EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Mid-year report

January–June 2014

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 2 October 2014.

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Explanation of symbols used in this document

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

Workload indicators	
	Results more than 10% above 2013 result
	Results within +/-10% of the 2013 result
	Results 10%~25% below the 2013 result
	Results more than 25% below the 2013 result
	New indicator/previous information not available/no activity

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

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

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

Highlights

This report describes the results and achievements of the Agency during the first six months of 2014 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 have **increased by 16%** as compared to the same period in 2013.
- ✓ Number of **orphan designation** applications reached 138, a **30% increase** over results in Q1-Q2 2013.
- ✓ **Paediatric procedure applications** have also seen a slight **increase (8%)**.
- ✓ **Requests for ATMP classification** reached 13 in Q1-Q2 2014. Whilst remaining on **similar level** as in 2013, the annual forecast has been revised upwards.
- ✓ The Agency sees **stable trends in initial evaluation applications**, with 43 applications received in Q1-Q2 2014, an **increase of 19%** over Q1-Q2 2013. This increase is mostly due to higher number of generics applications received. As a result, the **annual forecast** for initial applications has been **revised upwards** to 118 (from initial forecast of 88).
  - New **orphan medicinal product applications** saw an **increase** to 9 applications (from 5 in 2013) in the first six months of 2014, thus returning to the level of applications in 2011~2012. At the same time, number of new **non-orphan medicinal product applications** received by the end of Q2 2014 has **fallen slightly**, as compared to end of Q2 2013 (20 vs. 24).
  - **Similar biological medicinal product applications** remain at the **same low level** as in 2013. Likewise, number of **hybrid and abridged applications** remains at the **same level** as in the previous year.
  - Following very low activity in 2013, the **generic products** have seen a **jump in applications** with 7 applications received in 2014, vs. 2 in Q1-Q2 2013. Increasing industry activity in the field of generics has led to a revised annual forecast, up from 6 to 30 applications received by the end of 2014. This ***upsurge is not expected to continue*** beyond 2014 and the generic application volumes are expected to return to usual levels in the coming years.
- ✓ Number of **type IA** variations has **decreased** slightly, while **type IB** applications have **remained** at the same level as in 2013.

- ✓ **Type II** variations have **increased** in Q1-Q2 2014 (**30%** increase over same period in 2013), reaching the level of type II variations in first half of 2012.
- ✓ Number of **referrals** initiated in Q1-Q2 2014 has **fallen by half** (13 vs. 25) and the annual forecast has been revised accordingly (to 28 from 55). However, this is only a reflection of the legislation changes and the grouping of CAPs and NAPs in the same procedure. The actual workload has remained at the forecasted level.
- ✓ The number of both, the reviewed and validated signals is lower than it was in the same period in 2013. **Reviewed signals** have **decreased** by **22%**, while the **validated signals** have **fallen by half**. The annual forecasts have been revised accordingly.
- ✓ After slightly lower results in first half of 2013, the number of **PSURs received** has returned to the **levels of 2011~2012**, reaching **302 PSURs received** in the six months of 2014.
- ✓ Number of **new herbal monographs** has **increased slightly** (7 vs. 4), whilst number of **revised herbal monographs** has **remained** at the **same level** (3 vs. 4) as in first half of 2013. **1 public statement** was **finalised** in Q1-Q2 2014.
- ✓ Main **performance indicators** related to assessment activities for human medicines have been met.

Assessment activities for veterinary medicines

- ✓ After an exceptional year in 2013, veterinary medicines assessment activities are gradually returning to the regular levels of activity. While this manifests as a decrease in number of applications received in most areas, this should only be regarded as return to usual activity levels and not as a negative longer-term trend.
- ✓ **Scientific advice** requests for veterinary medicines have **decreased by 42%** as compared to the same period in 2013; however this is in line with the forecasts for lower activity after the exceptional 2013.
- ✓ Requests for **MUMS classification** are **slightly below** the level of Q1-Q2 2013.
- ✓ The number of **initial applications** received has **decreased** to 7 (vs. 11 applications by the end of Q2 2013).
- ✓ **New MRL applications, extensions, modifications and extrapolations** have overall remained at the **same level** as in 2013.
- ✓ **Variations applications** saw an **increase** in the first half of 2014, as compared to the same period in 2013: **type I** applications increased to 126 (a **40% rise**), and **type II** applications reached 20 (a **33% increase**). This increase is in line with the annual forecasts.
- ✓ **Referral procedures** initiated have **fallen** to 4, returning to the level of Q1-Q2 2012.

- ✓ The number of **PSURs** has remained at the **same level** as Q2 2013, while number of **adverse event reports** has **increased** in line with the forecasts.
- ✓ Main **performance indicators** related to assessment activities for veterinary medicines have been met.

Inspections and compliance

- ✓ The number of **pharmacovigilance inspections** has **doubled** as compared to 2013, reaching 10 in the first half of 2014.
- ✓ The number of **GMP** and **GCP inspections** has **decreased** (9% & 22%). **Additional 29%** of **GCP inspections** were **addressed through information exchange** on inspections carried out by international partners.
- ✓ **No GLP inspections** were requested in Q1-Q2 2014.
- ✓ Number of **standard certificates requests** has **decreased** slightly (4%) with the uptake in urgent certificates requests.
- ✓ **285 requests** for **urgent certificates** were received in the first half of 2014, an **80% increase** over Q1-Q2 2013. Considering the popularity of this service, the annual forecast has been revised upwards.
- ✓ The number of **parallel distribution initial notifications** remains **steady**.
- ✓ With the introduction of parallel distribution annual updates to simplify and converge the high number of change notifications in 2013, the number of **parallel distribution notifications of change** has **fallen significantly** (51%). **1,274 parallel distribution annual updates** were received in the first 6 months of 2014.

