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European Medicines Agency

Mid-year report 2019

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 3 October 2019.

Temporary visiting address Spark building ● Orlyplein 24 ● 1043 DP Amsterdam ● The Netherlands
For deliveries refer to www.ema.europa.eu/how-to-find-us
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Brexit

Since the UK decision to leave the EU, EMA's priority has been to ensure that the activities relating to the authorisation, supervision and maintenance of medicines are not disrupted and continue to be undertaken on time and to the same high level of quality the Agency's stakeholders have come to expect, and that patients in Europe continue to have access to high quality, safe and effective medicines.

Information on the impact of Brexit and the Agency's work to prepare for it and ensure uninterrupted operations can be found on the EMA website: https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit.

EMA Brexit preparedness and implementation

To address the challenges presented by Brexit, the Agency established an internal Operations and Relocation Preparedness (ORP) task force to plan and prepare for the changes, and developed and implemented in a staged manner a business continuity plan (BCP). This plan aimed to prioritise EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss. The ORP organisation and focus areas as well as the categorisation of the Agency's activities for the purposes of BCP, are outlined in Annex 3.

BCP implementation:

The Agency implemented the first phase of its BCP in May 2017, ensuring delivery of its highest priority activities while temporarily scaling back or suspending lower priority activities. The second phase of the BCP was launched on 1 January 2018, affecting a further set of EMA activities, including medium priority activities.

On 1 October 2018 the Agency implemented phase 3 of the BCP, in order to safeguard core activities related to the evaluation and supervision of medicines, while intensifying the preparations for the Agency's physical move to Amsterdam in March 2019 and coping with an increased number of resignations (a total of 25 in 2018, a 56% increase compared to the average number of resignations over 2013-2017).

Additional temporary suspensions/reductions were launched as part of phase 4 of the Brexit BCP on 1 January 2019 to address further potential staff loss and to prepare for the critical period relating to the physical move from London to Amsterdam.

Phase 4 of the Agency's Brexit BCP focusses on existing category 1 activities, Brexit-related activities, preparation for the implementation of the new veterinary legislation (NVR) and the critical category 2A and 2B activities, as well as minimum required corporate governance activities.

Relocation to SPARK building:

The Agency, in close cooperation with the Dutch authorities, worked hard to ensure that the temporary premises would be ready to move into before 30 March, when EMA's seat formally changed from London to Amsterdam.

EMA left its London premises on 1 March 2019, and following a transitional week of teleworking, the Agency moved its operations to the Spark building in Amsterdam Sloterdijk during the week of 11-15 March.

To facilitate the relocation and taking into account staff members' personal situations, some flexibility was applied in terms of individual relocation dates, for example to accommodate schooling, spouse

employment, or housing situations. EMA staff members started to relocate to the Netherlands in summer 2018, and gradually continued doing so thereafter.

By June 2019, 464 staff members had already relocated to the Netherlands; 312 EMA staff members continued teleworking from London to allow them and their families a smooth transition to Amsterdam in the second half of 2019.

Relocation to final EMA premises:

Intense discussions have been taking place between EMA and the Dutch authorities to agree on definitions and timelines for the delivery of the final building, based on the principle that continuity of EMA operations has to be safeguarded and there cannot be any interruption in the Agency's work.

In June 2019 EMA senior management agreed the detailed timeline for the relocation to the final building. According to the plan, construction of the new building is expected to be completed by November 2019 and EMA staff is expected to move in as of 6 January 2020.

Update on 30 Churchill Place:

At the end of 2018 the Agency identified a potential tenant for sub-letting its premises at 30 Churchill Place, Canary Wharf, London, UK. Negotiations then took place over the first half of 2019 with both the potential tenant, WeWork, and Canary Wharf Ltd.

EMA reached an agreement with Canary Wharf Ltd over its London premises in accordance with the discussions held with the EU budgetary authorities, and sublet all of its 284,704 square feet (26,450 m^2) of accommodation at 30 Churchill Place to WeWork. WeWork took a sublease from EMA for a term to the expiry of EMA's lease in June 2039. WeWork has commenced the fitting out and was looking to open in December 2019.

Operational aspects:

In anticipation of the UK becoming a third country EMA has been monitoring and tracking industry preparations for Brexit and submissions of Brexit-related changes for centralised products (CAPs). The vast majority of companies have now taken the necessary steps concerning marketing authorisation transfers; good progress has also been made for products with Qualified Person for Pharmacovigilance (QPPVs) and pharmacovigilance system master files (PSMFs) based in the UK. At the beginning of June:

- 397 out of 400 marketing authorisations had been transferred;
- changes to qualified persons for pharmacovigilance were made for 243 out of 335 medicines;
- changes to pharmacovigilance system master files were made for 313 out of 376 medicines;
- changes to batch release sites were made for 95 out of 119 medicines.

No new pre- or post-authorisation procedures are allocated to UK (Co)-Rapporteurs and the redistribution of the UK product portfolio to the new (Co)-Rapporteurs is fully implemented.

Since 2018 EMA has tracked and monitored all Brexit-affected medicines and those considered 'at risk of supply' were subjected to a criticality assessment.

EMA received a total of 70 requests for a time-limited exemption to continue batch control testing in the UK after UK's withdrawal from the EU. Although the deadline for submission of requests for exemption has been extended to 31 October 2019, the submission of new requests has decreased considerably.

No-deal scenario

In March the EMA Management Board agreed to set up the EU Executive Brexit Task Force on Availability of Medicines, to coordinate a response to medicines shortages in case of a no-deal exit of the UK from the EU. The Task Force is composed of representatives of the European Commission, the EU Member States and EMA representing both the human and the veterinary medicines field. It will provide strategic direction in case of a crisis situation and will report to the European Commission's Pharmaceutical Committee, the EMA Management Board and the Heads of Medicines Agencies (HMA).

Staff retention:

In the first six months of the year the staffing levels permitted the Agency to perform activities according to phase 4 of its Business Continuity Plan.

At the end of 2018, the Agency's headcount was 901. As of June 2019, the Agency's available workforce was 776. Of those, 464 had relocated to the Netherlands and 312 were teleworking mainly from London due to their personal circumstances.

The staff turnover in the first half of the year has been somewhat lower than anticipated. By 30 June 29 staff members (TA and CA) had left the Agency. Of these, 90% (26 staff members) had left the Agency by resignation. It is expected that the previous pattern of higher than usual numbers of staff leaving, and specifically resigning, will continue also in the second half of 2019. By mid-July an additional 17 staff members (TA and CA) had either left the Agency or made known their intention to leave before the end of the year, with 14 of these being resignations. Thus, by mid-July the total number of staff leaving EMA in 2019 had reached 46. Of these 46 staff members, 83% (38 staff members) were leaving the Agency by resignation (compared to 26 staff members resigning by 30 June).

A recruitment exercise is currently ongoing to make sure that staff members who decide not to relocate can be replaced. By mid-year, a total of 77 new staff members had joined the Agency (TA, CA and national experts).

Priorities and reinstating activities:

Due to resource constraints, most activities temporarily suspended at the end of 2018 as part of the Agency's business continuity planning remain on hold. These include guideline development, most working party meetings, engagement in international activities and the proactive publication of clinical data.

EMA has started to reinstate some activities as of June 2019. The focus is on activities and projects that aim to increase the efficiency of EMA's operations to ensure that the Agency is fit-for-purpose in the longer term, e.g. IT systems supporting medicines evaluation and the digitalisation of administrative processes. In addition, some of the EU network working groups directly contributing to EMA's core activities will restart. More detail on activities to be reprioritised are outlined in Annex 4.

A further review by EMA's Management Board will take place in October 2019.

Mid-year report on Brexit activities planned for 2019:

During the first half of 2019, EMA continued to work on Brexit-related activities, including finalising and executing the actual move from London to Amsterdam, whilst maintaining the scientific assessment work uninterrupted and supporting staff members to facilitate staff retention.

Work stream	Activity planned for 2019	Status on 30/06/2019
Work stream 1:	Continue, in collaboration with the Dutch	Completed

Work stream	Activity planned for 2019	Status on 30/06/2019
Relocation preparedness	authorities, implementing the Memorandum of Understanding/Host State Agreement and monitor implementation	
	Finalise the necessary procurement procedures enabling EMA operation in Amsterdam	Ongoing
	Initiate and monitor the contractual activities related to the existing providers of services	Ongoing
	Implement the staff retention and relocation support measures	Completed
	Prepare for and carry out the transfer of knowledge on IT systems and programmes	Ongoing
	Implement the plan for relocating EMA to the temporary premises in close collaboration with the Dutch authorities	Completed
	Implement the plan for the permanent building and work with the Dutch authorities on the new premises' development project	Ongoing
	Support the Dutch authorities in the preparation of a plan for relocating EMA to the permanent premises and monitor the implementation of such plan	Ongoing
	Execute the relocation of the Agency to the temporary premises, including move of the archives	Completed
	Move the Agency's staff from the temporary to the permanent building in Amsterdam	Not started
	Prepare for and implement changes stemming from the physical relocation, e.g. changes of contact details on all Agency templates	Completed for the move to the temporary building
Work stream 2: Operational and financial preparedness	Finalise redistribution of work on evaluation and monitoring of medicines with NCAs	Ongoing
	Establish and conduct with NCAs the training programme identified through capacity and training surveys via the EU Network training centre (NTC)	Ongoing
	Prepare Q&As and guidance documents for pharmaceutical industry on Brexit-related changes to marketing authorisations	Q&A and guidance documents published and revised as needed
	Handle additional post-authorisation applications related to Brexit	Ongoing
	Identify remedies to address medicines shortages resulting from the impact of Brexit on the availability of centrally authorised products	Ongoing
	Draft and implement the next phases of the EMA Brexit preparedness BCP as need arises	Ongoing
	Implement additional business continuity measures during the relocation period in 2019	Completed
	Develop and implement additional business	Ongoing

Work stream	Activity planned for 2019	Status on 30/06/2019
	continuity measures for the relocation from the temporary to the permanent building	
	Monitor the implementation of the BCP and staff loss, and undertake remedial actions as necessary	Ongoing
	Prepare for and implement changes to EMA IT systems	
Work stream 3:HR related matters	Undertake any recruitments necessitated by staff loss	Ongoing
	Prepare for operational activities related to relocation of staff, including interaction with the Dutch authorities	Ongoing
Work stream 4: Communication	Provide timely and targeted communication to the EU regulatory network, stakeholders and pharmaceutical industry	Ongoing
	Provide timely communication to staff and contractors	Ongoing
	Ensure adequate communication on the operation of EMA to relevant decision-makers and citizens in the Netherlands/Amsterdam	Ongoing
Project coordination	Undertake efficient coordination of the overall project relating to the EMA relocation to the Netherlands and the impact of Brexit on EMA operations, including robust budgeting	Ongoing

Key figures

This report describes the results and achievements of the Agency, working closely with the national competent authorities (NCAs), during the first six months of 2019, and thus reflects the situation as of 30 June 2019. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

- Scientific advice and protocol assistance requests remain at the same level as in 2017-2018. The number of scientific advice requests for PRIME products fell compared to 2018 (15 vs 22).
- After a peak in the first half of 2018, the number of protocol assistance requests (81) in the first half of 2019 has returned to the level seen in previous years.
- Applications for eligibility to PRIME (24) saw a slight decrease compared to 2018. The expectation for the full year is hence lowered from 100 to 50.
- Applications for paediatric procedures saw a drop in the first half of 2019, as compared to 2018 (279 vs 375).
- Requests for ATMP classification have remained stable, at the same levels as in previous years.
- 63 initial evaluation applications were received in the first half of 2019, considerably more than in the first half of previous years, leading to an upward revised annual forecast.
  - New non-orphan medicinal product applications remained at a similar level as in the previous year while orphan product applications doubled as compared to the first half of 2018 (17 vs 9).
  - Biosimilar medicinal product applications saw a slight increase compared to the previous year.
  - Generic products and hybrid and abridged applications saw a significant increase from last year (20 vs 13), exceeding the initial annual forecast for 2019 which has been revised accordingly.
- The number of type IA variations related to Brexit was higher than expected, reaching 1,898 applications in the first six months. Other variation applications remained at the same level as in 2018.
- The number of applications for transfer of marketing authorisation has dropped significantly from the 2018 figures, returning to the level seen in 2017. This is because most of the Brexit-related transfers had been submitted by the end of 2018.
- Article 61(3) applications increased significantly during the first half of 2019 (157 vs 103 in 2018), as a result of change in local representatives of applicants.
- Due to Brexit BCP, the development of only two therapeutic guidelines continued in the first half of 2019.
- The number of pharmacovigilance referrals received saw an increase in the first six months of 2019 (6 vs 2~3 in the previous year), while non-pharmacovigilance referrals dropped compared to 2018 mid-year figures.

- The number of peer-reviewed and validated signals remained at similar level as in 2018, reaching 1,063 reviewed signals and 35 validated signals.
- The number of PSURs started (278) and PSUSAs started (138) in Q1-Q2 2019 remained at a similar level as in 2018.
- Four emerging safety issues were received in the first half of 2019 – a figure similar to the previous year.
- 354 entries were on the list of products subject to additional monitoring at the end of Q2 2019, exceeding the annual forecast by mid-year.
- No new or revised herbal monographs were processed in the first half of 2019.
- Most performance indicators relating to assessment activities for human medicines were met in the reporting period. Of note,
  - There was no increase in scientific advice requests in the first half of 2019;
  - The average clock-stop for new active substances and biosimilars was 214 days in the first half of 2019 compared to 203 days in 2018. The longer than expected average clock-stop was due to six products having had a clock-stop between 310 and 715 days (2 oncology, 2 ECV (endrocrinology, metabolism and cardiovascular), 1 CNS (central nervous system) and 1 AIV (anti-infectives and vaccines) Art 58 applications).
  - The average clock-stop for variations, including extensions of indication, was 77 days. While the clock-stop continues to increase over the last years, it is still within the target set (90 days).

