc teleconferences and document exchange.
	Deliver training and capacity-building activities for inspectors and clinical assessors	In Q2 the online basic training course for GCP inspectors was delivered, with representatives from 31 EEA and 36 non-EU countries attending. Quality working party assessors' training was held in June 2015.

Objective	Activity	Achievements / results
		Preparations for the GCP IWG workshop and BE forum in October 2015 started in the first half of the year, including drafting the agendas and identifying speakers and participants.
	Identify, develop (2015) and implement (2016) tools for GCP related information exchange within international GCP network	In the first half of 2015 information exchange continued through regular communication channels and meetings. Preliminary contacts on expanding the collaborative framework on GCP information exchange with PMDA were established in May.
	Prepare (2015) and set up (2016) a pilot phase with FDA on sharing information on pharmacovigilance inspections	Preparatory work for an FDA fellowship for Q3 2015 was done in the first half of the year. Preliminary discussion on a pilot phase of information sharing on pharmacovigilance is expected to take place during the fellowship.
	Develop (2015) and implement (2016) tools to support pre-clinical assessors in identification of triggers for GLP inspections	The checklist of triggers for GLP inspections was adopted in February 2015. The pre-submission guidance was also amended in February to reflect the new requirements regarding GLP to be provided by marketing authorisation applicant.
	Identify, develop (2015) and implement (2016) a plan for further co-operating with Member States in co-ordinating 3rd country inspections	The re-inspection programme was re-framed in Q2 2016, to encompass inspection plans from EDQM and 3rd country inspection planning module from NCAs.
	Establish a mutual reliance framework with US FDA based on the existing mutual recognition agreements to increase the scope of EU international inspections activities	US FDA reaffirmed their support to the initiative in the first half of 2015. EMA response to FDA queries was finalised in Q1, while the EU assessment of the FDA system is still ongoing.
	Establish a mutual reliance framework with international partners performing inspections of manufacturers of active pharmaceutical ingredients and human and veterinary medicinal products	-
Maintain quality and continuity of medicines' supply chain and prevent circulation of falsified medicines	Develop procedures to link parallel distribution process with GMP procedures and allow use of parallel distribution information in the detection of falsified medicines in the supply chain	Internal discussions took place during the first half of 2015, to discuss the linkage between parallel distribution and market surveillance activities.
	Conduct lessons learnt exercise from the 2014 stolen medicines problem to further	Report “Operation Volcano” on stolen medicines was adopted by HMA in May

Objective	Activity	Achievements / results
	reflect on how the Network can address similar future threats to the supply chain	2015. The lessons learnt exercise will build on the report and the learnings identified in the report.
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects	Identify (2015) and implement (2016) process improvements on the handling of quality defects and non-compliance issues	The recording steps and tracking tool for quality defects were redesigned in Q2 2015. Updating the report form and related SOP will start towards end of the year.
	Research the root causes of quality defects and GMP non-compliance leading to shortages of human medicinal products	The spreadsheet template was re-designed in Q2, to facilitate reporting and analysis of root causes of quality defects. Work on a catalogue of root causes also started in Q2 2015.

3.3. Partners and stakeholders

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Requests for SME qualification	499	270	236	456	550	800	+250	+45%
SME status renewal requests	139	103	119	69	1,200	1,200	0	0%
Requests for access to documents	333	152	176	109	400	550	+150	+38%
Documents released following requests for access to documents	1,557	534	-	-	1,000	2,500	+1,500	+150%
Requests for information	2,338	2,313	3,031	2,614	6,000	4,500	-1,500	-25%

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Satisfaction level of SMEs	80%	92%	-	-
Percentage of responses to ATD requests provided within set timelines	99%	93%	-	-
Percentage of responses to RFI requests provided within set timelines	98%	99%	-	-