Key achievements

- ✓ One year report on human medicines pharmacovigilance tasks of the European Medicines Agency was published on 20 May 2014.
- ✓ The revised EMA policy on handling of conflicts of interests of experts was adopted by the Management Board in March 2014. The e-DoI form and guidance documents are currently being updated in line with the revised policy, and the implementation for the revised policy and updated e-DoI form is scheduled for 1 October 2014.
- ✓ The pilot project on adaptive licensing was launched in March, and 9 proposals were reviewed in depth during the first round of candidate review in June.
- ✓ During the 1st half of 2014, the Agency started preparing for the implementation of the upcoming Clinical Trials Regulation. This included formal initiation of the Clinical Trials Regulation programme, which includes 4 projects (Pre-inception; EU Portal and Database, including Workspace; Safety Reporting

and EudraCT; and EU-CTR legacy). Main focus was on the pre-inception project which delivers business cases for all the other projects within the programme.

- ✓ Work on EU Portal and Database for submission and regulatory management of clinical trials, commenced at the end of Q2, following publication of Clinical Trials Regulation on May 27, 2014. First meeting with stakeholders to discuss the requirements for these systems took place in June.
- ✓ In regard to finalising the EMA policy on publication of clinical data, 3 targeted stakeholder meetings were held in May, to further clarify and fine-tune the proposed policy. The draft policy was presented to the Management Board at its June 2014 meeting. The MB agreed to the policy in principle, but asked for the policy to be finalised through written procedure. As several comments were received during the written procedure, adoption is now postponed to October Management Board meeting.
- ✓ Business requirements for enhanced EudraVigilance system functionalities were finalised in May. Implementation of the requirements will start in second half of the year, with the functionalities being implemented progressively over the next two years.
- ✓ Business requirements for essential auditable requirements for the PSUR repository were finalised in Q2 2014. The repository is now in the development phase, on target for delivery by January 2015 to be ready for audit.
- ✓ Draft guideline on literature monitoring for case reports to be entered in EudraVigilance was prepared and published for a 2-month public consultation in June. Following assessment and implementation of comments, the guideline is expected to be finalised in Q4 2014.
- ✓ 21 research proposals were submitted to IMI in January 2014, to support addressing public health needs with corresponding research.
- ✓ The EMA Innovation Task Force considered its first veterinary product in Q1 2014, since the procedure was made available to veterinary products in 2013.
- ✓ Draft responses to the remaining three of four questions of the European Commission related to the risk to man from the use of antimicrobials in veterinary medicine were finalised by the Antimicrobial Advice ad hoc Expert Group in June. These are expected to be adopted by CVMP and CHMP in July, and the final responses sent to the EC after the public consultation.
- ✓ A progress report on the TransAtlantic Task Force on Antimicrobial resistance (TATFAR) work was published in May, recording good progress in 15 out of 17 recommendations, and the addition of a new recommendation to identify knowledge gaps in the area of limiting transmission of resistance from animals to man.
- ✓ Due to the Court Cases there were many rejections for access to documents requests which is reflected in the significant reduction of the number of pages released.

- ✓ The EU Telematics Strategy was adopted by the EU Telematics Management Board in May and endorsed by the EMA Management Board in June. It is expected to be endorsed by Heads of Medicines Agencies in July.
- ✓ In order to set up the EU Network Training centre, the mandate of the Training Centre was endorsed by the Agency management team in March and by HMA in May. The vision, road map and project plan of the Training Centre have been developed and will be presented to the HMA at the November meeting.
- ✓ The project to relocate the Agency to new premises continued according to plan in 2014. The fit-out of the new premises was completed in the first half of the year and the pilot move was carried out on June 16. Premises were practically completed on July, 1, as planned. The first move is planned for July 2 and last move will take place on July 30, with the Agency fully relocated on August 1.
- ✓ In order to increase efficiency of project management, control and delivery in the Agency, new project governance structure was put in place and a Programme Management Office was established in April 2014.
- ✓ Following an extensive bottom-up exercise involving all staff of the Agency, a set of core EMA values was selected in February. The new core values were launched in May, with implementation activities planned for the 2nd half of the year.
- ✓ Budget situation at the end of June is in line with expectations. 44% of revenues were registered and 65.5% of expenses were committed as of 30 June 2014.
- ✓ 76.4% of the EU special contribution for orphan medicines was used in the first half of the year.