Assessment activities for veterinary medicines

- Scientific advice requests for veterinary medicines decreased slightly compared to the previous year, and reached 12 requests in the first half of 2019.
- 20 requests for MUMS classification were received in the first six months of 2019, significantly higher than in previous years and close to the annual forecast set for 2019. Of these, 3 were re-classification requests.
- The number of initial evaluation applications increased compared to 2018, reaching 13 applications (vs 7) and matching the number of applications received in the first half of 2016.
- Type IA variation applications for veterinary medicines also experienced an increase in the first half of 2019 compared to 2018, reaching 147 applications (vs 106 in 2018).
- Two applications for transfers of marketing authorisation were received in the first half of the year, leading to downwards revised forecast for the full year. This is because most of the Brexit-related transfers had been submitted by the end of 2018.
- 2 referral procedures were initiated during the first half of 2019, in line with the forecasts.
- The number of PSURs received reduced slightly compared to 2018 (71 vs 81).
- The number of adverse event reports (AER) continued to increase, reflecting the success of the measures implemented to promote AER reporting.
- The main performance indicators relating to assessment activities for veterinary medicines have been met.

Inspections and compliance

- The number of GMP inspections increased after the 2018 lower figures. 247 inspections were requested in the first half of 2019, returning to the levels of 2017. The annual forecast has been revised upwards to reflect this increase.
- Three pharmacovigilance inspections were requested in the first half of 2019, significantly less than the number of inspections requested in 2017 and 2018.
- As a result of introducing a new system for applicants to include all inspection systems, and inclusion of WHO data for generics, an additional 73% of GCP inspections were addressed through information exchange on inspections carried out by international partners.
- The number of notifications of suspected quality defects increased in the first half of 2019, returning to the levels of 2015-2017. Three GMP non-compliance notifications were received in the reporting period.
- 1,284 standard certificate requests and 1,349 urgent certificate requests were received in the first half of 2019. There was a shift from standard to urgent certificates due to resourcing and knowledge transfer issues, as well as increased processing time for standard certificates. As a result, annual forecasts for both types have been revised: the forecast for standard certificates has been reduced to 3,000 while the forecast for urgent certificates was increased from 500 to 2,030.
- Only 14% of standard certificates were issued within the established timelines, and the average time to issue standard certificate reached 65 days.
- 1,369 parallel distribution annual updates were received in the first six months of 2019, even though annual update submission was frozen for three months to allow for implementation of the new regulatory & scientific information management platform (IRIS) implementation.
- As a result of the loss of interim staff after relocation and the freezing of notifications processing while switching to the new IRIS platform and associated development problems, only 27% of parallel distribution notifications were checked for compliance within the established timeline in the first half of the year.
- Brexit circumstances resulted in a lower than usual number of meetings – while committee meetings and trainings remained at the same stable level, no workshops were held during the first half of 2019 and other meetings, including meetings of working groups, working parties, and scientific advisory groups (SAG), were reduced (93 vs 142 in 2018 and 191 in 2017).
- 362 requests for access to documents were received in the first six months of 2019, a decrease from the previous years. The number of documents released also fell to almost half of the 2017-2018 levels (792 vs 1,364 in 2018 and 1,411 in 2017). The number of requests for information remained stable.

Key developments

Working under Brexit BCP conditions has inevitably left a mark on the Agency's work programme. Out of 147 activities included in the work programme 2019, 79 have been suspended, 18 have continued at a reduced volume and pace, and only 50 have been maintained in their full scope.

Some of the key activities that took place during the first half of 2019 are highlighted below.

- Work continued to support the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation.
  - A first package of 6 mandates was received in January and a further mandate was received in February. The CVMP convened 10 expert groups to work on scientific and technical recommendations. Recommendations for 3 of the mandates were discussed at the June CVMP meeting and are expected to be adopted at the July meeting. The delivery of these mandates is on track for submission to the Commission by 31 August 2019.
  - A second package of mandates from the European Commission is expected in July 2019.
- In addition, a gap analysis and the impact assessment of the new veterinary regulation were being reviewed during the first half of 2019, taking into consideration the final text of the adopted regulation. Finalisation is expected by end 2019.
- Work continued with the EMA/HMA task force on the availability of authorised human and veterinary medicines.
  - A definition of a shortage, new guidance for marketing authorisation holders (MAHs) on reporting shortages and guidance for NCAs and EMA on communication on shortages, as well as a metrics document on availability/shortages were developed and agreed by the Network. A regulatory manual is under preparation and the need for guidance on withdrawal applications is under evaluation.
  - Support was also provided to the establishment of a process for cooperation and sharing of information on shortages within the EU network (single point of contact system in human and veterinary agencies in the EU), which has been piloted since April 2019.
- The Agency contributed to combatting the Ebola outbreak in the Democratic Republic of Congo through collaboration with WHO in designing the strategy and trials for investigational vaccines and therapeutics. The Ebola task force, comprising EMA and a group of experts from NCAs, continued working on scientific and regulatory issues related to potential use of investigational products in EU Member States.
- The Agency continued its involvement in the sartans issue, by contributing to international collaboration and by observing and conducting joint inspections on sartans.
- With the current Network strategy coming to a close, work on the new Network strategy to 2025 was agreed at the HMA meeting in June.
- In preparation for the implementation of the Medical Devices and In vitro Diagnostics Legislation (MDR/IVDR):
  - Guidance on medical devices composed of substances that are systemically absorbed (MEDDEV 2.1/3) was agreed with the CMDh for consultation procedure;
  - A scientific opinion on the definitions of pharmacological, immunological, metabolic (PIM) and medical diagnosis (linked to revision of MEDDEV 2.1/3) was adopted by CAT/CHMP in February,

and the Agency supported discussions on definitions of PIM and medical diagnosis with the EC Borderline and Classification Working Group;

  - Regarding the article 117 on medicinal products with an integral device, the first set of Q&A for the implementation of the MDR/IVDR was published in collaboration with the CMDh in February 2019, and a guideline on quality requirements for drug-device combinations was published for a 3-month public consultation in June.

- The HMA's and EMA Management Board's consultation on the Agency's input to the EC's report on the performance of pharmacovigilance tasks by the EU Member States and EMA ended with the endorsement of a report on 28 June 2019. The EC will use this as a key source of information for its formal report which is expected to be translated and published in all EU languages in line with the Commission's publication requirements.
- At the end of June 2019, 182 centres, 26 networks and 136 data sources were included in the ENCePP database.
- In 2019 a summary report of the first phase of the joint EMA-HMA Big Data Task Force was published. The Task Force's work continued with a focus on prioritisation and planning of recommendations from the first phase.
- EMA continued working with ECDC and EFSA on updating their advice to the EC on the impact on public and animal health of the use of antibiotics in animals. The updated advice on the 'categorisation of antimicrobials' was circulated for a 3-month public consultation in February 2019. 41 stakeholders responded extensively to the consultation, and the comments are now being evaluated. The revised advice is expected to be ready for adoption in Q4 2019. The 'Preliminary profiling for new antimicrobial veterinary medicinal products' part of the scientific advice was adopted by CVMP and CHMP in June 2019.
- As part of activities to strengthen collaboration with international partners, especially in relation to GCP and pharmacovigilance compliance, and inspections activities in areas of interest, EMA, the EU Member States and Swissmedic agreed on a process to exchange information for inspections in Switzerland.
- As part of the implementation of the EU-US mutual recognition agreement (MRA) for inspections, the US FDA confirmed the capability of further 7 EU Member States to carry out inspections at a level equivalent to the US, bringing the total to 27 Member States recognised. The Joint Audit Programme will continue to support the extension of the MRA scope to veterinary medicinal products.
- Due to the need to prioritise EMA Brexit preparedness and relocation activities, no progress was made during the first half of 2019 to further improve or rollout the multinational assessment team approach both pre- and post-authorisation.
- In June the EMA Executive Director Guido Rasi was elected to become chair of the International coalition of Medicines Regulatory Authorities (ICMRA). Handover of the ICMRA secretariat from the UK MHRA was to take place in September.
- The project methodology and plan for the implementation of the EU IT systems required by the Clinical Trial Regulation (CTIS) were revised in the first half of 2019 to improve delivery; the EU Member States and stakeholders are now directly engaged in the development of CTIS through nominated 'product owners' to ensure that their expectations are taken into account. In 2019 the system has undergone testing and key bug fixing. The safety reporting functionalities have also been developed. The project remains behind timeline and above budget.

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted EMA work programme 2019.

Explanation of symbols used in this document

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

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

Linear patterns are assumed for workload indicators, and the mid-year forecast is assumed to be 50% of the annual forecast of the adopted 'Work programme 2019'. For performance indicators that are expressed as a percentage, the mid-year target is assumed to be equivalent to the annual target.

In general, the traffic light system reflects the direction and magnitude of changes, as described above.

However, for some performance indicators, where the optimal results should be lower than the targets, such as average assessment or clock-stop days, the traffic light system is reversed to better reflect the essence of these indicators: results below the ‘target’ are marked green or blue, while results above the target will appear amber or red.

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

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

1. Pre-authorisation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Scientific advice/protocol assistance pre-submission meetings	53	52	66	87	75	139	99	-40	-29%
Scientific advice and protocol assistance requests, of which:	342	350	345	287	291	708	654	-54	-8%
Parallel scientific advice with international regulators	2	3	4	2	2	5	-	0	0%
Joint scientific advice with HTA bodies	10	16	17	9	21	34	22	-12	-35%
Scientific advice for PRIME products	15	22	12	0	-[1]	26	28	+2	+8%
Protocol assistance requests	81	103	79	59	82	175	150	-25	-14%
Novel technologies qualification advice/opinions	9	6	11	8	7	24	17	-7	-29%
PRIME eligibility requests	24	29	46	48	-[1]	100	50	-50	-50%
Scientific advice finalised	279	228	264	203	199	563	520	-43	-8%
Protocol assistance finalised	80	102	79	61	86	167	146	-21	-13%
Orphan medicines applications, of which:	127	127	127	164	120	275			
Parallel orphan applications with international regulators	n/a[2]	13	30	50	48	0			
Submitted applications on the amendment of an existing orphan designation	5	1	2	3	-	5			
Oral explanations for orphan designation	44	39	49	38	-	95			

	Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	279	375	310	265	229	500			
	Finalised procedures for compliance check on PIPs	40	57	35	37	35	70			
	Annual reports on paediatric deferred measures processed	108	100	87	84	-	170			
	EMA paediatric decisions processed	222	183	180	175	-	350			
	Requests for classification of ATMPs	27	27	27	40	13	50			
	Innovation Task Force briefing-meeting requests	11	10	12	24	36	25			
	Innovation Task Force Art 57 CHMP opinion requests	0	0	0	2	1	1			

[1] PRIME initiative was launched in March 2016.
[2] Parallel submissions with international regulators not applicable since IRIS implementation.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of				
		Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	100%		100%	100%	100%[1]
PRIME eligibility requests assessed within regulatory timeframe	100%	100%			-	-
Orphan designation opinions delivered within the legal timeframe	100%	100%	100%	100%	99%	-[1]
PDCO opinions sent to applicants within legal timelines	100%	99.6%		100%	100%	-[1]
Increase in scientific-advice requests	7%	0%		20%	0%	6%
SME requests for scientific advice (percentage of total SA requests)	30%	28%		28%	25%	34%

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

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Facilitate research and development of new medicines	1.3-5	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	50%	REDUCED Activity limited to high level presence in IMI scientific committee with no proactive identification of topics. Input was provided into the ENVI Agencies' joint bid for priority topics in Horizon Europe, IMI annual work plan and call texts. Feedback to the EC on funding for tuberculosis medicines development was given through IMI scientific committee.
		Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation		SUSPENDED
		Based on the horizon scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, involving also NCAs, to address specific areas for innovation		SUSPENDED
	1.3-8	Reinforce collaboration via EU Innovation Network with academia and research hospitals that could benefit most of the innovation offices regulatory support		SUSPENDED
	3.1-1	Use business forecasting and analysis tools to better inform the EU Network about past and prospective development and improve regulatory preparedness	50%	MAINTAINED 2 quarterly reports were provided to the Agency's scientific committees (SCs), as well as the 3-year forecast report to HMAs and SCs. Ad-hoc reports were prepared for specific topics: 1xCVD (feedback on European Cardiovascular strategic research agenda); 1xAnti-infectives (for WHO); 2xATMP (for the ATMP Matrix & CAT Secretariat), 2xBiosimilars (Biosimilars Matrix), 1xOncology (Oncology Community), 1xMigraine (Registry

