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Mid-year report 2020

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 1 October 2020.

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Covid-19 pandemic

Following the successful relocation to Amsterdam in 2019, the Agency planned to gradually resume its full scale of operations taking due account of the available resources after the relocation in 2020, reinstating some activities that had previously been temporarily reduced or suspended.

Following the outbreak of the COVID-19 global pandemic in the Union in Q1 2020 the Agency invoked its business continuity and public health threat plan in order to protect staff, delegates and contractors' health and safety while delivering on its mandate.

While it is still impossible to foresee the full impact of this pandemic, it is clear it will be significant and multifaceted. Unlike Brexit, where the impact focussed a lot on the operation of the Agency (i.e. execution of the physical relocation and retaining staff to ensure Agency's ability to deliver its core activities), the COVID-19 crisis has changed the landscape in which the Agency operates. Furthermore, the COVID-19 pandemic has affected the whole European Medicines Regulatory Network (EMRN) – National Competent Authorities (NCA), EMA and the Commission, albeit to a different extent and not necessarily at the same time. Therefore, EMA had to react to the impact of the pandemic both in terms of the impact on the Agency itself and of the impact on the network.

Business continuity planning

By invoking its business continuity and public health treat plan, the Agency focused on the protection of staff, delegates and contractors and on the prioritisation of COVID-19 related activities, while safeguarding regular continuity of core operations. The resulted in the launch of the EMA COVID-19 BCP.

Considering how the work of the EMA is interlinked with that of the EU Regulatory Network, guiding principles for the prioritisation of COVID-19 related work and of regulatory procedures were defined in a dedicated EMRN Business Continuity Plan agreed with the whole EU Regulatory Network and aligned with BCP measures set out by the Human and Veterinary Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh, CMDv). It should be emphasised that the phases of the EMA COVID-19 BCP are not necessarily fully aligned with those of the EMRN COVID-19 BCP, as additional aspects may have to be considered for each BCP.

To manage and coordinate the execution of its business continuity plan, the Agency established an ad hoc governance structure led by the COVID-19 task Force. The work of the Task Force is organised in 4 work-streams, each focusing on a specific aspect of the crisis:

- Work stream 1: therapeutic response
- Work stream 2: supply chain
- Work stream 3: business continuity and impact
- Work stream 4: Human Resources

EMA COVID-19 BCP is being implemented in a staged approach, and the first phase was invoked on 9 March 2020 due to the increased spread of COVID-19 within Europe. Phase 1 provisions foresee that:

- Staff consecutively telework from home
- All meetings of Scientific Committees, working parties and stakeholders events are held virtually

- For essential activities to be carried out on site, strict safety and physical distancing measures are followed

COVID-19 impact on EMA core activities

The Agency will strive to remain "business as usual" as long as possible whilst prioritising any COVID-19 related activity, in terms of

1) coordinating all activities of the scientific Committees on scientific aspects of the crisis related to management of medicinal products,
2) liaising with developers to provide scientific contribution to new drugs/vaccines development,
3) coordinating the actions required to manage the risk of shortages of medicines, and
4) providing enhanced coordination of the EU regulatory network to ensure the least possible impact on time and quality of evaluation and supervision of medicines.

A number of prioritisation measures have been introduced through BCP measures, allowing the Agency to mobilise approximately 40 FTEs to face the challenges originating from the pandemic.

Impact on the Agency's activities

In order to safeguard the delivery of its core activities and to ring-fence resources to deal with COVID-19, the Agency has implemented a prioritization of the activities, based on their impact on public health and the Agency's ability to function.

The starting point of the COVID-19 prioritisation was the Brexit BCP, adjusted to reflect the reality of COVID-19.