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Scientific-advice and protocol-assistance requests, of which:	216 (275)*	237	258	223	357	Unchanged	0	0%
Joint scientific advice with HTA bodies	6	1	3	3	10	Unchanged	0	0%
Parallel scientific advice with international regulators	1	3	2	6	4	Unchanged	0	0%
Designation of orphan-medicine applications, of which:	138	106	103	79	213	Unchanged	0	0%
Parallel orphan designations with international regulators (applications)	47	25	22	42	120	Unchanged	0	0%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	234	215	212	206	485	Unchanged	0	0%
Requests for classification of ATMPs	13	12	11	7	15	20	+5	+33%
Innovation Task Force briefing-meeting requests	12	n/a	n/a	n/a	30	Unchanged	0	0%
Innovation Task Force Art 57 CHMP opinion requests	4	n/a	n/a	n/a	10	Unchanged	0	0%

* In 2014 scientific advice and protocol assistance are split in pre-authorisation and post-authorisation. Total number of SA and PA requests in Jan-Jun 2014 was 275, with 216 of requests received in pre-authorisation phase

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Outcome at the end of Q2 2013
Percentage of scientific procedures completed within regulatory timeframes*	100%	99%**	99%
Percentage increase in scientific-advice requests	9%	16%	-

* This includes scientific advice and protocol assistance, orphan designation and paediatric procedures, as well as recommendations on ATMP classification
** 5 PIP/waiver decisions signed after legal deadline due to regulatory/legal issues.

Achievements

- ✓ As part of developing framework that would satisfy the needs of the EMA, regulators and HTA bodies, exchange of guidelines for mutual input started in early 2014.
- ✓ A report on the first European collaboration between regulators and HTA organisations, underlining the relevance of EMA/HTA collaboration was prepared by the EMA and representatives of EUnetHTA. The article, titled "Improving the Contribution of Regulatory Assessment Reports to Health Technology Assessments—A Collaboration between the European Medicines Agency and the European network for Health Technology Assessment" was published in Value in Health, the Journal of The International Society for Pharmacoeconomics and Outcomes Research in June.
- ✓ To increase engagement of HTA bodies in the lifecycle of medicines, guidance on HTA procedure was prepared and published for consultation in April 2014.
- ✓ The pilot project on adaptive licensing was launched in March, and 9 proposals were reviewed in depth during the first round of candidate review in June. Another round of review and discussions with the selected candidates will take place in Q3.
- ✓ 21 research proposals were submitted to IMI in January 2014, to support addressing public health needs with corresponding research.
- ✓ Common application form with FDA for qualification of novel methodologies was finalised in June.
- ✓ In the area of collaboration on nanotechnologies, a meeting with US-EU NCL, JRC and EC was held in June, in order to share experience with US-NCL and facilitate the EC decision on the establishment of an EU-NCL.
- ✓ The EMA organised and chaired a webinar of International Regulators on Nanomedicines in May. Participants included FDA, Health Canada, MHLW, TGA and Swissmedic. Webinar focused on exchange of on-going and submitted MAA and major issues discovered; international definition of nanotechnology and nanomedicines; and agreement on draft rules for participation of additional regulators in the exchange forum.

1.2. Initial evaluation activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Initial evaluation applications, of which:	43	36	52	49	88	118	+30	+34%
New non-orphan medicinal products	20	24	25	15	47	48	1	+2%
New orphan medicinal products	9	5	8	8	23	Unchanged	0	0%
Similar biological products	2	1	6	0	4	5	1	25%
Generic products	7	2	11	21	6	30	+24	+400%
Hybrid and abridged applications	4	3	2	4	6	10	4	67%
Scientific opinions for non-EU markets (Art 58)	1	0	0	0	1	Unchanged	0	0%
Paediatric-use marketing authorisations	0	1	0	1	1	Unchanged	0	0%

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Q2 2013
Percentage of applications evaluated within regulatory timeframes	100%	100%	99%

Achievements

- ✓ The first product targeting a nonsense mutation in Duchenne Muscular Dystrophy, Translarna, was granted a positive opinion by CHMP in May.
- ✓ Proposal on a pilot for further integrating patient values in benefit-risk evaluation was agreed upon at CHMP in Q1. The pilot will start in September.

- ✓ As part of implementing updated benefit-risk assessment methodology, use of the Effects Table was piloted in first half of 2014, and used for 12 products, from D80 AR to D120. Detailed guidance on Effects Table was developed, based on the feedback from the pilot. Decision on further implementation of the Effects Table is expected at the September CHMP.
- ✓ Draft guideline on the investigation of subgroup analyses in confirmatory clinical trials was published for public consultation in January. The guideline is expected to be finalised and published in 2015. Biostatistics Working Party (BSWP) also commented on a number of therapeutic area guidelines, in regards to biostatistical input in the review process.
- ✓ Reflection paper on comparison of methods to assess analytical biosimilarity was being drafted, and information exchange between BSWP and FDA was initiated on this topic in June.
- ✓ The test run of the project on improving data scrutiny was completed in Q1.

1.3. Post-authorisation activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Extensions and variations applications, of which:	2,553	2,675	2,693	2,498	5,592	5,104	-488	-9%
Type-IA variations	1,253	1,480	1,478	1,547	2,880	2,506	-374	-13%
Type-IB variations	805	817	739	558	1,498	1,610	+112	+7%
Type-II variations	485	370	468	386	1,196	970	-226	-19%
Line-extensions of marketing authorisations	10	8	8	7	18	Unchanged	0	0%
Post-authorisation scientific-advice requests	59*	n/a*	n/a	n/a	125	Unchanged	0	0%

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

Performance indicators

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

Achievements

- ✓ In order to develop a guideline on post-authorisation efficacy studies, a Rapporteurs' group from PRAC/CHMP/CMDh was formed in June. Preliminary discussion of the guideline took place at the CHMP Informal in May. Following consultations with the rapporteurs and the EC, agreement on the structure and scope of the guideline was agreed upon in June. The guideline is expected to be completed in Q2 2015.
- ✓ Exploring the use of various data sources, the collection of additional data on European data sources on drug consumption (with integration of additional countries) continued over the first half of the year. This will be published in Q4 2014, in the 3rd revision of Drug Consumption inventory.
- ✓ Risk Management Plan summaries for newly authorised medicines are being published since March 2014, as part of one year pilot.
- ✓ The business process for type II variations was redesigned in Q1. The remaining processes for assessment of major changes to marketing authorisation will be reviewed and implemented in Q3 2014.
- ✓ Systematic peer review of environmental risk assessment for all centralised procedures has been implemented since January 2014.