Objective	MAWP initiative	Activity	% complete	Achievements/results
				initiative), 1x eHealth devices (quality office). In addition, input was provided into the Horizon scanning dialogue with HTA/payers.
	3.2-2	Establish a platform for project-specific engagement with developers, to optimise activities during the development phase		SUSPENDED
	1.3-5	Support a coordinated approach to ATMP-related activities in the Agency and maximise the outputs by involving all relevant actors and stakeholders	100%	REDUCED Activities directly related to product support are maintained. Non-product support activities suspended. Dedicated product team activated and working well. Communication with the network and stakeholders reinforced. Committees and working parties interaction strengthened.
Ensure needs of specific populations are met, including elderly, children, patients with rare diseases and others	1.1-6	Identify specific actions for EMA and PDCO that allow implementation of the European Commission/EMA action plan following the EC 10-year report on the Paediatric Regulation	10%	REDUCED Activities addressing public health needs and operational improvement are maintained. All other activities suspended. Ongoing activities included regular discussions with FDA colleagues with respect to paediatric oncology.
		Contribute to the activities of the International Neonatal Consortium (INC)		SUSPENDED
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders		SUSPENDED
	1.3-5	Review the experience with the “Orphan Notice” and interaction with stakeholders	20%	MAINTAINED The impact of the Notice has been monitored for orphan designations and maintenance procedures.
Improve cooperation with	1.2-3	Coordinate delivery of actions under the	50%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle		EMA/EUnetHTA work plan, in conjunction with Joint Action 3		Progress of the activities under the EMA/EUnetHTA work plan is regularly reviewed through the HTA.
Increase involvement of stakeholders in relevant regulatory activities	1.2-6	Capture and incorporate patients' values and preferences into the scientific review process, in particular in benefit-risk evaluation	40%	REDUCED Follow up through new initiative to create a framework to guide patient data generation for medicines development and benefit-risk evaluation
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-6	Analyse experience with legislative provisions, identify gaps in regulatory framework and provide technical support to the EC and the Network in relation to optimising existing regulatory framework, including development and/or implementation of new or amended laws and regulations		SUSPENDED
		Prepare for implementation of Medical Devices and In vitro Diagnostics Legislation, in relation to the implementation of the new consultation procedures involving the Agency, i.e., consultation on borderline products, on products that may be systemically absorbed by the human body, and on companion diagnostics	100%	MAINTAINED Consultation on medical device composed of substances: • MEDDEV 2.1/3 guidance agreed with CMDh for the consultation procedure on medical devices composed of substances that are systemically absorbed Consultation on borderline products: • Scientific opinion by CAT/CHMP (February 2019) on the definitions of pharmacological, immunological, metabolic (PIM) and medical diagnosis (linked to revision of MEDDEV 2.1/3) and supporting discussions on definitions of PIM and medical diagnosis with EC Borderline and Classification Working Group

Objective	MAWP initiative	Activity	% complete	Achievements/results
				• Support revision of MEDDEV guidance 2.4/1(classification) and 2.1/3 (borderline) Article 117 (Medicinal products with integral device): • Publication of the first set of Q&As for implementation of the MDR/IVDR in collaboration with CMDh (February 2019) • Support publication of Guideline on quality requirements for DDC for 3 month public consultation (June 2019) General implementation activities: • Publication of medical device webpage to support general implementation activities • Organised 2 TCs with DG GROW and DG SANTE to facilitate implementation of new legislation; • Agreement on proposal for fee model for new consultations by the EMA Executive Board (EXB) and FIT; • Participated in one external conference (RAPS) to support/raise awareness of the changes introduced by the medical device Regulations. • Participated in IVD WG meeting on 24th June 2019 with focus on future implementation of companion diagnostic consultation; • Support HMA-EMA Big Data Taskforce in subgroup on medical devices and in vitro diagnostics • Support to HMA-CAMD strategic and operational group (TCs)
Contribute to removing obstacles to optimal utilisation of biosimilar medicines	1.3-5	Coordinate efforts and drive activities to enhance the benefits of biosimilar medicines for public health		SUSPENDED
Ensure and run highly effective and efficient	3.2-2	Review and implement optimised operations for all functions supporting medicines'	50%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
processes to deliver pre-authorisation activities		development, including knowledge management		Trainings were delivered to support operational changes. Walk in clinics to address implementation of operational changes were created. Trainings of assistants and shadowing systems were implemented in support of PSUR activities

2. Initial evaluation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Number of MAA pre-submission meetings	48	40		37	-	60	80	+20	+33%
Initial evaluation applications, of which:	63	47	36	42	45	102	113	+11	+11%
New non-orphan medicinal products	18	20	16	18	14	53	35	-18	-34%
New orphan medicinal products	17	9	9	11	12	28	-	0	0%
Similar biological products	8	5	5	3	3	18	15	-3	-17%
Generic products, hybrid and abridged applications	20	13	5	10	16	13	34	+21	+162%
Scientific opinions for non-EU markets (Art 58)	0[1]	0	0	0	0	3	1	-2	-67%
Paediatric-use marketing authorisations	0	0	1	0	0	1	0	-1	-100%
Number of granted requests for accelerated assessment	3[2]	1	4	7	-	10	5	-5	-50%
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	11	9	7	4	-	24	-	0	0%
Reviews on the maintenance of the orphan designation criteria at MAA stage	20	28	17	12	-	40			

[1] One opinion expected in July, no other Art 58 ongoing.
[2] A reflection at CHMP on performance of accelerated assessment initiated at Romanian presidency CHMP informal meeting.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Applications evaluated within legal timeframes[1]	100%	100%	100%	100%	100%	100%
Average assessment time for new active substances and biosimilars (days)	205	205	196	180	210	205
Average clock-stop for new active substances and biosimilars (days)	180	214[2]	203	182	175	142
Requests granted for accelerated assessment (percentage of total requests)	70%	33%[3]	14%	57%	54%	-
MAAs initiated under accelerated assessment that have been completed as accelerated assessment	75%	100%[4]	33%	75%	56%	-
Initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	80%	86%	56%	65%	60%	77%
Labelling review of the English product information annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	90%	95%	100%	99%	100%	-
Therapeutic guidelines progressed to next step or finalised (percentage vs planned)	70%	5%[5]	35%	80%	-[6]	-[6]
Early background summaries drafted and sent to assessment teams (percentage vs planned)	100%	100%	100%	100%	-[6]	-[6]
Percentage of outcomes/results of workshops on therapeutic objectives published on EMA website	100%	n/a[7]	50%	n/a[7]	-[6]	-[6]

[1] Includes marketing authorisation and plasma master file applications.
[2] 6 products had a clock-stop between 310 and 715 days (2 Oncology, 2 ECV, 1 CNS and 1 AIV Art 58)
[3] 3 of 9 requests granted. A reflection at CHMP on performance of accelerated assessment initiated at Romanian presidency CHMP informal meeting
[4] Value is not representative of longer-term trends as it is based on a single opinion
[5] As a result of a decision by the ORP-BCP subgroup the development of the majority of scientific guidelines are put on hold. Out of 42 therapeutic guidelines, development of only two oncology guidelines continued in Q1-Q2 2019.

[6] New indicators introduced in the 2017 work programme.
[7] No workshops were held in the first half of the year.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-14	Strengthen the support in clinical pharmacology and non-clinical aspects to centrally authorised products along their life-cycle		SUSPENDED
	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: improve the structure and information on benefit/risk in the EPAR by including the effects table, and implement new templates and guidance. Explore feasibility of using a more explicit approach in describing value-judgements in the benefit risk assessment		SUSPENDED
		Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: increase patients' involvement in assessment work and support the IMI PREFER project.		SUSPENDED
		Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: explain the rationale for single-arm trials-based approvals to the public and explore the need for wider discussion of such approvals.		SUSPENDED
Provide high quality, robust, scientifically sound and	3.3-6	Implement EMA action plan on EC's report to improve Product Information	100% on track	REDUCED

Objective	MAWP initiative	Activity	% complete	Achievements/results
consistent product information				Public consultation on the ePI key principles that was endorsed at the multi-stakeholders workshop in November 2018 was launched in January 2019 for 6 months. Numerous meetings took place to prepare and finalise the roadmap (due to be adopted in December 2019), leading to the selection of the common electronic standard.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	1.3-4	Support activities stemming from Joint Action 3/work package 4, by providing relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments (REA)	50%	MAINTAINED Requests for collaboration in the context of REA production are processed in accordance with operational guidance and evaluation timelines. REA-4 is complete; REA-5, 6 and 7 are currently in preparation. Furthermore, review of experience with the collaboration took place, and fine-tuning will be proposed for second half of 2019. In addition, two specific engagements between HTAs and regulators were facilitated, outside REA production.

3. Post-authorisation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Variation applications, of which:	3,408	3,095	3,021	3,041	2,941	6,563	6,526	-37	-1%
Type IA variations	1,898[1]	1,604	1,536	1,578	1,483	3,207	3,258	+51	+2%
Type IB variations	1,011	993	952	968	896	2,144	2,143	-1	0%
Type II variations	499	498	533[2]	495	562	1,212	1,125	-87	-7%
Line extensions of marketing authorisations	9	10	12	11	8	18	16	-2	-11%

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
PASS scientific advice through SAWP	1	2	0	2	-	2	-	0	0%
Consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	3[3]	6	6	7	-	12	-	0	0%
Renewal applications	42	40	25	43	-	100	90	-10	-10%
Annual reassessment applications	7[4]	5	2	7	-	28	25	-3	-11%
Transfer of marketing authorisation applications	39[5]	232	36	8	-	100	60	-40	-40%
Article 61(3) applications	157[6]	103	112	102	-	200	220	+20	+10%
Post-authorisation measure data submissions	446	405	368	490	-	900	-	0	0%
Plasma master file annual update and variation applications	20	7	17	10	-	18	38	+20	+10%

[1] Higher than expected number of Brexit-related submissions received in March-April 2019.
[2] First half of the year normally sees lower volume of type II variations than the second half.
[3] High number of meetings expected to take place in second half of the year.
[4] This is a seasonal procedure and 2/3 of these are submitted in second half of the year.
[5] Lower than expected activity as most of Brexit-related transfers were submitted by end of 2018.
[6] Surge of 61(3) linked to change of local representatives for applicants.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Post-authorisation applications evaluated within legal timeframes	99%	99%	99%	99%	99%	100%
Average assessment time for variations that include extension of indication	180	154	152	161	169	-
Average clock-stop for variations that include extension of indication	90	77	70	61	75	-
Percentage of submitted risk-management plans peer-reviewed by the Agency as part of the extension of indication and line extensions	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	3.2-1	Optimise processes that include interactions among multiple Committees		SUSPENDED
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)	1.3-6	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indication		SUSPENDED
Strengthen the quality of the scientific review process	3.2-16	Improve the benefit-risk methodology and expand it to post-authorisation updates		SUSPENDED

4. Referrals

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	6	2	3	4	3	8	10	+2	+25%
Non-pharmacovigilance referrals started	4	8	2	8	4	8	-	0	0%

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Referral procedures managed within legal timelines	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and run highly effective and efficient processes to assess referrals	3.2-1	Development of a common understanding with the Network on the best use of referrals	100%	MAINTAINED A mapping of benefit-risk balance reviews by CHMP in referral procedures, including relevant lessons learned was presented to the relevant Committees (CHMP, CMDh) in Q1 2019. Training has been organised to the PRAC in Q1 2019 and an awareness session will be organised by the end of Q4 2019. Work is ongoing in mapping key referrals that are initiated following GMP/GCP non-compliance. Reports summarising experience and learnings are expected by Q2 2020

5. Pharmacovigilance and epidemiology activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Number of signals peer-reviewed by EMA	1,063	1,395	1,323	1,217	1,354	1,800	-	0	0%
Number of signals validated by EMA (assessed by PRAC)	35	44	19	21	29	35	40	+5	+14%
Number of signals validated by MAHs (pilot phase	2	1	-	-	-	-	4	-	-

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
only)									
Total PSUR/PSUSA started	416	417	487	369	390	889	823	-66	-7%
PSURs (standalone CAPs only) started	278	256	309	240	275	555	558	+3	+0.5%
PSUSAs started	138	161	178	129	115	264	265	+1	+0.4%
Number of imposed PASS protocol procedures started	6	7	8	10	13	20	15	-5	-25%
Number of imposed PASS result procedures started	1	5	1	1	-	15	6	-9	-60%
Number of emerging safety issue notifications received	4	5	4	18	19	10	-	0	0%
Number of notifications of withdrawn products received	187	217	138	102	83	430	400	-30	-7%
Cumulative number of products on the list of products to be subject to additional monitoring	354	332	321	282	231	320	350	+30	+9%
Number of incident-management plans triggered	1	4	4	5	-	9	7	-2	-22%
Number of non-urgent information (NUI) or rapid alert (RA) notifications submitted through EPITT	26	32	28	25	-	55	-	0	0%
Number of external requests for EV analyses	7	9	18	24	-	20	15	-5	-25%
Number of MLM ICSRs created	5,033	6,378	5,816	3,826	-	12,000	-	0	0%

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%	100%	100%	-

Performance indicators related to core business	Target 2019	Outcome at the end of				
		Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	95%	100%	100%	100%	100%	-
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%	100%	100%
Percentage of reaction monitoring reports supplied to the lead Member State monthly	94%	100%	95%	100%	100%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%		100%	100%	-

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	1.2-4	Coordinate data collection and analysis to measure pharmacovigilance impact as feedback to improve processes	continuous	MAINTAINED The prioritisation of regulatory actions for impact research has been improved with a specific impact section in assessment report templates agreed for selected post-authorisation processes in 2018 and is foreseen for implementation in 2020 due to BCP.
	1.2-4 3.4-1	Provide input into the EC 2019 report on EU network pharmacovigilance tasks	continuous	MAINTAINED The HMA and EMA Management Board consultation on the Agency's input to the EC's report on the performance of pharmacovigilance tasks by the EU Member States and the EMA ended with the endorsement of the report on 28 June 2019. The EC will use this as the key source of information for its formal report which is expected to be translated and published in all EU languages in line with Commission publication requirements. The contribution from the EMA and Member

Objective	MAWP initiative	Activity	% complete	Achievements/results
				States will also be published at the time of publication of the EC report.
	3.3-2	Conduct a lessons-learned exercise after one year experience of public hearings	100%	Completed in 2018.
	1.4-1	Finalise (2019) GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in Q1 2019		SUSPENDED
		Conduct public consultation and finalise GVP product- or population-specific considerations V on geriatric population		SUSPENDED
		Consider review of GVP Module VII on Periodic safety update report and GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators		SUSPENDED
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	1.2-4	Build and maintain capacity for EU Network analysis of epidemiological data	continuous	REDUCED Activity limited to the EMA/HMA task force on Big Data. A new study continues with regulatory authorities on measurement of switching patients from codeine to alternative treatment following earlier regulatory action. It is also proposed to extend the testing of new analytical approaches for electronic health records with PRAC involvement.
		Develop and maintain inventory to facilitate access to data on real-world data	continuous	REDUCED Activity limited to maintenance activities. The ENCePP database of resources is continuously updated including description of disease registries and other real world data sources used for regulatory decision-making. At the end of the first half of 2019, 182 centres, 26 networks

Objective	MAWP initiative	Activity	% complete	Achievements/results
				and 136 data sources were included in the database.
		Initiate at least four EMA studies on real world evidence data		REDUCED Activity limited to initiating EMA studies on real world evidence data at the request of PRAC. 12 in-house studies have been initiated between January and June 2019. In February 2019, EMA signed the contracts for 4 externally-funded studies concerning the impact of EU label changes, and revised pregnancy prevention programmes for oral retinoid containing medicinal products (2 studies) and for valproate and related substances (2 studies).
		Review the scientific advice process for post-authorisation studies to identify possible process improvement opportunities		SUSPENDED
	1.2-5	Based on evaluation of the options and feasibility provide support to the use of registries for targeted products on the EU market from learnings from the pilot process	continuous	MAINTAINED Article "Barriers and Opportunities for Use of Patient Registries in Medicines Regulation" published in Clin Pharmacol Ther. 2019 Apr 10. doi: 10.1002/cpt.1414. The report and summary poster of follow-up survey of stakeholder actions following the 4 workshops on stakeholder registry-related activities was published on EMA website. Contribution to DG-SANTE Registries meeting (20 February 2019).
		Implement the recommendations from 2017 guidance on key principles for use of registries from a regulatory perspective		SUSPENDED
	1.4-1 3.2-3	Implement phase 1 of the pilot on the new process of signals submitted by MAHs, including analysis of operational capacity, functionality of	80%	MAINTAINED Information of the operation of the pilot was collected during the

Objective	MAWP initiative	Activity	% complete	Achievements/results
		EV tools, added value of MAH involvement, and areas of process and guidance improvements (2018-2019). Analyse the outcome of phase 1 of the pilot and initiate phase 2 of the pilot (2019-2020)		pilot in Q1/Q2 to support a report to the European Commission in Q3.