For the purposes of COVID-19 BCP, Agency's activities have been categorized into 3 levels of priority:

- Category 1 activities – highest priority activities related to core business, legal obligations, and ensuring Agency operations – such as core scientific activities (including all COVID-19 related activities); supporting IT applications as per the existing BCP core tasks; fee generating activities to ensure a stable income for EMA; and corporate, communication and other IT activities necessary for the operation of EMA.
- Category 2 activities – strategic activities or other core activities not captured in category 1, including, e.g., secretariat activities related to Working parties (WP), Working Group on Quality Review of Documents (QRD-WG), Name Review Group (NRG) , Generic good practice (GxP), guidelines, data governance and data modelling; maintenance, scientific advice and certification, and paediatrics activities that are not linked to specific procedures/products; projects other than those listed under category 1; clinical data publication; and other public health activities, such as The small and medium-sized enterprise (SME) office activities, antimicrobial resistance (AMR), Health Technology Assessment (HTA), influenza pandemic, innovation and emerging therapies and technologies, regulatory science, availability of human and veterinary medicines, minor use, minor species (MUMS) , European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), EU Institutional and Member States cooperation, enlargement, international cooperation.
- Category 3 activities – lowest priority non-strategic activities such as governance and support activities, and transparency & information activities such as requests for information.

During Phase 1 of EMA COVID-19 BCP, the Agency continued its activities as per the Work Programme 2020 (which is based on the Brexit BCP) with the exception of tasks that had not yet started or yet

restarted thereby allowing the Agency to take on-board the additional COVID related tasks through postponement of those tasks.

In the following sections the key deviations have been identified; it must be noted that all the activities requiring physical presence were heavily affected. At the same time, most of the activities listed in the Work Programme 2020 experienced an implementation pace slower than planned due to workload adjustments driven by the need to tackle the pandemic.

Key figures

This report describes the results and achievements of the Agency, working closely with the national NCAs, during the first six months of 2020, and thus reflects the situation as of 30 June 2020. Here below we highlight the most relevant deviations vs the annual work programme registered in the first half of 2020. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

Joint scientific advice with HTA bodies saw a significant decrease due to the reduced European network for health technology assessment (EUnetHTA) capacity to handle parallel Scientific Advice procedures, the expectation for the full year is hence lowered from 23 to 5.

The **Scientific advice finalised** continued the growing trend of the last two years reaching 324.

Requests for advanced-therapy medicinal products (ATMP) classification saw a notable increase, doubling the result obtained in the last three years (54 vs 27).

Initial evaluation applications received in the first half of 2020 (65) remained at the same level of 2019.

The finalised protocol assistance requests, after a peak in 2018 (102), returned to the same level registered in 2016 (60).

Initial evaluation applications of new **non-orphan medicinal products** grew over 50% compared to 2019 (28 vs 18), leading to an upward revised annual forecast.

The **number of granted requests for accelerated assessment** saw a sharp increase, due to the COVID-19 pandemic, reaching a 5 year peak.

After 3 years of growing trend, **the average clock-stop for new active substances and biosimilars** remarkably improved, reaching the same level of 2016 (175 days) and below the set target days (180 days).

The number of variation applications increased in the first half of 2020. Especially **type IB and type II variations** grew almost by 30% compared to 2019.

Line extensions of marketing authorisations saw a significant increase compared to the average of the previous five years (24 vs 11). The annual forecast was revised accordingly (from 21 to 37).

Article 61(3) applications decreased significantly (66 vs 157 in 2019) as a result of a drop in the submissions during the first half of 2020.

The average clock-stop for variations that include extension of indication, while remaining under the 2020 target, worsened compared to the last 5 years.

Assessment activities for veterinary medicines

The number of **initial evaluation applications decreased** by 50% compared to 2019, but in line with the annual forecast since the majority of applications is expected for the second half of 2020.

The number of variation applications increased in the first half of 2020, in particular **type IA variations** (191 vs 147 in 2019) **and type IB variations which** grew by more than 50% compared to 2019 (111 vs 72).

The number of **adverse event reports** (**AER**) saw a slight decrease compared to 2019, especially with regard to CAPs.

All the periodic safety-update reports (PSUR) received were evaluated within the established timelines, thereby improving the already excellent performances of the previous years.

Five applications for transfers of marketing authorisation were received in the first half of the year (vs 2 in 2019), in line with the expected forecast for the full year.

Inspections and compliance

The number of good manufacturing practice (**GMP**)**,** good clinical practice (**GCP**) and Plasma Master File (**PMF**) **inspections notably decreased** in the first half of 2020 due to the travel restrictions related to the COVID-19 pandemic.

Standard certificate requests significantly increased compared to the first half of 2019 (1538 vs 1284), whereas **urgent certificate requests** saw a major drop (729 vs 1349). Both trends can however be explained as the reversion of the shift happened in 2019 from standard to urgent certificates.