1.4. Arbitration and referrals

Workload indicators

Procedure		2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
	Arbitrations and Community referral procedures initiated	13*	25	22	27	55	28	-27	-49%

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

Performance indicators

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

1.5. Pharmacovigilance activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Reviewed signals (for CAPs)	1,095	1,400	1,106	876	2,500	2,100	-400	-16%
Validated signals	11	22	26	33	55	35	-20	-36%
PSURs received	302	256	288	300	490	530	+40	+8%
PASS/PAES	21	n/a*	n/a	n/a	35	41	+6	+17%

* PASS/PAES are new procedures established in 2014

Performance indicators

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

Achievements

- ✓ One year report on human medicines pharmacovigilance tasks of the European Medicines Agency was published on 20 May 2014.
- ✓ Business requirements for enhanced EudraVigilance system functionalities were finalised in May. Implementation of the requirements will start in second half of the year, with the functionalities being implemented progressively over the next two years.
- ✓ Business requirements for essential auditable requirements for the PSUR repository were finalised in Q2 2014. The repository is now in the development phase, on target for delivery by January 2015 to be ready for audit.
- ✓ Draft guideline on literature monitoring for case reports to be entered in EudraVigilance was prepared and published for a 2-month public consultation in June. Following assessment and implementation of comments, the guideline is expected to be finalised in Q4 2014.
- ✓ Tender for service provider for Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance was initiated in March. The results of the tender will be evaluated in Q3.
- ✓ The final audit report on quality system of the pharmacovigilance system was released in May. Draft report on all pharmacovigilance audits conducted in the last two years was prepared in Q2 and will be presented to the Management Board in October.
- ✓ A structure and delivery plan for updating signal detection methodology guidance and development of new complementary guidance combining amended statistical guide on use of statistical methods in EudraVigilance (based on PROTECT research outcomes) and signal detection guidance for specific topics (e.g. medication errors, lack of efficacy, etc) was presented at the PRAC informal meeting in May. The 1st revision will be available in Q1 2015.
- ✓ Pilot survey of 21 ENCePP centres' experience with HTA and their capacity to generate data useful for HTA bodies was conducted in April. Complete survey was sent to 150 centres in June, with the results expected in August 2014.
- ✓ A draft manuscript on current practice in pooling data from multiple sources was prepared and submitted for internal peer review in April.
- ✓ Survey of ENCePP centres on the use and understanding of ENCePP database of studies (also known as the EU PAS register) and the ENCePP Seal was conducted and the results reported to the ENCePP Steering Group at the end of June.
- ✓ ENCePP guide on methodological standards was revised to include a new chapter on design and analysis of pharmacogenetic studies and data in pharmacoepidemiology, and integrate the final results of PROTECT WP3 on duplicate detection and assessment of masking effects. The revised guide will be published in July 2014.
- ✓ The 3rd revision of the ENCePP Code of Conduct, providing further clarifications on the key concept of scientific independence and conditions for the ENCePP Study Seal, was published in March 2014.

- ✓ In order to develop a programme for studying public health impact, several meetings with stakeholders were held to develop the business case as well as scope and methodology of the programme.
- ✓ Recommendations report on methodology and visualisation techniques to be used in benefit–risk assessment was published in the journal Pharmacoepidemiology and Drug Safety in May and June 2014, and presented to the informal PRAC meeting in May 2014.
- ✓ Tools and methods of Visualize study (assessment of patients' preferences) were finalised in June 2014. A survey to help improve communication of benefits and risks of medicines was launched for patients and healthcare professionals in June 2014.
- ✓ Signal detection process was reviewed in first half of 2014, finding the process to be well established. No major changes are required to signal detection process.

1.6. Other specialised areas and activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Herbal monographs, new*	7	4	9	5	15	13	-2	-13%
Herbal monographs, revised	3	4	0	n/a	5	Unchanged	0	0%
List entries	0	0	0	0	2	1	-1	-50%

* Where assessment does not lead to the establishment of a monograph, a public statement will be prepared. 1 public statement was finalised in Q1-Q2 2014

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Q2 2013
Number of workshop/training sessions on clinical-trial supervision held with international partners	At least 1	1	-
Number of workshops held in the area of GMP inspections and quality defects	At least 1	1	-