6. Other specialised areas and activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Herbal monographs, new	0[1]	1	3	6	6	3	0	-3	-100%
Herbal monographs, reviewed	6					12			
Herbal monographs, revised	0[1]	10	5[2]	3	1	4			
List entries	0[1]	0	0	2	0	1	0	-1	-100%

[1] Cancellation of HMPC March meeting, BCP related suspension of MLWP activities.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Strengthen the quality of the scientific review processes	3.2-14	Establish a pragmatic approach setting European standards for herbal combination products		SUSPENDED
Promote application of harmonised international standards	3.2-15	Provide technical and scientific contribution to the development of ICH guidelines (Carcinogenicity assessment document evaluation for ICH S1)		SUSPENDED
Effectively manage risks to the environment arising from the use of human medicines	4.2-6	Collaborate with the EC on the roadmap “Strategic approach to pharmaceuticals in the environment” and update EMA guideline on environmental risk assessment (ERA). Participate in EC cross-service group on medicines in the environment		SUSPENDED
Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective	1.1-1	Establish and run cross-Agency Task Force on anti-microbial resistance. Provide proposals and implement them for EMA activities to address antimicrobial resistance		SUSPENDED
Enhance ability to respond quickly to public-health emergencies	1.1-9	Collaborate with international stakeholders on the clinical study design and emergency use of medicines in case of a public health emergency and interact with medicines developers in the early stages of the development to facilitate early introduction of appropriate treatments or preventive measures	20%	MAINTAINED In relation to Ebola outbreak in Democratic Republic of Congo, the Agency was working with WHO in designing the strategy and trials for investigational vaccines and therapeutics. Regular contact with manufacturers was maintained for updates on development. Communication and collaboration with the EU member states (MS) continued through a group of expert from NCAs (Ebola Task Force) on scientific and regulatory issues related to potential use in EU MS of investigational products, and

Objective	MAWP initiative	Activity	% complete	Achievements/results
				through regular updates to CHMP. Collaboration with EC aimed at the creation of an EU stockpile mechanism for the investigational products also took place during the first half of the year. Chikungunya, Zika and Lassa vaccines' clinical development are under discussion.
		Contribute to Joint Action on Vaccines and EC vaccines task force on vaccines (action the plan from the Council Recommendations on vaccination). This includes activities related to support research and development of vaccines including dialogue with the national immunization technical advisory groups of WHO (NITAGs); discussion with EC and ECDC on platform for benefit/risk monitoring of vaccines	10%	MAINTAINED Interaction with NITAGs has started. Benefit/Risk platform still requires further scoping activities.
Contribute to European and international initiatives and collaborations in the area of AMR	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) initiative	50%	MAINTAINED A virtual meeting was organised by EMA in April 2019 to follow up on the assigned action 1.4, where one of the objectives is to develop the "Reflection paper on the harmonisation of the reporting of consumption of antimicrobials". The reflection paper is foreseen to be completed by 2020. EMA also participated in one other teleconference organised by other TATFAR implementers.
	1.1-3	Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and the World Organisation for Animal Health (OIE) strategy		MAINTAINED A representative to the newly established (permanent) OIE working group on antimicrobial resistance (AMR) was appointed in May 2019, and the group will have its first meeting in October 2019.

Evaluation activities for veterinary medicines

1. Pre-authorisation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	3	1	1	3	2	4			
Scientific advice requests received	12	16	14	8	10	15	20	+5	+33%
Requests for classification as MUMS/limited market	20	13	14	11	14	25			
of which, re-classification requests	3	1	3		-	5			

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide support and incentives to development of new medicines for MUMS/limited markets	2.1-1	Publish annual report on MUMS/limited market activities	100%	MAINTAINED The MUMS/Limited market activities report has been endorsed by Management Board in March 2019 and subsequently published on the EMA website.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		Develop training material on the latest revision of MUMS guidelines on data requirements and other guidance		SUSPENDED
Promote innovation and use of new approaches in development of veterinary medicines	2.1-5	Promote access to the Agency's Innovation Task Force through presentations to industry, and as part of existing pre-authorisation procedures	50%	MAINTAINED ITF briefing meetings have been promoted in all suitable early contacts with companies, either during meetings, or when answering written or telephone queries. Three ITF meetings for veterinary products were held during this period.
	2.1-6	Develop and publish Q&As developed by ADVENT in priority areas for technologies that are new to veterinary medicine	20%	MAINTAINED The group had a virtual meeting in January 2019 and its activity continues. A second meeting is foreseen in Q3.
		Develop an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials, to control infectious diseases in animals	10%	MAINTAINED Agreement from CVMP will be sought at its July 2019 meeting to progress with the finalisation of the "Discussion document on alternatives to antibiotics" to review comments received from the restricted consultation phase and with a view to publish a reflection paper by Q4 2019. The content of the document will be used as the basis for presentations on the topic to be given at upcoming conferences (TOPRA, FDA Alternative to antibiotics symposium 2019).
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	2.1-5	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice		SUSPENDED
Support development and	2.1-2	Review recommendations from the CVMP ad hoc		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
availability of veterinary medicines		group on veterinary vaccine availability (CADVVA) and agree on CVMP and working parties actions		
		Develop a reflection paper on promoting availability of veterinary vaccines in emergency situations		SUSPENDED
	2.1-4	Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities		SUSPENDED
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis		SUSPENDED
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases		SUSPENDED
		Revise Note for guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use		SUSPENDED
		Develop a concept paper for revision of SmPC guideline for anthelmintics		SUSPENDED

2. Initial evaluation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Initial evaluation applications	13	7	7	12	3	14	22	+8	+57%
New MRL applications	2	1	2	3	2	3	-	0	0%

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
MRL extension and modification applications	0	0	3	0	1	2	-	0	0%
MRL extrapolations	0	0	0	0	0	1			
Art 10, Biocides	0	0	0	0	0	0			
Review of draft Codex MRLs	0	5	0	0	0	0			

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Procedures completed within legal timeframes	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality and consistent scientific outputs of the EMA	2.2-7	Finalise training material on revised guideline, procedures and templates for CVMP assessment reports, and provide training on these, with emphasis on benefit-risk		SUSPENDED
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	2.1-8	Finalise, in collaboration with ECHA and the EC, the procedure for the establishment of MRLs of biocidal substances used in animal husbandry, included in the 10-year review programme (long-used substances)		SUSPENDED
	2.1-7	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products	100%	Completed in 2018.

Objective	MAWP initiative	Activity	% complete	Achievements/results
Promote uptake of harmonised standards at international level	4.2-5	Reflect on the need for increased international harmonisation in relation to the evaluation of consumer safety of veterinary medicines		SUSPENDED

3. Post-authorisation activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Variations applications, of which:	252	211	188	132	215	367	498	+131	+36%
Type IA variations	147	106	110	80	115	191	310	+119	+62%
Type IB variations	72	61	47	40	72	125	-	0	0%
Type II variations	33	44	31	12	28	51	63	+12	+24%
Line extensions of marketing authorisations	0	1	4	2	2	3	-	0	0%
Transfers of marketing authorisations	2					25	10		

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure efficient delivery of post-authorisation procedures	2.2-8	Revise and update post-authorisation procedural guidance		SUSPENDED

4. Arbitrations and referrals

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated[1]	2	3	0	4	3	3			

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

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Arbitration and referral procedures managed within legal timelines	100%	100%	100%	100%	100%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-1	Provide the EC with CVMP recommendation on prioritisation developed in 2017, for the EC to consider the need for further referrals		SUSPENDED

5. Pharmacovigilance activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	71	81	91	88	73	160			
Total adverse-event reports, of which:	34,491	29,143	20,216	19,168	15,383	60,000			
Adverse-event reports (AERs) for CAPs	16,057	14,864	9,838	9,230	6,949	30,000			
Adverse-event reports (AERs) for NAPs	18,434	14,279	10,378	9,938	8,434	30,000			

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
PSURs evaluated within the established timelines	90%	95%	95%	97%	95%	99%
Adverse event reports for CAPs monitored within the established timelines	95%	96%	99%	96%	98%	94%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	2.2-4	Support Member States in the upload and quality control of data into the European database of veterinary medicinal products, and link these data to adverse event reports for CAPs and non-CAPs, to allow signal detection	50%	MAINTAINED The mapping tool to import Eudrapharm data was further updated in Q1 2019 to improve importing product data from Member States. Support to Member States continued through Q1-Q2 2019.
	2.2-5	Organise dedicated focus groups with specialised		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		veterinarians/healthcare professionals to obtain further detailed insight on key aspects to improve pharmacovigilance reporting, and feedback for further development		
	2.2-6	Ongoing monitoring of incidents, evaluation of lessons learned and update of the incident management plan (IMP) and process in light of experience		SUSPENDED
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	100%	MAINTAINED The Pharmacovigilance bulletin has been published in April 2019.
		Develop and implement criteria for proactive risk communication concerning CAPs		SUSPENDED This activity is superseded by the new veterinary legislation (NVR) implementation activities: the draft strategy document has been taken forward as part of the NVR expert group on pharmacovigilance communication (GVP practices IA).

6. Other specialised areas and activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
n/a									

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Support increased availability of veterinary medicines	2.1-3	Conclude the report on the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) and consider follow up	20%	MAINTAINED The report on the group actions was published in July 2018 for public consultation ending in January 2019. Comments were received from 5 stakeholders and the PPHOVA authors started revising the reflection paper which is foreseen to be finalised in Q3/Q4.
	2.1-11	Develop a reflection paper on resistance in ectoparasites		SUSPENDED
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	50%	MAINTAINED Work on the draft guidelines continued throughout the first half of 2019. The revision of the nine VICH GLs is staged in different topic groups. Work at the VICH Expert working group will continue in 2019 and the publication of draft guidelines for consultation is expected for the end of 2019. Contribution by EWP-V to this activity via their experts group is expected to be requested until finalisation.
	2.2-2	Set up and develop a work plan for an ad hoc expert group, to explore practical measures that could form the basis for harmonisation of the		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		SmPCs of veterinary medicinal products in the context of the revision of the veterinary medicines legislation		
	2.2-9	Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation	50%	MAINTAINED Following receipt of the first package of mandates in January, the CVMP convened 9 expert groups to work on the recommendations. • Revision of Annex II (DA, 2 expert groups, deadline Q3 2019) • List of variations not requiring assessment (IA, 1 expert group, deadline Q3 2019) • Criteria for designation of antimicrobials (DA, 1 expert group, deadline Q4 2019) • Collection of data for antimicrobials (DA, 1 expert group, deadline Q3 2019) • Good pharmacovigilance practices (IA, 3 expert groups, deadline Q2 2020) • Pharmacovigilance system master file (IA, 1 expert group, deadline Q2 2020) In February a further mandate was received and an expert group established in collaboration with the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation. • Technical specifications for the Union Product Database (IA, 1 expert group, deadline Q3 2019) The recommendations concerning 3 of the mandates have been discussed by CVMP at their June meeting and the adoption is foreseen for the July meeting. The delivery of these mandates is on track for submission to the Commission by 31 August 2019.