97% of standard certificates were issued within the established timelines, and the **average time to issue standard certificate** reached **26 days**, hence remarkably improving the performances registered in the previous years.

The extremely high increase in the number of parallel distribution annual updates received in the first six months of 2020 (7,778 vs 1369 in 2019) is due to the inclusion of notifications of change as well as the backlog of 2018-2019 annual updates which have been processed from December 2019.

98% of parallel distribution notifications were checked for compliance within the established timeline, returning to the excellent levels of 2016-2018.

A huge variation in **number of meetings** was caused by COVID-19 Pandemic. The number of physical meetings (committees, management board, trainings, workshops) dropped in the first half of 2020 (52 vs 143 in 2019) and concurrently there was a spike of the number of virtual meetings (2,660 vs 1,659 in 2019). As a result, the number of reimbursed and non-reimbursed delegates sharply fell.

Requests for access to documents (ATD) decreased in the first six months of 2020. The **number of documents released** also fell by more than 50% compared to 2019 levels (382 vs 792 vs 2019). The annual forecasts have been revised downwards to reflect both decreases.

Key developments

The outbreak of COVID-19 pandemic has undoubtedly impacted the Agency's work programme and significant resources have been absorbed to tackle the crisis - the Agency managed to mobilise around 40 FTEs - and around 52% of the planned activities have been affected. Some of the key activities that took place during the first half of 2020 are highlighted below.

In the context of the **emergency use of medicines in case of a public health emergency**, COVID-19 EMA pandemic Task Force (COVID-ETF) contributed to the CHMP assessment following a rolling review of Remdesivir, the first treatment for COVID-19 to be recommended for authorisation in the EU.

Regarding the **new veterinary legislation** the Agency continued to support the European Commission in drafting delegated and implementing acts. In particular, five different recommendations have been submitted in the first half of 2020. Furthermore, the Union Product Database and the Union Pharmacovigilance Database have been initiated and are progressing as planned.

The **EMA/Heads of Medicines Agencies (HMA) task force on the availability of authorised human and veterinary medicines** progressed the actions of the thematic working groups. The second phase of the pilot on the single point of contact system for products availability (SPOC) has been currently delayed due to the COVID-19 outbreak, however, the newly created SPOC network was activated in the context of the pandemic. Furthermore, the EU Executive Steering Group on shortages caused by major events was established in the first half of the year.

Progresses were made with regard to **opioid misuse and abuse**: the Steering committee and the task force, with adopted mandate and rules of procedure, were established and four workstreams have been created.

The dialogue with the EC on COVID-19 vaccines, the launch of the European Vaccines Information Portal and the approval of the second Ebola vaccine were among the most significant developments of **EMA activities related to vaccines** in the first half of the 2020.

The **review of Nitrosamines impurities** in medicinal products has been ongoing and the report on the lessons learned related to the sartans review has been published in June.

The draft of the **new Network strategy to 2025** was completed in the first half of 2020 and it is ready to be sent out for consultation in early July. The **Regulatory Science Strategy** has been finalised and its adoption will take place in the second part of the year.

In preparation for the **implementation of the Medical Devices and In vitro Diagnostics Legislation** (MDR/IVDR): Work has continued with the EC to finalise the guidance on drug-device combinations;

The revision of MEDDEV 2.1/3 and 2.4/1 continued and EMA supported medical device-companion diagnostic product discussions for scientific advice (SA), Innovation Task Force (ITF), Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT).

The **HMA – EMA Joint Big Data Taskforce** final report and the top priority recommendations were published in January. The Big Data Steering Group was established to take forward the Task Force recommendations and held its first meeting in May.

The Agency has continued to support the **use of registries for targeted products on the EU market** and has developed a SOP providing step by step guidance for real-world evidence input into scientific advice, PRIME and pre-submission meetings.

The **ENCePP database** has been continuously updated and at the end of June included 187 centres, 26 networks and 144 data sources.

In the first half of 2020 the agency continued to work on **AMR,** participating to the OIE AMR working group meetings and to the One Health European Joint Programme (EJP) Stakeholder Committee meeting held virtually in April, June and May 2020 respectively.

In addition to this, EMA, in cooperation with the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC), continued to work on the third joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA), however, a 6 months extension of the original submission deadline was requested to the EC to cope with the impact on resources due to COVID-19.