Achievements

- ✓ During the 1st half of 2014, the Agency started preparing for the implementation of the upcoming Clinical Trials Regulation. This included formal initiation of the Clinical Trials Regulation programme, which includes 4 projects (Pre-inception; EU Portal and Database, including Workspace; Safety Reporting and EudraCT; and EU-CTR legacy). Main focus was on the pre-inception project which delivers business cases for all the other projects within the programme.
- ✓ Work on EU Portal and Database for submission and regulatory management of clinical trials, commenced at the end of Q2, following publication of Clinical Trials Regulation on May 27, 2014. Monthly meetings of the EU Clinical Trial Information System subgroup (composed by representatives of 10 Member States) have taken place since January. First meeting with stakeholders to discuss the requirements for these systems took place in June.
- ✓ In order to streamline data requirements Infectious Diseases Working Party (IDWP) has been discussing the on-going scientific advice procedures for new antibiotics with FDA.
- ✓ The proposal for the establishment of Ethics Advisory Group was discussed at CHMP in May-June, and is expected to be finalised in Q4 2014.
- ✓ In relation to influenza pandemic preparedness, draft influenza vaccines clinical and non-clinical guideline was prepared in the first half of 2014, with the draft guideline to be released for consultation in July. The guideline expected to be finalised by Q1 2015.

2. Evaluation activities of veterinary medicines

2.1. Pre-authorisation activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	1*	-	-	-	2	Unchanged	0	0%
Scientific-advice requests	11	19	15	13	32	28	-4	-12.5%
Requests for MUMS classification	9	13	12	5	18	Unchanged	0	0%

*ITF procedure made available to veterinary products in 2013

Performance indicators

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

Achievements

- ✓ The MUMS policy review continued in the first half of 2014, including the consultation with CVMP on the refined MUMS criteria. The revised policy will be presented to the Management Board in December.
- ✓ The EMA Innovation Task Force considered its first veterinary product in Q1 2014, since the procedure was made available to veterinary products in 2013.
- ✓ In March CVMP endorsed draft mandate and terms of reference of an ad hoc expert group on veterinary novel therapies (ADVENT). EMA Management Board endorsed the mandate, objectives and rules of procedure for the group in its June meeting. Endorsement from the HMA will be sought in July 2014, with a view of the group becoming operational in 2015.

2.2. Initial evaluation activities

Workload indicators

Procedure		2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
	Initial evaluation applications	7	11	3	3	20	18	-2	-10%
	New MRL applications	3	3	0	1	3	5	+2	+66.6%
	MRL extension and modification applications	1	3	2	5	5	2	-3	-60%
	MRL extrapolations	2	0	0	0	1	2	+1	+100%
	Art. 9, Biocides	0	0	0	0	2	Unchanged	0	0%
	Review of draft Codex MRLs	0	0	6	0	3	5	+2	+66.6%

Performance indicators

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

Achievements

- ✓ In order to embed more clearly the benefit risk methodology in the assessment process of antimicrobials used in animals, work continued with the Antimicrobials Working Party of the CVMP on a guideline on the benefit–risk assessment of veterinary antimicrobials. The guideline is planned to be completed early 2015. Work continues on revision of assessment report templates for veterinary medicinal products, including review of a dedicated section on benefit-risk assessment.

2.3. Post-authorisation activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Extensions and variations applications, of which:	148	108	118	91	245	Unchanged	0	0%
Type-I variations	126	90	84	80	200	Unchanged	0	0%
Type-II variations	20	15	30	9	40	Unchanged	0	0%
Line-extensions of marketing authorisations	2	3	4	2	5	Unchanged	0	0%

Performance indicators

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

2.4. Arbitration and referrals

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated*	4	9	4	9	12	10	-2	-16.7%

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

Performance indicators

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

Achievements

✓ Informal procedural advice on referrals to CVMP was endorsed by HMA in March 2014.

2.5. Pharmacovigilance activities

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	80	80	67	63	150	Unchanged	0	0%
Total adverse-event reports, of which:	13,000	10,139	10,047	8,011	22,500	Unchanged	0	0%
Adverse-event reports (AERs) for CAPs	5,282	3,731	2,440	2,256	7,200	Unchanged	0	0%

Performance indicators

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

2.6. Other specialised areas and activities

Achievements

- ✓ Draft responses to the remaining three of four questions of the European Commission related to the risk to man from the use of antimicrobials in veterinary medicine were finalised by the Antimicrobial Advice ad hoc Expert Group in June. These are expected to be adopted by CVMP and CHMP in July, and the final responses sent to the EC after the public consultation.
- ✓ In order to facilitate the supply of data to the ESVAC database, work started on development of IT solution for web-based collection of data in January. 3rd iteration testing access to the IT solution from the Member states took place in June. The work is on schedule to complete user acceptance testing by the end of 2014 and launch the system in Q1 2015.
- ✓ A progress report on the TransAtlantic Task Force on Antimicrobial resistance (TATFAR) work was published in May, recording good progress in 15 out of 17 recommendations, and the addition of a new recommendation to identify knowledge gaps in the area of limiting transmission of resistance from animals to man.
- ✓ EMA chaired the VICH international conference in Brussels in June 2014.