Objective	MAWP initiative	Activity	% complete	Achievements/results
				The second package of mandates from the EC is expected in July 2019. • Good Distribution Practice for VMPs (IA, deadline Q2 2020) • Good Distribution Practice for active substances (IA, deadline Q2 2020) • Rules on VMP for oral administration (DA, deadline Q2 2020) • List of antimicrobials reserved for humans (IA, deadline Q4 2020) • Format of data collection for antimicrobials (DA, deadline Q2 2020) Four expert groups will be established in collaboration with the CVMP and the Inspectors Working Group to prepare the recommendations on the 5 mandates.
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	50%	MAINTAINED Contribution has been provided to two steering committee meetings during the first half of the year.
	2.4-9	Contribute to the considerations of the proposals for the joint HMA task force on availability at the European Surveillance Strategy group for the perspective of CAPs, as part of developing systems to facilitate management of shortages and ensure the adequate supply of essential veterinary medicines	50%	MAINTAINED A new guidance for MAH on reporting shortages (H&V) and a guidance for NCA and EMA on communication on shortages (H&V) were developed with the involvement of CMD groups. A pilot will be launched regarding the guidance for MAH. A pilot for single point of contact system (SPOC) on availability/shortages (H&V) is ongoing. A regulatory manual (H&V) and a metrics document (H&V) on availability/shortages are under preparation. The need for an H&V guidance on withdrawal applications is under evaluation.
Provide high-quality and consistent scientific outputs	3.2-15	Revise guideline on summary of product characteristics for antimicrobials		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
	2.2-7	Consider and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity	50%	MAINTAINED Three veterinary trainings in areas of interest (quality and pharmacometrics) have been held in cooperation with NCAs in Q1-Q2. Pharmacovigilance signal detection discussion sessions are also held every two months to keep the network adequately trained.
Promote uptake of harmonised standards at international level	4.2-6	Contribute to training events that raise awareness and enhance uptake of VICH standards by non-VICH countries		SUSPENDED
	4.2-5	Continue dialogue with international risk assessment bodies with a view to increasing harmonisation of scientific approaches and methodologies for the establishment of MRLs		SUSPENDED
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-4	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins		SUSPENDED
	2.4-3	Set up a system for the stratification of sales data per species as part of the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals	0%	MAINTAINED This activity was temporarily suspended in Q1-Q2 2019, due to the need to redeploy the assigned resources to supporting the EC in drafting implementing and delegated acts specified in the new veterinary legislation. It is expected to be re-instated in the second half of the year.
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	50%	MAINTAINED A virtual meeting was organised by EMA in April 2019 to follow up on the assigned action 1.4, where one of the objectives is to develop the "Reflection paper on the harmonisation of the reporting of consumption of antimicrobials". The reflection paper

Objective	MAWP initiative	Activity	% complete	Achievements/results
				is foreseen to be completed by 2020. EMA also participated in one other teleconference organised by other TATFAR implementers.
	1.1-3	Contribute to implementation of the next phase of the EC action plan on antimicrobial resistance, the WHO global action plan, OIE strategy and other action plans (such as the G8)	50%	MAINTAINED A representative to the newly established (permanent) OIE working group on AMR was appointed in May 2019, and the group will have its first meeting in October 2019.
	2.4-2	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine and publish the outcome in the ESVAC annual report	40%	MAINTAINED The outline of the 9th ESVAC report has been agreed with the ESVAC Sales Expert Advisory Group. The consultation period for the 9th ESVAC report has been postponed till mid-August, due to the delayed validation and approval of 2017 data for some Member States. The final report is expected to be circulated to the EC, Member States and CVMP, and published in October 2019.
	2.4-5	Provide advice to the EC, in collaboration with ECDC and EFSA, on updating the previous advice on the impact on public health and animal health of the use of antibiotics in animals (categorisation of antimicrobials and early hazard characterisation)	80%	MAINTAINED The updated advice on the 'categorisation of antimicrobials' was circulated for public consultation in February 2019 with deadline for comments by end of April 2019. Due to the large amount of comments received (41 stakeholders responded extensively), the Antimicrobial Advice ad hoc Expert Group (AMEG) at their meeting in May decided to ask EC a further extension of the deadline for completing the task. The comments are being evaluated and the revised advice will be for adoption in Q4 2019. The other part of the scientific advice, 'Preliminary risk profiling for new antimicrobial veterinary medicinal products' was

Objective	MAWP initiative	Activity	% complete	Achievements/results
				adopted by CVMP and CHMP in June 2019 and published on the EMA's website.
		Finalise, in cooperation with EFSA and ECDC, the third report on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals prepared	15%	MAINTAINED The JIACRA group had its first meeting in May 2019 to outline the work on the third report. Two more meetings are foreseen in 2019 and the 3rd report should be finalised by Q4 2020.
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	Finalise the draft guideline on higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome		SUSPENDED
		Develop a reflection paper on the potential risks associated with the use of veterinary medicinal products in aquaculture		SUSPENDED
	2.4-6	Reflect on a methodology that could be used to better characterise the exposure to the environment following the use of veterinary medicinal products containing PBTs		SUSPENDED
	2.4-8	Provide advice to the European Commission to assist the preparation of their strategy on managing pharmaceuticals in environment		SUSPENDED

In addition to the above, gap analysis and the impact assessment of the new veterinary regulation were being reviewed during the first half of 2019, taking into consideration the final text of the adopted regulation. Finalisation is expected by end 2019.

Horizontal activities and other areas

1. Committees and working parties

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Number of reimbursed meetings	143	213	261	238[1]	222[1]	348			
Committee meetings	38	35	40	-[1]	-[1]	88			
Trainings	12	8	10	-[1]	-[1]	33			
Workshops	0	28	20	-[1]	-[1]	6			
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	93	142	191	-[1]	-[1]	221			
Number of virtual meetings (audio, video and web conferences)	1,659	2,524	2,460	2,665	2,341	6,799			
Number of reimbursed delegates	2,856	3,969	4,159	4,277	4,240	6,500			
Number of non-reimbursed delegates	227	564	1,464	1,724	1,678	1,000			

[1] Detailed split by types of meeting introduced in the work programme only in 2017. For previous years, all meetings counted under a single, overall entry.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Percentage of delegate satisfaction with meeting support services	-[1]	-[1]	n/a[2]	n/a	n/a	-
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%[3]	100%	99.5%[4]	98%	99%

Performance indicators related to core business	Target 2019	Outcome at the end of				
		Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
First-stage evaluations of conflicts of interests for committee members and experts completed prior to their participation in the first meeting after the submission of a new or updated declaration of interests	100%	100%	100%	100%	100%	100%
Ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	100%	100%	100%	100%	100%	100%

[1] No survey due to BCP.
[2] As of 2017, delegate survey is being aligned with the annual delegate survey conducted by the Scientific Committees Service of the Agency. However, as this service will not be conducting a survey in 2017, no delegate satisfaction survey will take place in 2017.
[3] Members who did not submit an up-to-date declaration of interest prior to the meeting did not participate in the meeting.
[4] Nine committee members did not submit their up-to-date declaration of interests on time.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-1	Support the activities of the HMA Regulatory Optimisation Group (ROG) to simplify and optimise the processing of Type IA variations		SUSPENDED
Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Develop a regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines		SUSPENDED

During the first half of 2019, a preliminary list of EMA research questions addressing evolution in science, technology and regulatory tools for human and veterinary medicines was drafted. Work on this will continue in the second part of the year.

2. Inspections and compliance

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
GMP inspections	247[1]	162	226[2]	374[3]	350[3]	150	370	+220	+147%
GLP inspections	0	0	0	0	1	1	-	0	0%
GCP inspections	79	74	69	56	35	130	-	0	0%
Pharmacovigilance inspections	3	13	9	3	10	12	8	-4	-33%
PMF inspections	66	87	40[4]	-[5]	-[5]	85	66	-19	-22%
Notifications of suspected quality defects	93	69	98	90	91	200	-	0	0%
Notifications of GMP non-compliances[6]	3	10	44	36	8	20	-	0	0%
Number of medicinal products included in the sampling and testing programme	67[7]	55	1[8]	48	52	78	67	-11	-14%
Standard certificate requests	1,284[9]	1,961	2,057	2,042	1,581	3,750	3,000	-750	-20%
Urgent certificate requests	1,349[9]	365	230	273	447	500	2,030	+1,530	+306%
Parallel distribution initial notifications received	1,265	1,264	1,414	1,629	1,423	2,300	2,200	-100	-4%
Parallel distribution notifications of change received	1,038	840	832	1,211	1,054	2,200	2,000	-200	-9%
Parallel distribution notifications of bulk change received	8	4	4	4	8	11	15	+4	+36%
Parallel distribution annual updates received	1,369[10]	46[11]	2,938	2,202	2,064	5,400	6,000	+600	+11%

[1] Higher than previously forecast results due to further additions to the EMA inspection programme, for example re-inspections after short interval.
[2] Results significantly higher than forecast due to high number of unplanned inspections (pre-approval and for-cause); a number of inspections requested in the US for products not in the scope of the mutual recognition agreement (vets, vaccines, ATMPs, blood-derived products), and the original estimate assuming a 100% deferral rate for sites in the US that manufacture biological active pharmaceutical ingredients (APIs).
[3] Includes PMF inspections.

[4] Large part of PMF inspections' requests usually received in the first half of the year.
[5] Included in GMP inspections results.
[6] Other GMP inspections-related notifications previously included under suspected quality defects.
[7] Several products were not on the market at the time of sampling and had to be removed.
[8] Reports from the sampling and testing programme are usually expected starting in June. One report was received before the end of reporting period.
[9] Due to resourcing and loss of knowledge as well as increased processing time of standard certificates, a shift towards more requests for urgent certificates took place.
[10] To allow for IRIS implementation annual update submission were frozen for 3 months.
[11] Estimated 3,175 annual updates to be received but not yet processed.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Inspections conducted within established regulatory timeframes	100%	100%	100%	100%	100%	100%
Standard certificates issued within the established timelines	90%	14%	0%	93%	85%	82%
Average days to issue standard certificate	10	65.0	21.5	8.4	7.9	8
Urgent certificates issued within the established timelines	100%	99%	99%	100%	100%	100%
Parallel distribution notifications checked for compliance within the established timeline	90%	27%[1]	98%	94%	98%	99%
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	35%	73%[2]	31%	37%	31%	37%
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%	n/a[3]	100%	100%

[1] Due to loss of interim staff after relocation, freezing of processing of notifications while switching to IRIS from Filemaker and associated development issues.
[2] New system has been introduced for applicants to include all inspection information. WHO data for generics is now included.
[3] Only year-end results are available for this indicator, due to the nature of the procedure, where the outcome reports are received in the second half of the year.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Increase efficiency,	4.3-2	Strengthen collaboration with trusted	continuous	REDUCED

Objective	MAWP initiative	Activity	% complete	Achievements/results
consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities		international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan) on GCP and pharmacovigilance compliance, and inspections activities in areas of interest		Activity limited to exchange on product specific issues. Within the EMA-FDA GCP initiative, regular and specific product-related teleconferences took place over the first half of the year. The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) also participated in the teleconferences as an observer to the EMA/FDA GCP initiative. Two joint EMA-FDA GCP inspections and four observational inspections were coordinated. In addition, regular teleconferences took place within the EMA-EU Member States-FDA GCP BE Inspections initiative. In the first half of 2019 teleconferences with WHO under the confidentiality agreement between EC-EMA-WHO continued in the area of GCP BE Inspections. EMA-EU MS and Swissmedic agreed on the process of exchange of information for inspections in Switzerland.
	4.3-2 4.3-4	Explore the possibility to set up a pilot phase with the FDA on sharing information on pharmacovigilance inspections	continuous	REDUCED Activity limited to exchange on product specific issues. Information on pharmacovigilance inspections is shared on an ad hoc basis. No product related discussions were held during the first half of 2019.
	4.1-5	Monitor and review effect of implementing EudraGMDP rules for planning module on cooperation with Member States in coordinating third-country inspections	100%	Completed in 2018.
Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-14	Provide regulatory support to the work of the EU Observatory, to facilitate the transition from high enriched uranium to low enriched uranium	continuous	REDUCED Activity limited to exchange on product specific issues. Continued regulatory support to the work of the European

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Observatory on the Supply of Medical Radioisotopes to facilitate the transition from High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) is being provided. EMA will participate at the meeting on 25th September.
	1.1-20 1.1-12 1.1-11	Support and collaborate with the EMA/HMA task force on the availability of authorised human and veterinary medicines	65%	MAINTAINED Continued support has been provided to the HMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use in the first half of 2019. Concerning the Thematic working group 2 - Supply chain disruptions, a definition of a shortage, reporting guidance and metrics have been developed and agreed by the Network. Support was also provided to the establishment of a process for internal cooperation and sharing of information on shortages within the EU network (SPOC - single point of contacts system), which is being piloted since April 2019.
Improve application of equivalent standards of good manufacturing and clinical practice throughout the world	4.2-1	Support training activities in India and China, including establish a panel of European inspectors available to participate in capacity-building workshops in these countries		SUSPENDED
Improve knowledge and understanding of data integrity and implications for regulatory decision-making	4.1-2	Develop further GxP guidance for industry on data integrity		SUSPENDED
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors from international regulators		SUSPENDED
Expand work-sharing and	4.3-1	Coordination of Joint Audit Programme in	75%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
mutual-reliance initiatives		support to the implementation and extension of the EU US MRA		The Joint Audit Programme continues to support the EU-US MRA initiative. FDA confirmed the capability of further 7 Member States bringing the total to 27 Member states recognised. The Joint Audit Programme will continue to support the extension of the MRA scope to veterinary medicinal products.