In the context of the continuous data collection on the consumption of antimicrobials in veterinary medicine, EMA drafted the 10th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report and its publication is foreseen in October.

Although the second phase of its implementation has been postponed to 2021 due to COVID-19 priorities, the **multinational assessment team** (MNAT) **approach** was adopted by CHMP for the quality part of the assessment of REMDESIVR which was characterised by an urgent timeline.

The implementation of the **Data protection Regulation for EU institutions and bodies** (EU-DPR) has progressed with the publication of the Agency's Central Register of records of data processing activities and the completion of IT Security Review. Data protection support and continuous consultation has been provided in relation to all initiatives and activities involving the processing of personal data.

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted EMA work programme 2020.

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 2020'. 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 disproportionate variation, discretion should be used to reflect more accurately the significance of the change. For example, a number of applications falling from 3 to 2 (or rising from 2 to 3) 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.

In line with the BCP implemented at the Agency, some activities in the adopted work programme were delayed or postponed. To reflect the current impact of the COVID-19 crisis on the implementation of the Agency's work programme, the activities are indicated in the report as *maintained*, *reduced* or *suspended*, according to their status by 1st September. Traffic lights are also attached to the status indication (green, orange and red, respectively), to allow for a quicker, more visual assessment of the BCP impact on Agency's activities. Of note, *this traffic light is not linked to the results delivered in 2020* but only reflects the BCP status of a given activity. No traffic light or BCP status is provided for the activities that have been completed previously (e.g., in 2019) or those that were not included in the work programme at the time of adoption by the MB in December 2019.

Evaluation activities for human medicines

1. Pre-authorisation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Scientific advice/protocol assistance pre-submission meetings	48	53	52	66	87	102	102	0	0%
Scientific advice and protocol assistance requests, of which:	377	342	350	345	287	674	701	+27	+4%
Parallel scientific advice with international regulators	4	2	3	4	2	5	6	+1	+20%
Joint scientific advice with HTA bodies	1[1]	10	16	17	9	23	5	-18	-78%
Scientific advice for PRIME products	19	15	22	12	0	29	29	0	0%
Protocol assistance	65	81	103	79	59	155	126	-29	-19%
Novel technologies qualification advice/opinions	9	9	6	11	8	18	18	0	0%

[1] In the first half of 2020 EUnetHTA capacity to handle parallel Scientific Advice procedures was reduced. The outbreak of the COVID-19 pandemic led to the temporary suspension of the programme.

	PRIME eligibility requests received	28	24	29	46	48	55	52	-3	-5%
	Scientific advice finalised	324	279	228	264	203	535	592	+57	+11%
	Protocol assistance finalised	60	80	102	79	61	150	120	-30	-20%
	Orphan medicines applications	123	127	127	127	164	280	280	0	0%
	Submitted applications on the amendment of an existing orphan designation	0	5	1	2	3	5	1	-4	-400%
	Oral explanations for orphan designation	28[1]	44	39	49	38	85	75	-10	-12%
	Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	339	279	375	310	265	500	500	0	0%
	Finalised procedures for compliance check on PIPs	43	40	57	35	37	70	70	0	0%
	Annual reports on paediatric deferred measures processed	104	108	100	87	84	170	170	0	0%
	EMA paediatric decisions processed	243	222	183	180	175	350	350	0	0%
	Requests for classification of ATMPs	54	27	27	27	40	50	70	+20	+40%
	Innovation Task Force briefing-meetings	15	11	10	12	24	25	30	+5	+20%
	Innovation Task Force Art 57 CHMP opinion requests	0	0	0	0	2	1	1	0	0%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	100%	100%		100%	100%

[1] Slight decrease of the initial estimate due to many Oral Explanations cancelled.