3. Horizontal activities and other areas

3.1. Committees and working parties

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Number of meetings	187	187	221	288	426	355	-71	-16.7%
Number of teleconference meetings*	1,549	1,434	440**	317**	2,850	3,050	+200	+7%
Number of delegates	3,686	3,548	4,035	4,318	8,500	7,000	-1,500	-17.6%

* 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 2014	Outcome at the end of Q2 2014	Q2 2013
Percentage of delegate satisfaction with the service level provided by the secretariat	80%	-	-
Percentage of up-to-date electronic declarations of interests submitted by committee members and experts prior to participating in a committee, SAG or other meeting	100%	100%	n/a*
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%	n/a*
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%	88%	n/a*

*New performance indicators introduced in 2014

Achievements

- ✓ The revised EMA policy on handling of conflicts of interests of experts was adopted by the Management Board in March 2014. The e-DoI form and guidance documents are currently being updated in line with the revised policy, and the implementation for the revised policy and updated e-DoI form is scheduled for 1 October 2014.
- ✓ The centralised committees' secretariat for human medicines was established in Q1 2014, along with the experts and declarations of interest management team. Scientific Coordination Group to support Scientific Coordination Board was also formed. Harmonisation of the administrative processes of the centralised committee secretariat will continue until late 2014/early 2015.
- ✓ Work on establishing coordinated secretariat for the working parties will begin in Q3.
- ✓ Cross committee oncology scientific advisory group was established in April. The first meeting is scheduled for 10 September. Analysis of the results of this initiative will be carried out in 2015.

3.2. Inspections and compliance

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
GMP inspections	235	259	196	183	360	Unchanged	0	0%
GLP inspections	0	0	0	1	2	1	-1	-50%
GCP inspections	33	42	34	29	71	Unchanged	0	0%
Pharmacovigilance inspections	10	5	8	5	11	14	+3	+27.3%
Quality-defect reports	74	90	82	66	180	Unchanged	0	0%
Number of medicinal products sampled*	5	10	5	5	45	48	+3	+6.3%
Standard certificate requests	1,663	1,729	1,604	1,527	3,500	Unchanged	0	0%
Urgent certificate requests	285	159	-	-	350	450	+100	+28.6%

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Parallel-distribution initial notifications	1,226	1,268	1,199	1,281	3,000	2,700	-300	-10%
Parallel-distribution notifications of change	744**	1,504	1,675	954	1,600	Unchanged	0	0%
Parallel-distribution annual updates***	1,274	n/a	n/a	n/a	1,300	2,500	+1,200	+92.3%

* Including all testing completed
** Significant decrease attributed to companies shifting to annual updates
*** Parallel-distribution annual updates only introduced since May 2014

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Q2 2013
Percentage of inspections conducted within established regulatory timeframes	100%	100%	100%
Percentage of standard certificates issued within the legal timelines	90%	0.5%*	28%
Percentage of urgent certificates issued within the legal timelines	100%	100%	100%
Percentage of parallel-distribution notifications checked for compliance within the standard timeline	90%	97%	99.8%
Number of training/workshop activities organised in the area of inspections	At least 4**	2	n/a
GCP inspections addressed through information exchange on inspections carried out by international partners	Additional 10%	Additional 29%	-
Routine re-inspections of manufacturing sites addressed through exchange of information with international partners	Additional 10%	Additional 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%

* Average issuing time in first six months – 17 days (instead of 10). Delay mostly due to shift of resources to deal with growing number of urgent certificates requests Gradual improvement seen in later months
** Annual target to be reached at year-end
*** Low results due to delay in receiving reports from partners

Achievements

- ✓ The EMA–FDA initiative on exchange of information on GCP inspections was extended to generics, starting January 2014. A first joint GCP inspection on generics will take place in September 2014.
- ✓ The Agency, in collaboration with ANSM (Agence nationale de sécurité du médicament et des produits de santé) is preparing both, a Bioequivalence Forum dedicated to senior GCP inspectors (to be held on 10 November 2014) and a Bioequivalence inspections basic training course to train new EU BE inspectors (to be held 20-21 November 2014). WHO will also participate in these events.
- ✓ The EMA together with the GCP IWG developed an on-line basic GCP Inspectors' training course accessible to the EU Network via EudraPortal and to non-EU GCP inspectors via secure links. The first webinar took place on 27th June and received positive feedback from the participants.
- ✓ A draft proposal for the visiting experts' training programme is also being developed.
- ✓ Annual GCP IWG workshop is being prepared and will take place in November. Invitation to the workshop has been extended to international GCP inspectors' network.
- ✓ The EMA also participated in the APEC LSIF MRCT/GCP inspections workshop in May.
- ✓ To improve public information on GCP inspections, a proposal on publication of GCP/PhV/GLP inspections that also harmonises the information on GCP inspections in the EPAR was prepared in January.
- ✓ The Agency is cooperating with the EC and Member States to implement the provisions of the Falsified Medicines Directive regarding identification of authorised internet pharmacies. This includes development and introduction of a logo (in June) and conducting awareness campaigns.
- ✓ Checklist on risk indicators for shortages (manufacturing and quality) for assessors to use during the assessment of MA applications in order to identify potential future supply risks was agreed with BWP and QWP in January, and will be introduced into Day80 Quality assessment reports by the end of 2014.
- ✓ The Agency oversees development of the plan to address medicines' shortages due to manufacturing issues (through receiving regular progress updates from industry associations). Report on the work done by the industry associations is expected to be discussed with EMA in the 2nd half of 2014.
- ✓ The revised procedure for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public or animal health was sent to the EC in June, for adoption and publication in the "Compilation of Community Procedures on Inspections and Exchange of Information".
- ✓ A workshop for quality defect contact points took place in June 2014. Three Working Groups were formed to explore the 3 key areas in international cooperation of managing quality defects – communication, cooperation and coordination. Other potential improvements to the EU system for managing defects were identified at the workshop and will be considered by the GMP/GDP IWG at its next meeting (September).