3. Partners and stakeholders

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Requests for SME qualification	328	254	312	357	499	751	543	-208	-28%
SME status renewal requests	134[1]	163	392	260	139	1,617	1,466	-151	-9%
Number of cases of patient/consumer engagement in EMA activities	333[2]	200[2]	350	302	-	400	550	+150	+38%
Number of cases of healthcare professionals' engagement[3] in EMA activities	110	102	450	399	388	200	-	0	0%
New scientific, regulatory and telematics curricula developed	1	0	0	-[4]	-[4]	1	-	0	0%
Number of training events advertised to the EU Network	27	25[5]	69	-[4]	-[4]	60	50	-10	-17%
Number of reimbursed training events to the EU Network	7	1[5]	11	-[4]	-[4]	8	12	+4	+50%
Number of messages circulated via 'Early Notification System'	215	217	198	-[4]	-[4]	400	-	0	0%
Number of EMA communications pro-actively sent to stakeholders	68	100	63	-[4]	-[4]	150	-	0	0%

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Number of EPAR summaries and EPAR summaries updates published	144	149	145	-[4]	-[4]	300	-	0	0%
Number of summaries of orphan designation published	55	87	87	-[4]	-[4]	200	110	-90	-45%
Access to documents requests	362	462	464	418	333	850			
Documents released following requests for access to documents	792	1,364	1,411	1,179	1,557	2,700			
Requests for information	3,677	3,651	3,241	2,441	2,338	5,500			
Number of documents published on EMA website	3,533	3,871	3,713	4,416	-	7,000			
Number of pages published and updated on EMA website	1,821	2,534	2,261	2,824	-	4,000			
Number of press releases and news items published	63	99	63	88	102	80			
Requests for interviews and comments by media representatives	564	732	927	1,110	1,080	1,800			
Number of reports, brochures, leaflets produced	33	28	20	5	7	30			

[1] SME renewal applications typically submitted towards year-end.
[2] Due to a change in methodology as a result of BCP, only engagements related to products are counted.
[3] These include any interaction a healthcare professional may have with the EMA, in addition to those occurring with healthcare professionals nominated by the national agencies.
[4] New indicators introduced in the 2017 work programme.
[5] Limited number of courses being developed and offered to Network.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Satisfaction level of patient and consumers' organisations	n/a[1]	n/a[1]	n/a	n/a	97%	n/a

Performance indicators related to core business	Target 2019	Outcome at the end of				
		Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Satisfaction level of healthcare professionals	n/a[1]	n/a[1]				
Satisfaction level of SMEs	80%	88%[2]	n/a	98%	93%	92%
Percentage of responses to ATD requests provided within set timelines	90%	92%	97%	96%	90%	93%
Percentage of responses to RFI requests provided within set timelines	95%	96%	97%	99%	97%	99%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	75%	89%	90%	85%	68%	-
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	7	6	4	6	-[3]	-[3]
Number of users registered to the EU NTC Learning Management System	4,600	4,842	4,020	2,850	-[3]	-[3]
Number of NCA experts[4] registered to the EU NTC Learning Management System	3,600	3,888	3,060	1,950	-[3]	-[3]
Satisfaction level of partners/stakeholders with EMA communications	n/a[1]	n/a[1]	n/a	79%	n/a	84% / 87%
Average rating of pages on corporate website during the year	3.5	3.2[5]	3	4	3.6	-

[1] No survey due to BCP.
[2] Indicator from 2018 info day.
[3] New indicators introduced in the 2017 work programme.
[4] The number of NCA experts is a subset of total users registered, and is also included in the indicator for number of users registered to the EU NTC learning management system.
[5] Possibly due to unfamiliarity of users with new corporate website and greater range of pages available with rating system.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Strengthen stakeholder relation focusing on patients	1.3-3 3.1-7	Implement a framework for collaboration with academia with respect to human medicines and	60%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
and consumers, healthcare professionals, industry associations and academia		consider the need for any specific adaptations to the framework with respect to veterinary medicines		Proposal for fee waivers for academia applying for scientific advice/protocol assistance was presented to FIT in May. Dialogue with European Research Infrastructures was maintained in the first half of 2019. Regular dialogue with ERNs and identification of experts on both sides took place as needed.
	3.4-6	Publish annual report on EMA interactions with industry associations		SUSPENDED
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals and their organisations		SUSPENDED
	3.4-5	Implement recommendations to promote GPs' interactions with EMA and support regular engagement with GPs, including through written consultations, teleconferences, participation in dedicated meetings and other		SUSPENDED
Further develop support to, and strengthen stakeholder relations with SMEs	1.3-8	Implement action plan arising from 10-year report on the implementation of the SME Regulation		REDUCED Activities directly related to product support are maintained. Non-product support activities suspended.
Further strengthen Agency's transparency and open data commitments	1.4-3	Complete the reflection paper on providing access to individual patient data		SUSPENDED
	1.4-5	Assess implementation of the policy on publication of clinical data and publish annual report		SUSPENDED
		Hold regular discussions in the technical group on anonymisation of clinical data		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
	1.4-5 1.4-6 1.4-7	Publish the transparency road map for public consultation (2018). Agree draft principles of transparency (2019)		SUSPENDED
Ensure a more optimal organisation of the available expertise within the network for services provided to EMA	3.1-5	Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation	0%	MAINTAINED No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
	3.1-6	Implement the second phase (2018) and launch the third phase (2019) of the multinational assessment team approach post-authorisation	0%	MAINTAINED No progress has been made due to the need to prioritise the EMA Brexit preparedness project.
Ensure 'fit-for-purpose' scientific capability of the Network	3.1-1	Identify emerging topics and gaps in expertise which require action to increase capability of the EU Network	50%	MAINTAINED Report was provided to EXB outlining needs in the context of the future proofing exercise.
		Develop in collaboration with the Network, the EU Medicines Agencies Network Strategy to 2025	5%	MAINTAINED Work on the new Joint Network strategy to 2025 was agreed in the June HMA meeting. It will be progressed during Q3-4 this year and into 2020.
	3.1-3	Work with the Network to include training courses in NTC learning management system and to promote the use of NTC courses, to maximise the use of the EU NTC learning management system		MAINTAINED To date, 24 new courses have been made available through the EU NTC Learning Management system, including 12 online courses. Over 220 experts have participated in face to face courses. The EU Regulatory Network has been particularly proactive in hosting face to face training events (11 events have taken place or are planned in coming months).
		Work with the Network to prioritise training	30%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		needs		Further to the Workshop of Curriculum Leads in December 2018, work on prioritisation of needs in the Veterinary area continued under the direction of the Veterinary Co-ordination group, with over 30% of the face to face training in 2019 covering Veterinary topics. Work is also ongoing on the development of training in the Oncology area, further to the initiative of the CHMP Chairman and identification of oncology as an area of need. An outline on training needs for Big Data including a curriculum for real world evidence (RWE) has been presented to the EU NTC steering group.
	3.1-2	Review and update existing curricula to ensure provision of up-to-date training	40%	MAINTAINED Contact is being made with individual curriculum leads to identify training priorities in 2020 (update provided to TrSG in June 2019). Work is ongoing on the development of new curricula in the areas of Herbal Medicine Assessment and Internal Audits. Discussions are also taking place regarding the development of curricula on RWE and Medical Devices.
	1.3-8	Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency	50%	REDUCED Activity limited to observer status. No meetings January to April 2019. Meetings resumed in May and full secretarial support was provided for plenaries and drafting groups from then on.
		Foster the visibility and activities of the EU Innovation office network to ensure effective and harmonised support to early innovators at local	0%	REDUCED Activity limited to observer status.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		and European level		
Increase awareness on the evolution of the regulatory framework	1.3-8	Identify in cooperation with the EU Innovation office network and the scientific committees priority areas (therapeutic areas, technologies, other) for which there is a need to develop communication tools, such as regulatory guidelines, white papers, publications in peer review journals etc.	25%	REDUCED Activity limited to observer status. Participation in the finalisation of the ICMRA project.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency .work, outputs and medicinal products	3.3-6	Review and improve the format and content of EMA information on medicines for patients and healthcare professionals (i.e. EMA summaries in lay language)		SUSPENDED
	3.3-6 3.3-7	Implement user-testing for EMA communication products which target the general public		SUSPENDED
	3.3-10	Run a pilot to test and improve the crisis communication plan		SUSPENDED
	3.3-7	Carry out an EMA perception survey to better understand communication opportunities and challenges, and review the Agency's communication products and tools as per the results of the survey		SUSPENDED
	3.3-3	Improve the corporate website by adding new tools and features, such as tools to improve search, search-engine optimisation, accessibility, analytics and others		MAINTAINED
	3.3-1	Develop and implement an annual communication plan, in line with the framework strategy for external communication	100%	MAINTAINED Communications plan was adopted by EXB in June 2019.
	3.3-4	Continue development and implementation of a social media strategy, including consolidate		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		social media channels and grow followership		
	3.4-6	Develop streamlined process to support the planning, monitoring and reporting of membership organisation activities and events Propose yearly strategy content for external meetings such as BIO, DIA, RAPS and TOPRA Represent the Agency in steering committees, programme committees and advisory boards of such organisations	100%	Strategic planning, coordination and preparation of Agency participation at: - DIA Euro Meeting, February 2019 - DIA China meeting, May 2019 - BIO International Convention, June 2019 - DIA US Annual meeting, June 2019 - TOPRA annual symposium, October 2019 - DIA Japan, annual meeting, November 2019 Participation in Programme Committee Meetings for DIA Europe, DIA US Annual Meeting, TOPRA symposium 2019 Participation in Steering Committee for DIA Europe 2020 Participation in DIA Regional Advisory Committee 2019 Interacting with BIO and RAPS to ensure Agency's participation Strategic planning and coordination of submission of Agency abstracts for the DIA Europe 2020 Development of tools to monitor impact of Agency's participation in professional membership organisation conferences
	3.3-5	Develop new digital and multimedia communication tools		SUSPENDED
Improve provision of and access to strategic information resources		Implement Information Literacy Programme		SUSPENDED
		Proactive development and provision of InfoCentre collection and services, including e.g., journals, eBooks and databases that address the changing needs of the Agency	50%	REDUCED Activity reduced to all relevant resources are purchased, reviewed, maintained and made accessible in 2019 All relevant subscriptions were renewed/reviewed to date. Books have been purchased proactively. Access to online resources are monitored continuously.
		Support open access publication of relevant scientific articles (Open access requests	50%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		reviewed and approved as necessary, payment procedure initiated)		Following up on 17 open access requests approved. The InfoCentre also helped authors of 11 publications get the open access fees reimbursed (the remaining publications are awaiting or were denied acceptance by the journal and for 1 publication the author was not required to pay for open access).
		Develop pilot to measure reach of open access publications (Assessment on the methods to measure the impact of open access publications completed)		SUSPENDED

4. International activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Interactions with FDA[1]	-[2]					700			
Interactions with PMDA/MHLW[1]	-[2]					200			
Interactions with Health Canada[1]	-[2]					90			
Interactions with Membership organisations[1]	-[2]					100			
Interactions with any other stakeholders[1]	-[2]					500			
Answers to membership organisations' speaker requests[1]	-[2]					100			
Number of information and/or document exchanges[1]	-[2]					750			
Number of teleconferences organised[1]	-[2]					150			

[1] New indicators introduced in 2018 work programme.
[2] Data not available as tracking of activities was not a priority for Q1/Q2 in 2019.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure best use of resources through promoting mutual reliance and work-sharing	4.2-3	Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators	100%	REDUCED Activity limited to product specific issues only. - Follow up on Dapivirine application - Strategy merger CAP/article 58 with EC - Updated infographic February 2019 - Research on impact of Article 58 - Submission of article on Article 58 - Fexinidazole article published in PLoS June 2019 - Ongoing CHMP review of dapivirine - Scientific advice requests for Article 58 products (MTBVAC, Acoziborole, Ivermectin/Albendazole) - Discussion with two potential applicants (FHI360 and MSF)
Promote convergence of global standards and contribution to international fora	4.2-8	Provide assistance to candidate countries, to align their standards and practices with those established in the European Union, and to further foster their integration process		SUSPENDED
Improve application of equivalent standards of	4.2-2	Enhance mechanisms to facilitate local observers' participation in inspections carried out	100%	REDUCED Activity limited to specific inspections' requests

Objective	MAWP initiative	Activity	% complete	Achievements/results
good manufacturing and clinical practices throughout the world		in non-EU countries		- MRA with US FDA - Human completed July 2019; work ongoing for Veterinary - Ongoing discussions with India and with international partners (PIC/S) - Observed and joint inspections on sartans - Ongoing work for pilot programme to rationalise international GMP inspection of sterile finished medicinal products' manufacturers of manufacturers located in third countries (pilot expected to start in October 2019)
Assure product supply chain and data integrity	4.1-1	Promote increased international cooperation in the area of supply chain security, in particular through efforts to coordinate and integrate initiatives at the level of ICMRA	100%	REDUCED Activity limited to support to topic lead - International collaboration on sartans - Creation of a joint regulators/industry Track & Trace group in the ICMRA context (EMA lead): 9 teleconferences have been organised, deliverables for the group have been agreed and 4 sub-groups have been formed working on different work-streams.
Support training and capacity building of non-EU regulators	4.4-2	Increase the number of opportunities for non-EU regulators, in particular those of candidate and potential candidate countries, to participate in scientific and regulatory training activities		SUSPENDED
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU		SUSPENDED
		In collaboration with WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO training platform		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
Prepare regulators for innovative products and technologies		ICMRA strategic priority on innovation	100%	- Active contribution to the deep dive case study on 3D printing with Health Canada - Contribution to the future ICMRA network of innovation
Ensure appropriate representation in relevant fora to ensure convergence of standards	4.2-7	Implement mechanisms to ensure representative and consistent representation of the network in international fora, and to provide feedback to the network including ICH, VICH, WHO, OIE, IRCH and PIC/S, ICMRA, IPRF, IGDRP	50%	- Participation at the DG DEVCO meeting in Brussels on Quality of Medicines: exchanges and possible areas of further cooperation and collaboration. It was in the context of trying to get better network coordination with the European Commission + Member States. - There have also been efforts for better coordination of EMA and Network at the level of the WHO Partnership Platform. - Concerning ICH and IPRP, participation in briefings of the CMDh and in briefings at CHMP - ICMRA executive committee teleconferences - ICMRA day at DIA (June 2019) - Reappointment of representatives from EMA and NCA in IPRP groups
Expand work-sharing and mutual reliance initiatives	4.3-1	Support the Commission with the implementation of a Mutual Recognition Agreement with the US	100%	- Active participation in EU-US MRA for Human medicinal products (completed July 2015) - Meetings with MS to support applications and reviews, in particular to resolve emerging assessment issues e.g. meeting in Hannover to progress CoI, teleconferences with MS/FDA, teleconferences with Member States to help advance responses. Escalation for resolution of critical findings and support to Slovakia - Support to collaboration of US FDA-EU EMA on pre-approval inspections - Active participation in EU-US MRA for Vet medicinal products - Support to EC with discussions on vets and vaccines
Expand work-sharing and mutual reliance initiatives	4.3-1	Increase collaboration with non-EU partners and organisations	100%	- Signature of confidentiality arrangement with European Directorate for the Quality of Medicines & HealthCare (EDQM)