Achievements

Objective	Activity	Achievements / results
Enhance cooperation within European medicines regulatory network	Develop common vision and strategy 2016-2020 for the EMA and Member States	Draft EU network strategy was adopted in March for 3 month public consultation, ending 30 June 2015. The final strategy is expected to be adopted by HMA in October and EMA Management Board in December 2015.
	Publish report on experience so-far on coordination of safety announcements, including outcomes of the survey on the use of 'Early Notification System' by NCAs	Surveys to provide information for the report (audit of communication practices by NCAs as part of SCOPE project and EMA communication perception survey) were concluded in the Q2 2015. Drafting the report will begin in Q3, once the results of all surveys are analysed.
	Establish an EU Network Training Centre	The interim platform for the network training centre was launched in January. Training activities for 2015 were mapped and the communication strategy and stakeholder engagement plan were developed. Processes for daily operation of the centre were also designed, and guideline for reimbursement of the training events by the EU NTC was prepared.
	Complete initiative to collect procedure-related time data	The pilot project gathering data on scientific advice/protocol assistance started in January and has achieved high rate of reporting from the network and EMA secretariat. The management Board extended the scope of the initiative to include veterinary procedures in March 2015. The current pilot study is due to finish in August. It is anticipated that additional data gathering will be initiated in Q4 2015 across a number of other major fee-generating procedures and later extend to non-fee generating procedures.
	Expand implementation of multinational teams' concept	Pilot scheme covering co-rapporteur team for initial marketing authorisation applications for human medicines has been formalised. Following earlier extension of the scheme in 2014 to rapporteur teams for initial MA applications for human and veterinary medicines, co-rapporteur teams for initial MA applications for veterinary medicines,

Objective	Activity	Achievements / results
		it was also extended to scientific advice procedures for human and veterinary products in Q2 2015. Guidance to rapporteurs and coordinators was finalised in June 2015. Template letters and SOPs are being revised to include the multinational assessment teams' concept.
Further strengthen Agency's transparency and open data commitments	Develop the EMA Transparency policy	Work on transparency policy will begin in Q3 2015.
	Develop (2015) and implement (2016) necessary processes for clinical data publication, including processes for document receipt, redaction consultation and decision, public access process and others	Business processes were developed and approved in June and work on IT solution will begin in Q3 2015. Drafting guidance documents for the pharmaceutical industry began in March and is expected to be finalised in October.
	Initiate stakeholder consultation (2015) and develop methodology (2016) for preventing identification of individuals in clinical reports	Draft guidance on anonymisation of individuals in clinical reports was prepared in the first half of the year, and targeted consultation with academics, pharmaceutical industry, NGOs and patients' organisations started in June.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency work, outputs and medicinal products	Publish EMA guidance on product-related communication' indicating to partners and stakeholders 'when' and 'what information' the EMA publishes on medicines	Work on the guidance is planned to start in August.
	Review communication products to streamline Agency information outputs	Preliminary discussions on the scope of Agency's communication product review started in Q2. The review will start after the analysis of the results of the EMA perception survey.
	Develop and agree with HMA a strategy paper on European Web Portal	The results of the Member States' survey (conducted in October 2014) were discussed at the HMA meetings in February and May and in the Telematics Management Board in June. Updating the strategy paper, to account for the results of the survey, will commence in August.
	Deliver analysis on information needs of different stakeholders regarding the Agency's scientific output (2015). Review Agency's communication tools as per the results of the analysis (2016)	EMA communication perception survey was carried out in February 2015. The analysis of the results will be presented to the Agency's management in September.
Strengthen stakeholder relation focusing on patients and	Implement the stakeholders' relations management framework	Draft principles for EMA Stakeholder relation management were finalised for internal approval in May 2015.

Objective	Activity	Achievements / results
consumers, healthcare professionals, industry associations and academia	Implement the revised EMA framework of interaction with patients and consumers' organisations	Pilot phase on involvement of patients in benefit-risk evaluation continued in the first half of 2015.
	Conduct satisfaction survey on healthcare professionals' involvement in EMA activities	The survey was completed in Q1 2015, and the results will be presented to the Management Board in October.
	Survey the SME stakeholders and prepare 10 year report	SME survey was updated in Q2 and will be sent to SMEs and all stakeholders, as well as published on EMA website in July.
	Develop (2015) and implement (2016) framework for collaboration with academia	Internal survey on the current EMA collaboration with academia – needs, expectations and development of the framework was completed in the first half of the year. Brainstorming discussion on the collaboration with academia was also held during HCPWP meeting in June. Development of the framework is expected to start in the second half of the year.
	Implement (2015) framework for interacting with industry stakeholders and conduct survey to monitor the progress (2016)	The framework for interactions with industry stakeholders was resent to the EC for inter-service consultation in June. Following the comments from the EC, the framework is expected to be adopted by the EMA Management Board in December 2015.
	Publish annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations	Drafting of the report began in January 2015 and it is expected to be finalised in Q3, for presentation to the EMA Management Board in October and publication afterwards.