Performance indicators related to core business	Target 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
PRIME eligibility requests assessed within regulatory timeframe	100%	100%	100%			-
Orphan designation opinions delivered within the legal timeframe	100%	100%	100%	100%	100%	99%
PDCO opinions sent to applicants within legal timelines	100%	100%	99.6%		100%	100%
Increase in scientific-advice requests	7%	4%	0%		20%	0%
SME requests for SA (% of total SA requests)	30%	27%	28%		28%	25%

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		REDUCED The activity is limited to high level presence in Innovative Medicines Initiative (IMI) scientific committee with no proactive identification of topics" Contact and collaboration with EC planned to restart Q3. Support has been given to the Scientific Committee of IMI and the Research and Innovation workstream has engaged in support to COVID-19 calls for research.
		Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation		SUSPENDED The activity is planned to restart in Q3 2020.
		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 The Activity is planned to restart in 2021.
	1.3-8	Reinforce collaboration via EU Innovation Network with academia and research hospitals		SUSPENDED The activity is planned to restart in 2021.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		that could benefit most of the innovation offices regulatory support		
	3.1-1	Use business forecasting and analysis tools to better inform the EU Network about past and prospective development and improve regulatory preparedness		SUSPENDED due to COVID-19 BCP The activity is planned to restart Q3 2020. In Q1/Q2 since special focus has been given on COVID-19 topics as support from business pipeline to COVID-ETF forecasting exercise.
	3.2-2	Establish a platform for project-specific engagement with developers in priority from SMEs and academia, to optimise activities during the development phase		SUSPENDED The activity is planned to restart in 2021.
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	20%	REDUCED The activity is limited to addressing public health needs and operational improvements. Preparation of multi-stakeholder meetings planned to be hosted at EMA in autumn 2020: Paediatric Oncology (ACCELERATE) and neonatology (International Neonatal Consortium - INC). Both have recently been decided to be held virtually. Preparation of interim outcome report on action plan (further steps to be finalised internally and with EC for publication. Operational: ongoing revision of Paediatric investigation plan (PIP) summary report and opinion template. Delays for further activities caused by Covid-19 BCP.
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders		SUSPENDED due to Covid-19 BCP The activity is planned to restart in 2021.
Improve cooperation with partners (e.g. HTA bodies,	1.2-3	Coordinate delivery of actions under the EMA/EUnetHTA work plan, in conjunction with	40%	MAINTAINED Review of the delivery of the EMA/EUnetHTA work plan at

Objective	MAWP initiative	Activity	% complete	Achievements/results
European networks, international partners) throughout the product lifecycle		Joint Action 3		bilaterals; major deviation: suspension of the parallel consultation platform from EUnetHTA's side; other topics progressing however impacted by EUnetHTA capacity (including companion diagnostics / combination products).
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		REDUCED The activity is reduced to product support and it is planned to fully restart Q3 2020.
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 The activity is planned to restart in 2021.
		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	40%	MAINTAINED Planning, conducting and reporting of a Workshop on Art 117 implementation which had to be held in March 2020; all planning activities were completed but the workshop had to be postponed due to COVID-19. Discussions with EC and Drug-device combination (DDC) guidance drafting group to finalise guidance; Other contributions were the EC discussion paper on artificial intelligence (AI); Q&A and publication on digital health technologies in relation to medical devices (contribution as part of CHMP workplan); new Q&A and Discussion paper submitted to EC for feedback and further discussion; contribution to MEDDEV 2.1/3 and 2.4/1 revision; supporting medical device-companion diagnostic product discussions for SA, ITF, CHMP and CAT

Objective	MAWP initiative	Activity	% complete	Achievements/results
Ensure and run highly effective and efficient processes to deliver pre-authorisation activities	3.2-2	Review and implement optimised operations for all functions supporting medicines' development, including knowledge management	40%	MAINTAINED i) developing, testing and stepwise implementation of the Assisted Validation System for Type IA variations; ii) development, testing & preparation of training on the Personal Data Redaction tool (PeDaR tool) for documents access and publications service; iii) establishment of a team to support Analytics Centre of Excellence (ACE) activities and a roadmap with a list of projects to be delivered by the end of 2020.
Prepare EU to prevent or manage an Opioid misuse in Europe	1.1-21	Establish a Task force and a Steering group to prevent Opioid misuse in Europe: Opioid abuse, misuse and dependence crisis in US and Canada ongoing.	100%	MAINTAINED The Steering committee and the task force were established with adopted mandate and rules of procedure, having monthly Steering committee meetings and quarterly task force meetings. Four workstreams (WS) are established: WS1 - review of best practice/mitigation measures; WS2 - Evaluation of data landscape; WS3 - Data collection and generation; WS4 - Collaboration with international stakeholders