Objective	MAWP initiative	Activity	% complete	Achievements/results
				- Ongoing confidentiality arrangement with Health Canada, text agreed between EMA and Health Canada, currently undergoing inter-service consultation at Commission level. - Face to face meeting with Japan and Taiwan in the margins of DIA US - Support for EU-US collaboration on complex generics (including possible parallel scientific advice) - Support for efficiency and growth of cluster platforms, e.g. inclusion of additional partners (Health Canada in patient engagement, SwissMedic in Biosimilars), supporting development (shortages), encouraging participation e.g. API, supporting development of terms of reference - Review of clusters finalised with submission of article for publication in July 2019 - Ongoing discussions on Heparin - Ongoing discussion on Ranitidine - Ongoing discussion on Sartans - Support to creation of opioid task force - Support to the use of parallel scientific advice in public fora and within FDA - suggestion for improvement of internal process for EMA - Start of support to South Africa for the SAHPRA's Backlog Clearance Program - Preparation of the bilateral meeting with NMPA - Contribution to the WLA document from WHO and agreement with Japan - Visit of Ministry of Health of Indonesia in June - Preparation of the visit of the expert from Malaysia in October

5. Information management

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
Number of Telematics information services provided by EMA	25[1]	23	23	21	-	25[1]			
Number of ongoing Telematics IT projects where EMA is the delivery organisation	3[2]	7	11	7	-	14[3]	4	-10	-71%
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	5[4]	7	10	5	-	5	8	+3	+60%

[1] Annual forecast equivalent to midyear expectation, as the figure represents number of services continuously provided throughout the year.
[2] EudraCT is for now postponed until further notice, due to the delays of CTIS. New Veterinary Legislation is still looking for a funding solution.
[3] Due to Brexit BCP, only 5 projects are actively progressing. 9 projects are currently put on hold.
[4] 3 other projects are planned for a Q3 2019 start.

Performance indicators

Performance indicators related to core business	Target 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Satisfaction of EMA internal and external users (% satisfied or very satisfied)	80%	84%	-	93.9%	90.4%	-
Availability of corporate/Telematics IT systems and corporate website	98%	98%	99%	99%	99.9%	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
n/a				

Support and governance activities

Workload indicators

Procedure	2019 Q1-Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2015 Q1–Q2	2019 annual forecast Initial	Revised	Change	
n/a									

Performance indicators

Performance indicators related to core business	Forecast 2019	Outcome at the end of Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Posts on the Agency establishment plan filled	97%	99%	99%	98%	98%	97%
Total TA staff recruited against vacant posts	42	23				
Staff turnover rate[1]	10%	4%[2]				
Time to fill position from vacancy notice to establishment of reserve list						
Standard procedure	<3 months	3 months[3]				
Medium procedure	<3 months	n/a[3]				
Large procedure	<6 months	n/a[3]				
Revenue appropriations implemented	97%[4]	41%	40%	42%	55%[7]	47%
Expenditure appropriations implemented	97%[4]	67%[5]	71%	73%	73%[7]	67%
Payments against appropriations carried over from year N-1	97%	71%[6]	68%	76%	83%[7]	73%
The maximum rate of carryover to year N+1, of total commitments within the title:						
Title 1	1%	n/a[4]	1.0%	0.86%	1.0%	0.9%
Title 2	15%	n/a[4]	11.8%	7.93%	8.0%	7.6%

Performance indicators related to core business	Forecast 2019	Outcome at the end of				
		Q2 2019	Q2 2018	Q2 2017	Q2 2016	Q2 2015
Title 3	25%	n/a[4]	31.1%	25.86%	27.0%	26.9%
Payments made within 30 days' time	98%	96.13%	97%	97.26%	98.98%[7]	100%
Availability of corporate/Telematics IT systems and corporate website	98%	98%		99%	99%	99.9%
Change in energy consumption (per workstation)	n/a[8]	n/a[8]	-2%	-9%	-[9]	-[9]
Change in water consumption (per workstation)	n/a[8]	n/a[8]	-7%	+22%	-[9]	-[9]
Change in paper consumption (per workstation)	n/a[8]	n/a[8]	-18%	-13%	-[9]	-[9]
Change in non-recyclable waste produced in restaurant and kitchenette (per workstation)	n/a[8]	n/a[8]	-12%	+25%	-[9]	-[9]
Change in recyclable waste produced (per workstation)	n/a[8]	n/a[8]	-21%	-3%	-[9]	-[9]
Change in recycling rate (per workstation)	n/a[8]	n/a[8]	-1%	-4%	-[9]	-[9]
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	n/a[8]	n/a[8]	-11%	+8%	-[9]	-[9]
Overall net CO_2 emissions (per workstation)	n/a[8]	n/a[8]	-12%	+7%	-[9]	-[9]

[1] Staff leaving against total staff (TA+CA).
[2] Some of the expected 2019 turnover might occur in 2020/2021.
[3] No medium or large selection procedures were done. 4 standard procedures took place in Q2.
[4] Annual target to be reached at year-end.
[5] The higher commitment rate is due to administrative expenditure being committed for the whole year.
[6] Includes C8 and C2 - at acceptable level at the end of Q2.
[7] Results at the end of July.
[8] Due to EMA's two-stage relocation to Amsterdam the environmental performance indicators cannot be estimated. During 2019-2021 EMA will occupy three buildings; 30 Churchill Place in London between Jan-Feb 2019, Spark building Mar-Nov 2019 and EMA building Dec 2019 to 2021. To provide meaningful environmental targets, at least one base year of gathering data with regular building occupancy is required and therefore it is envisaged that the new environmental indicators will be set up only for 2022.
[9] New indicators included in 2017 work programme.

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	3.2-4	Develop and implement a framework for integrated planning and monitoring activities		MAINTAINED In the framework of the Administration Digitalisation Programme, a work stream for Integrated Planning has been created to further establish the integrated planning framework: as one of the first activities, a pilot within the administration division for integrated planning was carried out during the reporting period, its results will be further incorporated to the development efforts.
	3.2-5	Implement a competency management framework		MAINTAINED
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	3.1-8	Conduct the annual review of the Agency's handling of independence		SUSPENDED
		Implement the action plan of the anti-fraud strategy		MAINTAINED Implementation of performance of proactive random verifications at divisions' level, performed by the Heads of Division in cooperation with the Anti-Fraud Office (OLAF) and with Information Security, is ongoing and on track.
Implement new GDPR legislation	4.1	Enhance the protection of personal data in all aspects of the Agency work	50%	MAINTAINED Several key documents have been prepared or already adopted and their publication is in the final stage, including Management Board decision on internal rules on restrictions of data subjects' rights under Article 25 EU Data protection regulation (DPR), EMA Implementing Rules under EU DPR, revised privacy statements; draft data protection impact assessment on the Clinical Trials Data Base.

Objective	MAWP initiative	Activity	% complete	Achievements/results
				IT security review has been launched and is targeted to be completed by September 2019. Internal audit consultancy confirmed that there are no gaps in the planned implementation measures for the new personal data protection legislation. All measures planned have been launched and are ongoing.

Annex 2: Project progress and delivery

Project progress and delivery as of 30 June 2019 against what was planned in the work programme 2019 is reported using the following traffic-light system:

Time / budget	
	Project within +/-10% of the plan
	Project 10%~25% behind timelines or above budget
	Project more than 25% behind timelines or above budget

Scope	
	No change to project scope
	Minor changes (expansion or reduction) to project scope (i.e. no significant effect on budget and/or timelines)
	Significant change (expansion or reduction) to project scope (i.e. impacting project budget and/or timelines)

The traffic lights reflect the change to the overall project timeline, budget and scope that has taken place during Q1 and Q2 2019, in comparison to what was planned and approved at the end of 2018 (i.e. as noted in the work programme 2019). Notes explaining the changes are added.

In cases where the project start or end dates foreseen in the work programme 2019 were revised during Q1 and Q2 2019, the current dates are added in the relevant cells, with the original date from the work programme 2019 shown as crossed out.

During the first half of 2019, EMA Portfolio Board supported the CTIS project in restructuring its fixed-price contract; on-boarded 4 new projects - DIMSIS II, E-recruitment and LMS optimisation, Staff On-boarding, Information Classification; managed the funding of the EvVet3 and NVR activities and closed 3 projects: Corporate Website, the Data centre relocation, and the IT Application Maintenance Transition. Draft the project prioritisation for 2020 to be submitted to EXB.

Projects in human medicines evaluation activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2019
				Time	Budget	Scope	
Clinical trials programme							
Clinical Trial Information System (CTIS) (previously EU portal and clinical trials database)	• Regulation (EC) 536/2014, art.80-82 • Regulation (EC) 536/2014, art.40-43	Q1 2018 (Q3 2014 for the old CTDB project)	2021				CONTINUES Due to the size of the backlog, the change of contractor and the introduction of a new of working involving more the Stakeholders, the project is facing some delays and it's now in the re-planning phase for the independent audit which will happen in 2020.
EudraCT & EU Portal (EudraCT legacy)	• Regulation (EC) 536/2014, Art. 80-82,98	2018	2020				CONTINUES Due to the delay in the CTIS project, the activities planned for 2019 will start in 2020.
e-Submission programme							
eCTD4 pre-project	n/a	2020	2021				SUSPENDED
Single submission portal	n/a	Q3 2016	2018				SUSPENDED

Projects in veterinary medicines evaluation activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2019
				Time	Budget	Scope	
Veterinary change programme							
EudraVigilance veterinary v3.0	• Regulation (EC) 726/2004, art.57(d)	2017	2019				CONTINUES, subj to budget availability Due to the introduction of the new Veterinary legislation, some resources had to be diverted to analyse the impact of the new legislation on this project and the limits on the budget slow down the execution.
New veterinary legislation	• New veterinary legislation (under drafting)	Q1 2019	2021				CONTINUES, subj to budget availability Project will start Q4 2019

Projects in horizontal activity areas

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2019
				Time	Budget	Scope	
Data integration programme							
Substances and products management services (including veterinary Union database)	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26 • Draft veterinary regulation, art.51 • Clinical trials regulation 536/2014, art.8193) • Pharmacovigilance fees regulation 658/2014, art.7	2017	2020				REDUCED temporarily Staff shortage during the relocation delayed delivery of the project, but Product data migration will happen in Q3 2019 and Substance data migration in Q4 2019.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2019
				Time	Budget	Scope	
	• Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU						
Online programme							
Extranet	n/a	Q1 2014	2021				SUSPENDED
Intranet	n/a	Q1 2014	2021				SUSPENDED
European medicines web porta	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	Q1 2014	2021				SUSPENDED
Standalone projects							
S-REPS, phase 3 – SIAMED with Knowledge Management	n/a	2019	2020				CONTINUES SIAMED roadmap has been approved, but due to resources issues related to the relocation the project is at risk.

Projects in corporate support and governance activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2019
				Time	Budget	Scope	
Administration digitalisation	n/a	2019	2021				CONTINUES E-recruitment and optimisation of learning management system will be delivered Q3 2019, Staff on-Boarding is planned for Q1 2020
Data centre relocation	n/a	2017	2019				CONTINUES Project was delivered on time and under budget Q1 2019
EMA move to permanent building	n/a	2019	2019				CONTINUES Project will be taken-over by the Dutch authorities.
Application Maintenance and Development (AM&D) sourcing project	n/a	2019	2019				CONTINUES Tender for the new Framework contract will be ready for Q3 2019.
Information classification	n/a	2019	2019				CONTINUES Project scheduled to start in Q3 2019 subj to resources availability Project will start Q4 2019
General Data Protection Regulation (GDPR)	Regulation (EU) 2016/679	2019	2019				CONTINUES Project scheduled to start in Q3 2019 subj to resources availability
Upgrade of the Data Analytics infrastructure	n/a	2019	2021				CONTINUES Project scheduled to start in Q3 2019 subj to resources availability

Annex 3: Brexit preparedness: ORP and activity categorisation

Operations and Relocation Preparedness task force

EMA internal Operations and Relocation Preparedness (ORP) task force, established in June 2016 to address the challenges presented by Brexit, continued its work to plan and prepare for the upcoming change and ensure all the necessary steps are taken to maintain continuity of the EMA business operations throughout this period. The work of the ORP task force is organised into 2 areas of activities:

- EMA Brexit preparedness and implementation, and
- EMA-Dutch Authorities' collaboration for relocation to Amsterdam.

Each area of activity is divided into various work streams.

EMA Brexit preparedness and implementation

Work streams include:

- Scientific committees procedures and inspections, which focus on the preparedness of the scientific committees and working parties, in particular with respect to how the scientific assessment and monitoring of medicines will be shared between the Member States in view of the UK's withdrawal from the EU. It also includes the necessary activities to be undertaken to enable as much as possible an undisrupted supply of medicines.
- Brexit preparedness business continuity plan which has been developed to address a situation where a "business as usual" scenario is no longer possible. The BCP covers prioritisation of EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss which cannot be compensated through the recruitment of replacement resource.
- Staff relocation and support, which encompasses the work to address HR-related aspects of the EMA preparedness and its implementation.
- Communication activities, covering both internal and external communication to EMA's staff, its key stakeholders and the wider public.

EMA-Dutch Authorities' collaboration for relocation to Amsterdam

In January 2018 the Agency and the Dutch Authorities agreed and put in place a dedicated joint governance structure to steer and oversee the relocation to Amsterdam project, with plans to progress activities within the individual work streams dealing with:

- The new EMA permanent building.
- The temporary premises.
- Staff relocation.
- Financial and legal aspects.
- External communication.
- Removal and logistics.