3.4. International activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
n/a								

Performance indicators

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

Achievements

Objective	Activity	Achievements / results
Enhance international cooperation activities to increase efficiencies and synergies through greater work-sharing	Implement strategy to enhance cooperation between regulators in the field of paediatric medicines	SOP for common commentaries was agreed between FDA Office of Pediatric Therapeutics and the EMA paediatric office, and was published on the FDA website in June. TIGRE initiative (Team of International Global Rare Disease Experts Working Group (TIGRÉ Working Group)) was started in the first half of the year, and support to develop it within the paediatric cluster was expressed by both sides at the June FDA/EMA/EC bilateral. Following a teleconference in 2014 on increasing collaboration, FDA has been actively participating in the internal EMA extrapolation working group during 2015, and is invited to take part in the EMA extrapolation workshops in September 2015 (and May 2016).
	Implement pilot information sharing on generic medicines	The IGDRP pilot for sharing generic medicines' assessment reports was extended to centralised products in January 2015. A call for expression of interest for the applicants was launched in January. 3 companies have expressed their interest to participate in the pilot.
	Increase involvement of non-EU regulators in assessment activities as observers to further develop Article 58 as a capacity building opportunity	WHO-nominated experts/observers from Ghana and Tanzania participated in the Article 58 procedure for malaria vaccine Mosquirix. In addition, EMA together with the EC and Bill & Melinda Gates Foundation, with the support of external consultants, carried out a strategic review of the use, role and vision of its Article 58 scientific opinion.
	Finalise confidentiality arrangements with WHO and other international partners	EC/EMA – Swissmedic confidentiality arrangement on exchange of non-public information relating to medicines for human and veterinary use was finalised in the first half of 2015, and is expected to be signed and come into force in July 2015. EC/EMA – WHO confidentiality arrangement on exchange of non-public information relating to medicines for human use was finalised in the first half of

Objective	Activity	Achievements/results
		the year, and is expected to be signed in Q3.
Support the development of a strategic global vision and oversight of international activities	Map the progress of international initiatives to identify gaps and duplications	Analysis of the various incentive packages offered by different international regulators to encourage pharmaceutical R&D innovation was completed in February 2015. Mapping of the interactions with FDA and PMDA within the new organisational structure of EMA was completed in March-April this year.

3.5. Data management support

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
n/a								

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of substance data registered in 4 working days	75%	90%	n/a*	-
Percentage of substance data registered in 8 working days	90%	97%	n/a*	-
Percentage of calls reopened due to incorrect handling	<3%	1%	2.7%**	-
Percentage of stakeholders satisfied with service level of data management services	80%	n/a	n/a	-

* Q2 2014 results incomparable due to change in indicator in 2015
** Data only available for June 2014

Achievements

Objective	Activity	Achievements/results
Engage the Agency's stakeholders in the governance of data and promote a wider and deeper understanding of the value of data assets	Consolidate the EU Network Data Board (EUNDB)	The EUNDB has been consolidated as a key group for the implementation of the ISO IDMP in 2015. Additional 4 NCAs joined the group in the first half of 2015, bringing additional relevant experience to the group.
	Establish the IDMP Implementation	ISO IDMP Implementation working group

Objective	Activity	Achievements / results
	Working Group with EMA and NCAs	(task force) was established in March and the Terms of Reference were agreed by the task force in June 2015 and will be reviewed by Data integration steering committee in Q3. In order to increase efficiency, subgroups to discuss the four individual SPOR domains were created and started working in April.
	Develop and implement common policies, procedures and standards to maximise the sharing and optimise investment in data	The next version of HL7 SPL message which will carry all the EU requirements in line with ISO IDMP DTSs was sent out for ballot in June. Following the comments it is expected to end the ballot before the end of 2015. Discussions with CDISC and FDA started in June, on the way to integrate ISO IDMP in the clinical trial data model and to assess feasibility of ad-hoc, CDISC or HL7 based message for exchanging clinical trial data.
	Develop and implement appropriate security and privacy policies to protect data assets	Identity and access management (IAM) project started in January 2015. During the first half of the year the Agency's IAM strategy and roadmap were defined, IAM solution was selected and IAM processes were analysed and designed. The implementation of the selected IAM solution is planned to start in October. Review of the Agency's Security policy for internal and external users started at the beginning of 2015. It is expected to be finalised and approved in September.
Increase consistency of information shared across the EU Network	Develop an end-to-end process map to integrate data flow across all systems (PhV, regulatory submissions, xEVMDP, etc.)	The principles of the EU implementation strategy for the MDM solution, including the target operating model, were drafted in Q2 2015, and will be presented to HMA in July. Once the EU implementation roadmap is finalised, end-to-end process maps for data flow integration across systems will be developed.
	Analyse (2015) and implement (2015-2016) ISO IDMP roadmap with EU NCAs and industry	Work on EU IDMP Roadmap started in May 2015, and builds on the EMA roadmap, that was adopted in March. The first proposal of a high level EU IDMP Roadmap (with a phased implementation) was agreed at the ISO IDMP task force in June and presented to the IT directors and EU