2. Initial evaluation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Number of MAA pre-submission meetings	39	48	40		37	70	70	0	0%
Initial evaluation applications, of which:	65	63	47	36	42	114	108	-6	-5%
New non-orphan medicinal products	28	18	20	16	18	36	42	+6	+17%
New orphan medicinal products	17	17	9	9	11	27	27	0	0%

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Similar biological products	7	8	5	5	3	14	12	-2	-14%
Generic, hybrid and abridged applications	12	20	13	5	10	34	24	-10	-29%
Scientific opinions for non-EU markets (Art 58)	0	0	0	0	0	2	2	0	0%
Paediatric-use marketing authorisations	1	0	0	1	0	1	1	0	0%
Number of granted requests for accelerated assessment	10	3	1	4	7	8	12	+4	+50%
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	10	11	9	7	4	24	24	0	0%
Reviews on the maintenance of the orphan designation criteria at MAA stage	21	20	28	17	12	60	30[1]	-30	-50%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Applications evaluated within legal timeframes[2]	100%	100	100%	100%	100%	100%
Average assessment time for new active substances and biosimilars	205	198	205	196	180	210
Average clock-stop for new active substances and biosimilars	180	175	214[3]	203	182	175
% of MAAs initiated under accelerated assessment that have been	75%	60%	100%[4]	33%	75%	56%

[1] The variation in the forecast can be explained by the timing of the involvement of the orphan team in the evaluation of the maintenance of the orphan drug designation criteria. This takes place more towards the end of the marketing authorisation application (from day 121 onwards for a normal procedure of 210 days/earlier in a case of approved accelerated review) for the reporting exercise only those that conclude in the reporting year are taken into account. The calendar for some procedures might be extended due to clock stops and as a consequence, the orphan evaluation postponed. Overall, a procedure for MAA might start in a particular year with no involvement of the orphan team until the year after.
[2] Includes marketing authorisation and plasma master file applications.
[3] 6 products had a clock-stop between 310 and 715 days (2 Oncology, 2 endocrinology, metabolism & cardiovascular (ECV), 1 central nervous system (CNS) and 1 anti-infectives and vaccines (AIV) Art 58).
[4] Value is not representative of longer-term trends as it is based on a single opinion.

Performance indicators related to core business		Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
	completed as accelerated assessment						
	% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	80%	72%	86%	56%	65%	60%
	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%	98%	95%	100%	99%	100%
	% of therapeutic guidelines progressed to next step or finalised (vs planned)	70%	-[1]	5%[1]	35%	80%	-[2]
	% of early background summaries drafted and sent to assessment teams (vs planned)	100%	100%	100%	100%	100%	-[2]
	% of outcomes/results of workshops on therapeutic objectives published on EMA website	100%	0%[3]	n/a[3]	50%	n/a[3]	-[2]

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Provide high quality, robust, scientifically sound and consistent product information	3.3-6	Implement EMA action plan on EC's report to improve Product Information with regards to ePI		SUSPENDED Key principles for ePI in the EU were adopted and published by HMA and EMA MB. The activity is planned to restart in Q4 2020.
Reduce time-to-patient of medicines through use of existing and new	1.3-4	Support activities stemming from Joint Action 3/work package 4, by providing relevant information from regulatory assessment to	50%	MAINTAINED Product-specific exchanges for all applications subject to Joint relative effectiveness assessment (REA) production by WP4; in

[1] As a result of a decision by the EMA Operation and Relocation Preparedness task force (ORP) - BCP subgroup, the development of the majority of scientific guidelines are put on hold since the end of 2018. Out of 42 therapeutic guidelines, development of only two oncology guidelines continued in Q1-Q2 2019. No work plan was developed for 2020 due to Covid-19 BCP
[2] New indicators introduced in the 2017 work programme.
[3] No workshop was held in the first half of the year.

Objective	MAWP initiative	Activity	% complete	Achievements/results
assessment approaches within existing legal frameworks, including through collaboration with international partners		HTA bodies for relative effectiveness assessments		accordance with operational guidance between EMA and EUnetHTA
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-15	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 The activity is planned to restart in 2021
		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.	80%	MAINTAINED In the first part of 2020 an oncology paper has been completed and a second overarching paper was submitted by the Biostatistics working party to the CHMP in June 2020. Formal review / consultation / communication is planned in the second half of 2020.
Contributing to the global regulatory environment	4.1-xx	Develop position paper on trial integrity in the presence of interim results in on-going clinical trials and handling of its confidentiality		SUSPENDED due to COVID-19 BCP The activity is planned to restart in 2021 with a concept paper drafted by the Biostatistics Working Party.
		Review the experience gained from patient level data (PLD) analysis by the EMA committees and formulation of a plan for a targeted pilot		SUSPENDED due to COVID-19 BCP The activity is planned to restart in Q4 2020 with a presentation at the CHMP Strategic Review and Learning Meeting under the German presidency which will be followed by a report of the review of experience on individual patient data in clinical trials, and a plan for a targeted pilot.