Brexit BCP and activity categorisation

The Agency's Brexit preparedness BCP categorises and prioritises tasks and activities according to their impact on public health and the Agency's ability to function. The plan sets out three layers or categories of priority:

- Category 1 includes the highest priority activities that are either directly related to the Agency's core scientific activities for medicines or vital to maintaining the infrastructure of the EU regulatory system for medicines. These include, for example, the coordination of actions to protect the safety of patients in all EU Member States, inspections across the EU or maintenance of the functionality and security of critical IT applications used by all Member States. It is absolutely crucial to uphold these activities as any disruption would almost immediately have a detrimental effect on the health and well-being of citizens in the EU and would also jeopardise production and distribution of medicines in the EU.
- Category 2, medium priority activities (subdivided in 2A and 2B), either strategic activities or other core activities not captured in category 1, which include various initiatives aimed at promoting availability of medicines as well as some political priorities of the EU, for example, EMA's contribution to the fight against antimicrobial resistance or the Agency's interactions with Health Technology Assessment (HTA) bodies. These medium priority activities will be maintained for as long as possible, workload and staffing situation permitting, in order to safeguard the development of new medicines.
- Category 3 activities are the lowest priority and cover governance and support activities, such as corporate governance, audits, participation in and organisation of meetings and conferences.

Some activities, for instance, missions, are topic-specific and cannot be classified into a single category, but are considered as part of the activity to which they contribute.

The options for managing the different priorities of activity in a business continuity scenario are that they will either:

- continue as "business as usual", with the understanding that they will be performed to the same high standards as before;
- be temporarily suspended or reduced, with the understanding that a reduced output should continue to adhere to the same high standards, although it may result in a reduction of volume or a delay in the time to achieve the agreed deliverables.

Annex 4: EMA activities that will continue in 2019

The tables below outline EMA activities other than the highest priority activities (category 1 activities), that will continue in 2019.

Theme 1: Contributing to human health

Objectives	Initiatives
• Focus on key public health priorities including availability of medicines and antimicrobial resistance (AMR)	• Contributing to European and international initiatives and collaborations in the area of AMR (TATFAR initiative, EC Action Plan on AMR, WHO Global Action Plan, OIE strategy) • Ensuring the needs of children are met by supporting activities related to innovation, early dialogue and research for paediatric medicines • Enhancing the ability to respond quickly to public-health emergencies by facilitating early introduction of appropriate treatments or preventive measures • Minimising the risk and impact of shortages due to manufacturing problems/quality defects by implementing a revised action plan, providing support to the EMA/HMA Task Force on availability of medicines and providing timely input on product specific issues to the European Observatory on the supply of medical radioisotopes
• Ensure timely access to new beneficial and safe medicines for patients	• Reducing time-to-patient of novel medicines through the development/enhanced collaboration with organisations such as EUnetHTA, HTAN, HTA/pricing and reimbursement bodies in the area of parallel regulatory-HTA scientific advice • Supporting effective and efficient conduct of pharmacovigilance through product related support as regards planned access to and analysis of real-world data, and conducting planned surveillance using patient registries • Capturing and incorporating patients' values and preferences into the benefit/risk evaluation of the scientific review process
• Support patient focussed innovation and contribute to a vibrant life science sector in Europe	• Facilitating the translation of innovation into medicinal products through streamlining interaction with academia • Strengthening collaboration with EUnetHTA, HTAN, HTA/pricing and reimbursement bodies to facilitate exchange between regulators and downstream

Objectives	Initiatives
	decision makers • Identifying areas in need of further science and innovation support for medicines development • Providing adequate product related regulatory support to innovation stemming from SMEs and academia by taking the necessary supportive measures
• Strengthen regulatory capability and transparency	• Strengthening pharmacovigilance capability across the network in the fields of signal management and activities directly related to the EMA/HMA Big Data Task Force

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Focus on key public health priorities including availability of medicines and antimicrobial resistance (AMR)	Depending on resource availability: • *Activities relating to EC/EMA Action Plan on the 10-year report on the Paediatric Regulation.*

Theme 2: Contributing to animal health and human health in relation to veterinary medicines

Objectives	Initiatives
• Increase the availability of veterinary medicines and promote the development of innovative medicines and new technologies	• Providing a clear framework to industry on the classification and incentives for the authorisation of products for MUMS/limited markets • Providing support to the EMA/HMA Task Force on availability of medicines • Developing a strategy and action plan to support retention on the market of long-used veterinary antimicrobials • Promoting access to the Agency's Innovation Task Force • Developing/implementing regulatory guidance in priority areas for new technologies
• Promote "Better Regulation"	• Providing technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary medicines legislation • Supporting efficient and effective conduct of pharmacovigilance by ensuring appropriate guidance, IT tools and data to allow effective signal detection • Providing high-quality and consistent scientific

Objectives	Initiatives
	outputs through the finalisation of CVMP assessment report templates and training on their use
• Focus on key public and animal health priorities including AMR	• Contributing to minimising the risk to man/animals from the use of antibiotics in veterinary medicine by continuing data collection on antimicrobials in veterinary medicine and by providing scientific advice to the European Commission on optimising the use of antimicrobials in veterinary medicine • Supporting increased availability of veterinary medicines by working with the European Surveillance Strategy Group to review existing approaches/systems for shortage management

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Promote “Better Regulation”	Depending on resource availability: • *Activities relating to the preparation for implementation of the new veterinary legislation in Q3-Q4;* • *Activities relating to availability of veterinary medicines.*

Theme 3: Optimising the operation of the network

Objectives	Initiatives
• Reinforce the scientific and regulatory capacity and capability of the network	• Ensuring “fit-for-purpose” scientific capability of the network by identifying gaps in expertise and providing continuous training through the EU NTC in accordance with an agreed action plan • Ensuring optimal organisation of the available expertise in the network for EMA activities by monitoring/improving the Multi National Assessment Team approach
• Strive for operational excellence	• Optimising the current regulatory framework by ensuring efficiency of the existing regulatory operations through improvements to the EMA (support) activities
• Ensure effective communication of and within the network	• Running necessary communication initiatives to support achieving strategic goals by implementing the EMA communication strategy to 2020 and developing the new 5 year strategy

Objectives	Initiatives
• Strengthen the link with other authorities and with stakeholders	• Involving civil society representatives more on product related aspects to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Reinforce the scientific and regulatory capacity and capability of the network	• Restart of GMDP-IWG, GCP-IWG, PhV-IWG, QWP and PAT team meetings. Depending on resource availability: • *Initiatives relating to the Regulatory Science Strategy;* • *Preparation of the EU Medicines Agencies Network Strategy to 2025.*
• Strive for operational excellence	• Initiatives relating to increasing efficiency of the processes for initial marketing authorisations for human products (e.g. IT systems); • Initiatives relating to increasing efficiency of administrative processes (increased digitalisation). Depending on resource availability: • *Activities relating to the preparation for the implementation of the medical devices legislation;* • *Activities relating to the implementation of the General Data Protection Regulation.*
• Ensure effective communication of and within the network	Depending on resource availability: • *Activities relating to EC's report to improve product information*
• Strengthen the link with other authorities and with stakeholders	• Restart of Patient and Consumer Working Party (PCWP) and Healthcare Professional Working Party (HCPWP) meetings.

Theme 4: Contributing to the global regulatory environment

Objectives	Initiatives
• Convergence of global standards and contribution to international fora	• Involving non-EU regulators in specific inspections to observe GCP/GMP inspections • Facilitating effective information-sharing by using international electronic standards for product specific exchanges

Objectives	Initiatives
• Ensure best use of resources through promoting mutual reliance and work-sharing	• Expanding work-sharing and mutual-reliance initiatives by supporting the European Commission with the implementation of the MRA with the US • Increasing product-related information-sharing between regulators responsible for the conduct of clinical trials/pharmacovigilance activities • Improving existing mechanisms for sharing/exchanging information with other regulators on products throughout their lifecycle

Activities added in Q3-Q4 2019

Objectives	Initiatives
• Convergence of global standards and contribution to international fora	Depending on resource availability: • *Activities relating to the International Coalition of Medicinal Regulatory Authorities (ICMRA).*

Annex 5: Terms and abbreviations

Term / abbreviation	Definition
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
AIV	anti-infectives and vaccines
AM&D	application maintenance and development
AMEG	antimicrobial advice ad hoc expert group
AMR	antimicrobial resistance
API	active pharmaceutical ingredient
Art	article
ATD	access to documents
ATMP	advanced-therapy medicinal product
BCP	business continuity plan
BE	bioequivalence
BIO	Biotechnology Innovation Organization, host of BIO International Convention
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
CA	contract agent
CADVVA	CVMP ad hoc group on veterinary vaccine availability
CAMD	
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CNS	central nervous system
CO_2	carbon dioxide
CoI	conflict of interest
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CTDB	clinical trials database
CTIS	clinical trials information systems
CVD	cardiovascular disease
CVMP	Committee for Medicinal Products for Veterinary Use
DA	delegating act
DG	Directorate-General of the European Commission
DG GROW	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG SANTE	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
DIMSIS II	development, implementation and maintenance support of information systems
DoI	declaration of interests
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
eCTD	electronic common technical document
ECV	endocrinology, metabolism & cardiovascular
EDQM	European Directorate for the Quality of Medicines & HealthCare
EFSA	European Food Safety Authority

Term / abbreviation	Definition
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
ERA	environmental risk assessment
ERN	European Reference Networks
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice database
EudraLex	EU legislation; collection of rules and regulations governing medicinal products in the European Union
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	European network for health technology assessment
EU NTC	EU Network training centre
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EWP-V	efficacy working party (veterinary)
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
DIA	Drug Information Association
FIT	EMA fee implementation team
GCP	good clinical practice
GDPR	General Data Protection Regulation
GL	guideline
GLP	good laboratory practice
GMDP	good manufacturing and distribution practice
GMP	good manufacturing practice
GP	General practitioner
GVP	good pharmacovigilance practice
H&V	human and veterinary
HCP	healthcare professional
HCPWP	healthcare professionals' working party
Health Canada	department of the government of Canada that is responsible for national public health
HEU	high enriched uranium
HMA	Heads of Medicines Agencies
Horizon 2020	EU Research and Innovation programme
HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority (Ireland)
HTA	health technology assessment
HTAN	HTA network
IA	implementing act
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	individual case-safety report
IDMP	Identification of Medicinal Products
IGDRP	The International Generic Drug Regulators Pilot
IMI	Innovative Medicines Initiative
IMI PREFER	Patient Preferences in Benefit-Risk Assessment during the Drug Life Cycle
IMP	Incident Management Plan
INC	International Neonatal Consortium
IPRF	International Pharmaceutical Regulators Forum
IPRP	International Pharmaceutical Regulators Programme

Term/abbreviation	Definition
IWG	inspectors' working group
IRIS	Regulatory & Scientific Information Management platform
IT	information technology
ITF	EMA Innovation Task Force
IVD	In Vitro Diagnostics
JIACRA	joint interagency antimicrobial consumption and resistance and analysis report
KPI	key performance indicator
LEU	low enriched uranium
LMS	learning management system
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MAWP	multi-annual work programme
MB	EMA Management Board
MDR/IVDR	Medical Devices Regulation / In vitro Diagnostics Regulation
MEDDEV	medical devices
Member State	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MLM	medical literature monitoring
MLWP	Working Party on European Union Monographs and European Union List
MNAT	multinational assessment team
MRA	mutual recognition agreement
MRL	maximum residue limit
MS	Member State of the European Union
MTBVAC	Mycobacterium tuberculosis (Mtb)-based vaccine
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
Network Strategy	common strategy to 2020 for the European medicines regulatory network
NITAGs	national immunization technical advisory groups of WHO
NMPA	National Medical Products Administration (China, formerly the China Food and Drug Administration or CFDA)
NTC	EU Network training centre
NUI	non-urgent information
NVR	new veterinary legislation
OIE	World Organisation for Animal Health
OLAF	European Anti-Fraud Office
ORP	EMA Operation and Relocation Preparedness task force, focusing on the Agency's preparedness for any possible scenario following the UK's eventual exit from the EU
PASS	post-authorisation safety study
PBT	persistent bioaccumulative and toxic substance
PCWP	patient and consumer working party
PDCO	Paediatric Committee
PEI	Paul-Ehrlich-Institut, agency of the German Federal Ministry of Health
PhV	pharmacovigilance
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIM	pharmacological, immunological, metabolic
PIP	paediatric investigation plan
PLoS	Public Library of Science
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file

Term / abbreviation	Definition
PPHOVA	pilot project on harmonisation of old veterinary antimicrobials
PRAC	Pharmacovigilance Risk Assessment Committee
PREFER	Patient Preferences in Benefit-Risk Assessment during the Drug Life Cycle
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PSMF	pharmacovigilance system master files
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
QPPVs	qualified person for pharmacovigilance
QWP	Quality Working Party
R&D	research and development
RA	rapid alert
RAPS	The Regulatory Affairs Professionals Society
REA	relative effectiveness assessment
RFI	request for information
ROG	Regulatory Optimisation Group
RWE	real world evidence
SA	scientific advice
SAG	Scientific Advisory Group
SAHPRA	South African Health Products Regulatory Authority
SAWP	Scientific Advice Working Party
SC	scientific committee
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	small and medium-sized enterprise
SmPC	summary of product characteristics
SPOC	single point of contact system on availability/shortages in human and veterinary agencies in the EU
S-REPS	scientific and regulatory evaluation procedure support
TA	temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TC	teleconference
TOPRA	The Organisation for Professionals in Regulatory Affairs
UK	United Kingdom
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	veterinary medicinal product
WG	working group
WLA	WHO-listed authorities
WHO	World Health Organization
WONCA	World Organization of Family Doctors
WP	working party