✓ Quality by Design workshop took place in February and the workshop on Quality Defects was held in June. The pharmacovigilance IWG training is scheduled for October.

3.3. Partners and stakeholders

Workload indicators

Procedure	2014 Q1 – Q2	2013 Q1 – Q2	2012 Q1 – Q2	2011 Q1 – Q2	2014 annual forecast Initial	Revised	Change	
Requests for SME qualification	270	236	456	172	500	Unchanged	0	0%
SME status renewal requests	103	119	69	50	1,000	Unchanged	0	0%
Requests for access to documents	152	176	109	103	350	Unchanged	0	0%
Pages released following requests for access to documents	26,591	242,097	381,000	574,420	400,000-700,000	100,000*	-300,000	-75%
Requests for information	2,313	3,031	2,614	2,404	6,500	5,000	-1,500	-23%
Number of EMA activities involving patients and consumers, of which:	276	n/a	n/a	n/a	575	Unchanged	0	0%
Information to the public reviewed by patients	92	n/a	n/a	n/a	300	200	-100	-33%

* Due to the Court Cases there were many rejections for access to documents requests which is reflected in the redaction of the number of pages released

Achievements

✓ In order to set up the EU Network Training centre, the mandate of the Training Centre was endorsed by the Agency management team in March and by HMA in May. The vision, road map and project plan of the Training Centre have been developed and will be presented to the HMA at the November meeting.

✓ In order to prepare for the future revision of the general fee legislation, a Steering Group was created in the first half of 2014, involving representatives of the European Commission, the Agency and the Member States. Analysis of the tasks and activities of the EMA and the NCAs also started.

- ✓ Framework for interacting with pharmaceutical industry organisations was drafted in Q2; it is expected to be finalised and presented to the Management Board by the end of 2014.
- ✓ Principles of the revised framework of interaction with Patients'/Consumers' Organisations were presented to Patients'/Consumers' Working Party and the EMA management team in January. The finalised framework is planned to be presented to the Management Board in December 2014.
- ✓ 1st report on interaction with healthcare professionals was presented to Healthcare Professionals Working Party in February. The report will be presented to the EMA Management Board in October.
- ✓ In regard to finalising the EMA policy on publication of clinical data, 3 targeted stakeholder meetings were held in May, to further clarify and fine-tune the proposed policy. The draft policy was presented to the Management Board at its June 2014 meeting. The MB agreed to the policy in principle, but asked for the policy to be finalised through written procedure. As several comments were received during the written procedure, adoption is now postponed to October Management Board meeting.
- ✓ The process of handling requests for access to documents was reviewed in the first half of the year. As part of this exercise, a centralised team to coordinate ATDs and manage RFI requests was established, redacting guidelines were prepared and ATD public guide was drafted. AskEMA IT tool was implemented to help manage ATD/RFI process.
- ✓ The proposal to establish a web managers' network with Member State authorities was discussed at the Working Group for Communications Professionals. The next steps and tasks relating to the cooperation on digital issues will be discussed at the next WG meeting.
- ✓ Work to review the process of coordination of medicines information, especially the safety information, started in Q2. Surveys have been sent to the Member States and drafting of the report begun in June. Final report is expected to be presented to PRAC and EMA Management Board by early 2015.

3.4. Data management support

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Outcome at the end of Q2 2013
Percentage of substance and referentials data registered in 24 hours	90%	20.1%*	n/a^
Percentage of substance and referentials data registered in 48 hours	99%	35.5%*	n/a^

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Outcome at the end of Q2 2013
Percentage of calls reopened due to incorrect handling	<3%	2.7%**	n/a^
Percentage of stakeholders satisfied with the responsiveness, cooperation and communication of data-management services	>80%	n/a***	n/a^

* Newly established service; performance gradually improving. **June** performance: **27.7%** data registered **in 24 hours** and **61.1%** registered **in 48 hours**
** Data only available for June 2014
*** Stakeholder survey not yet performed
^ Workload indicators newly established in 2014

Achievements

- ✓ Centralised substance management service is operational since Q1, following the completion of the IT solution for the Substance Management Service in January. Decision to continue development of data management service for products and organisations within the Data Integration Programme was also made in Q1.
- ✓ The operating model for Business and Data Support processes was designed in June, with the final model to be approved in September.
- ✓ Based on the analysis made in Q1 and Q2, the EMA is preparing a Data Integration roadmap for the next 3-5 years, to be approved in Q4. The roadmap will focus on 2 main areas: Master Data Management and Data Quality Management.

3.5. Process improvements

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Outcome at the end of Q2 2013
Percentage of existing regulatory procedures reviewed and improvement areas identified by the end of 2014	80%	n/a*	n/a

* Performance indicator to be measured at year-end

Achievements

- ✓ In the first half of 2014 a number of procedures were redesigned, including variations, MA transfers, PSURs/PSUSAs, PASS, and signal management, referrals, scientific advice, initial MA and EPARs. NCA consultations were completed for several processes (e.g., Type II Variations, Signal Management, PSURs) and the reviewed processes were implemented for variations, MA transfers, PSURs/PSUSAs and PASS.
- ✓ Process redesign for orphans, paediatrics and inspections, NCA consultation on initial MA, as well as implementation of the redesigned processes for signal management, referrals, scientific advice, initial MA and EPARs will begin in Q3.
- ✓ Development and implementation of process performance management framework is scheduled for 2nd half of the year. Identification and implementation of quality metrics and performance indicators is planned for 2015.