Objective	Activity	Achievements/results
		Telematics Management Board at the end of June.
Ensure effective decision making in the EU regulatory network by providing access to more analytical data	Develop and provide metrics and dashboards to EU NCAs on the state of the EU data management performance	NCA dashboard was updated in June to include data on human medicinal products as per NCA requirements. eRMR pilot phase to test methodological updates proposed by SMART MS 2-3 started in Q2 2015. And will end in September. Implementation of a new report using Article 57 data started in May and is expected to be completed in August. The 'Article 57 publication dashboard' is planned to be made available to NCAs in October 2015.

4. Support and governance activities

Workload indicators

Procedure	2015 Q1 – Q2	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2015 annual forecast Initial	Revised	Change	
Requests for interviews and comments by media representatives	1,080	-	-	-	3,000	2,000	-1,000	-33%
Number of press releases and news items published	102	-	-	-	240	180	-60	-25%
Number of reports, brochures, leaflets produced	7	-	-	-	6	8	+2	+33%

Performance indicators

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Percentage of posts on the Agency establishment plan filled	97%		97%	93%
Percentage of revenue appropriations implemented	97%		44.3%	47.5%
Percentage of expenditure appropriations implemented	97%		65.5%	71.7%
Percentage of payments against appropriations carried over from year N-1	97%		86.3%	79.9%
Percentage of payments made within 30 days' time	97%	100%	97.4%	-*

Performance indicators related to core business	Target 2015	Outcome at the end of Q2 2015	Q2 2014	Q2 2013
Satisfaction level of partners / stakeholders with EMA communications	80%	84% / 87%		
Media articles covering key messages of EMA press releases:				
At least one key message	95%	100%	-	-
At least two key messages	70%	100%	-	-
Quote included	60%	n/a**	-	-
Telematics and corporate IT systems availability against Agency working hours	98%	100%	99.5%	99.4%
ICT Service Desk: meeting of service-level agreements (SLAs) per system/priority level:				
Critical (resolution time: 4 hours)	80%	n/a	45%	31.8%
Severe (resolution time 1 business day)	80%	80%	46.5%	31.3%
Important (resolution time 10 business days)	80%	91%	74.8%	89.1%
Minor (resolution time 120 business days)	80%	99%	99.7%	99.4%

* 2013 results not comparable due to change in indicator (30 days vs 45 days' timeline in 2013)
** no quotes were included in press releases

Achievements

Objective	Activity	Achievements / results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Review IT operating model	Work is planned to take place during Q3 2015.
	Develop a corporate communications strategy 2015-2020	Internal discussions on the concept, scope and approach for the corporate communication strategy started in June.
	Select a new media monitoring and press office software management tool	Gathering business requirements for a new media monitoring tool started in Q1 2015 and is expected to be completed in Q3.
	Develop (2015) and implement (2016) electronic documents / records' management strategy	Work on the first draft of an Information Management strategy started at the beginning of 2015. The strategy is expected to be finalised before the end of the year.
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	Implement the policy on handling of conflicts of interest of scientific committees' members and experts	The revised policy on handling of conflicts of interests of scientific committees' members and experts entered into force on 30 January 2015. All experts in the EMA Experts database were reminded to submit an up-to-date declaration of interests in the revised format before the implementation date. The DoIs of experts involved in EMA activities after the

Objective	Activity	Achievements / results
		implementation date were evaluated against the revised policy. An impact assessment of the revised policy on the scientific committees was prepared for internal use. Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company was published in May. A revised EMA breach of trust procedure on conflicts of interests for scientific committee members was also adopted and published in May 2015.
	Implement antifraud strategy, including internal processes on reporting alleged fraud instances and anti-fraud office	As part of the activities to implement Agency's anti-fraud strategy, an Antifraud office was established in February 2015. Internal survey of senior management was conducted in February-April, benchmarking the antifraud awareness, and development of a mandatory antifraud e-learning course for all staff started in June. The course is planned to be launched in October. Standard procurement contracts were also amended in Q1, to include antifraud clauses. Work on internal reporting processes and templates will start in Q3.
	Develop and implement whistle-blower policy	Whistle-blower policy draft was prepared during the first half of 2015, and discussed with the Commission. Following the revision of the draft policy, further response from the Commission is awaited before finalising the policy. It is expected that the policy will be adopted before the end of the year.
	Revise (2015) and implement (2016) the conflicts of interest policy for Management Board members and EMA employees	Guiding principles for a revised policy were discussed at the EMA Management Board June meeting and topic coordinators were appointed. The revised policy is expected to be adopted by the Management Board in December.
	Develop (2015) and implement (2016) a policy on public consultations	Guiding principles for the policy on public consultations were established.
Highlight the public and animal health	Launch campaign on the 20th anniversary of the inauguration of the Agency	20th anniversary scientific conference was held on 18 March 2015. EMA 20th

Objective	Activity	Achievements / results
contribution of the Agency and the whole European medicines network in recognition of 50th anniversary of pharmaceutical legislation in Europe and 20th anniversary of the Agency		anniversary booklet, capturing the important progress in regulatory science and societal changes in the field of medicines regulation, as well as achievements of EMA in fulfilling its mission over the past two decades, was published and presented at the conference. Celebration of the 20th anniversary of the Agency with partners, stakeholders and staff was organised on 26 January 2015. Series of monthly events, including panel discussions and lectures on topical issues related to the work of EMA were organised in the first half of 2015 and will continue until the end of the year.

Annexes

Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
Art	article
ATD	access to documents
ATMP	advanced-therapy medicinal product
BE	bioequivalence
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CDISC	Clinical Data Interchange Standards Consortium
CHMP	Committee for Medicinal Products for Human Use
CIOMS	Council for International Organisations of Medical Sciences
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
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
DoI	declaration of interests
DTS	Draft Technical Standards
eAF	electronic application form
EC	European Commission
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
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPL	EMA product lead
eRMR	Electronic reaction monitoring reports
EU	European Union
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUGenMed	European Gender Medicine Network
EU NDB	EU Network Data Board
EUnetHTA	European network for health technology assessment

Term / abbreviation	Definition
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVVet	EudraVigilance veterinary
EVMDP	EudraVigilance Medicinal Product Dictionary
FDA	United States Food and Drug Administration
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HCPWP	Healthcare Professionals Working Party
HL7 SPL	Health Level 7 Structured Product Labelling
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
IAM	identity and access management
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	individual case-safety report
ICT	information and communication technologies
IDPM	Information Day on the New Identification of Medicinal Products
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
IPD	Individual patient data
IT	information technology
ITF	Innovation Task Force
ISO	International Organisation for Standardisation
IWG	inspectors working group
IWP	Immunologicals Working Party
MA	marketing authorisation
MAH	marketing authorisation holder
MB	Management Board of the EMA
MDM	master data management
MedDRA	Medical Dictionary for Regulatory Activities
Member State (MS)	Member State of the European Union
MLM	medical literature monitoring
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NGO	Non-governmental organisation
NTC	EU Network training centre
OMS	Organisations management service
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency
PMS	Product Data Management Service
PRAC	Pharmacovigilance Risk Assessment Committee
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSMF	Pharmacovigilance System Master Files
PSUR	periodic safety-update report

Term / abbreviation	Definition
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
OPPV	Qualified Persons for Pharmacovigilance
Q&A	questions and answers
RFI	request for information
RMS	Referentials management service
SA	scientific advice
SAG	Scientific Advisory Group
SCOPE	'Strengthening Collaboration for Operating Pharmacovigilance in Europe' project
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SME	small and medium-sized enterprise
SPOR	Substances, Products, Organisations, Referentials
SmPC	summary of product characteristics
SMQ	Standardised MedDRA Query
SOP	standard operating procedure
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
SUSAR	serious unexpected suspected adverse reaction
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TIGRE	Team of International Global Rare Disease Experts initiative
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WHO	World Health Organization
WP	working party