4. Support and governance activities

Performance indicators

Performance indicators related to core business	Target 2014	Outcome at the end of Q2 2014	Outcome at the end of Q2 2013
Percentage of posts on the Agency establishment plan filled	97%	97%	93%
Percentage of revenue appropriations implemented	99%*	44.3%	47.5%
Percentage of expenditure appropriations implemented	99%*	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%	97.4%	-**
Telematics and corporate IT systems availability against Agency working hours	98%	99.5%	99.4%
ICT Service Desk: meeting of service-level agreements (SLAs) per system/priority level:			
Critical (resolution time: 4 hours)	80%	45%	31.8%
Severe (resolution time 1 business day)	80%	46.5%	31.3%
Important (resolution time 10 business days)	80%	74.8%	89.1%
Minor (resolution time 120 business days)	80%	99.7%	99.4%
Projects delivered on time	100%	*Project delivery indicators reported separately.*	
Projects delivered to original specification	100%		
Projects delivered within budget	100%		

* Annual target to be reached at year-end
** Results not comparable with 2013 due to change in indicator (30 days vs 45 days' timeline in 2013)

Achievements

- ✓ The project to relocate the Agency to new premises continued according to plan in 2014. The fit-out of the new premises was completed in the first half of the year and the pilot move was carried out on June 16. Premises were practically completed on July, 1, as planned. The first move is planned for July 2 and last move will take place on July 30, with the Agency fully relocated on August 1.
- ✓ In order to increase efficiency of project management, control and delivery in the Agency, new project governance structure was put in place and a Programme Management Office was established in April 2014.
- ✓ Following the staff engagement survey that was carried out in October 2013, the results were presented to the Agency management in Q1. The action plan stemming from the survey results was developed in first half of the year and will be presented to the management in Q3. Next staff engagement survey is planned post-implementation of the above-mentioned action plan.
- ✓ Following an extensive bottom-up exercise involving all staff of the Agency, a set of core EMA values was selected in February. The new core values were launched in May, with implementation activities planned for the 2nd half of the year.
- ✓ Exercise on best-practice benchmarking within the European medicines regulatory network (BEMA III) began early 2014. The self-assessment was finalised in Q2 and the report was sent to the BEMA assessors on June 16. Arrangements for the assessors' visit starting September 15 were also completed in Q2.
- ✓ The audit on the quality system of the pharmacovigilance system was conducted in March, with the final report released in May. The audit on SAP took place in May, with the final report expected to be released in July. Preparations for the remaining two audits in 2014 (on record management and MRLs) have begun, with the fieldwork of these scheduled to begin in Q4.
- ✓ The review of regulatory content on the EMA website will start in Q3.
- ✓ The existing social media strategy was updated to take into account the new corporate website requirements. Development of an appropriate search engine marketing strategy is postponed to 2015, in order to account for the requirements emerging for the European medicines web portal.

Annex: Terms and abbreviations

Term	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ACPC	advisory committee on procurement and contracts
ADR	adverse drug reaction
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
APEC	Asia-Pacific Economic Cooperation
API	active pharmaceutical ingredient
AR	assessment report
Art	article
ATD	access to documents
ATMP	advanced-therapy medicinal product
BE	bioequivalence
BEMA	benchmarking of European medicines agencies
BI	business intelligence
BSWP	Biostatistics Working Party
BWP	Biologics Working Party
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CESP	Common European eSubmission Platform
CHMP	Committee for Medicinal Products for Human Use
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
CoI	conflict of interest
COMP	Committee for Orphan Medicinal Products
CT	clinical trial
CTA	clinical-trial application
CTR	Clinical Trial Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
D(80, 120)	day (80, 120)
DoI	declaration of interests
eAF	electronic application form
EC	European Commission
eCTD	electronic common technical document
EMA	European Medicines Agency

Term	Definition
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU contribution	EU special contribution for orphan medicines
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUTCT	European Union Telematics Controlled Terms
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVDAS	EudraVigilance data analysis system
FDA	United States Food and Drug Administration
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HCP	healthcare professional
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	individual case-safety report
ICT	information and communication technologies
IDVP	infectious diseases working party
IMI	Innovative Medicines Initiative
IT	information technology
ITF	Innovation Task Force
IWG	Inspectors Working Group
JRC	joint research centre
KPI	key performance indicator
LSIF	Life Science and Innovation Forum
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MB	Management Board of the EMA
MDM	master data management
Member State	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MRCT	Multi-Regional Clinical Trials
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
NCL	nanotechnology characterisation laboratory
Network	European Medicines Regulatory Network
OBIEE	Oracle Business Intelligence Enterprise Edition

Term	Definition
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PCO	patients'/consumers' organisation
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PIQ	product information quality
PRAC	Pharmacovigilance Risk Assessment Committee
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
PTL	product team leader
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
QRD	quality review of documents
QWP	Quality Working Party
R&R	'Review and Reconnect' programme
RFI	request for information
RMP	risk-management plan
SA	scientific advice
SAG	Scientific Advisory Group
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SMART WG	signal management review technical working group
SME	small and medium-sized enterprise
SMS	substance management service
SPOR	Substances, Products, Organisations, Referentials
SUSAR	serious unexpected suspected adverse reaction
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TGA	Therapeutic Goods Administration, Australia
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization
WP	working party