3. Post-authorisation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Variation applications, of which:	3,909	3,408	3,095	3,021	3,041	6,506	7,285	+779	+12%
Type IA variations	1,978	1,898[1]	1,604	1,536	1,578	3,154	3,684	+530	+17%
Type IB variations	1,301	1,011	993	952	968	2,200	2,410	+210	+10%
Type II variations[2]	630	499	498	533	495	1,152	1,191	+39	+3%
Line extensions of marketing authorisations	24	9	10	12	11	19	37	+18	+95%
PASS scientific advice through SAWP	1	1	2	0	2	2	2	0	0%
Number of consultations of SAGs/ad hoc expert groups in the context of post-authorisation activities	5	3[3]	6	6	7	12	12	0	0%
Renewal applications	44	42	40	25	43	81	78	-3	-4%
Annual reassessment applications[4]	7	7	5	2	7	27	25	-2	-7%
Transfer of marketing authorisation applications	27	39[5]	232	36	8	50	51	+1	+2%
Article 61(3) applications	66[6]	157[7]	103	112	102	220	220	0	0%
Post-authorisation measure data submissions	403	446	405	368	490	900	900	0	0%

[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] The lower result compared to last year is due to a drop in the submissions.
[7] Surge of 61(3) linked to change of local representatives for applicants.

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Plasma Master File annual update and variation applications	18	20	7	17	10	38	29	-8	-24%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2015
Post-authorisation applications evaluated within legal timeframes	99%	98%	99%	99%	99%	99%
Average assessment time for variations that include extension of indication	180	160	154	152	161	169
Average clock-stop for variations that include extension of indication	90	89	77	70	61	75
% 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%

4. Referrals

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	2	6	2	3	4	8	6	-2	-25%
Non-pharmacovigilance referrals started	5	4	8	2	8	8	8	0	0%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
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	The need to develop a common understanding within the Network on the best use of referrals was adopted by HMA in November 2017 (referrals roadmap). Working groups have been formed with the relevant Committees (PRAC, CHMP and CMDh). An agreement on deliverables for 2018 has been reached in Q1-Q2 2018. Finalisation of this activity to be expected for 2020	50%	MAINTAINED Report including analysis and recommendations has been finalised Q1 2020 on the CHMP referrals based on efficacy. Trainings were provided (dedicated rapid alert awareness sessions on referrals to be delivered in Q4 2020) An analysis and drafting of a report on temporary measures has been circulated to Pharmacovigilance Risk Assessment Committee (PRAC) subgroup.
Reliance		Review of Nitrosamines impurities in medicinal products	continuous	MAINTAINED The review of nitrosamines impurities has been ongoing since the publication of the guidance to Marketing authorisation holders (MAH) in September 2019. The implementation phase has started.

5. Pharmacovigilance and epidemiology activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Number of signals peer-reviewed by EMA	1,015	1,063	1,395	1,323	1,217	1,800	1,800	0	0%
Number of signals assessed by PRAC	25	35	44	19	21	40	40	0	0%
PSURs (standalone CAPs only) started	243	278	256	309	240	572	536	-36	-6%
PSUSAs started	141	138	161	178	129	332	308	-24	-7%
Number of imposed PASS protocol procedures started	0[1]	6	7	8	10	12	5	-7	-58%
Number of imposed PASS result procedures started	3	1	5	1	1	8	5	-3	-38%
Number of emerging safety issue notifications received	2	4	5	4	18	10	5	-5	-50%
Number of notifications of withdrawn products received	230	187	217	138	102	400	400	0	0%
Cumulative number of products on the list of products to be subject to additional monitoring	351	354	332	321	282	350	350	0	0%
Number of products included in the list of additional monitoring	30	-	-	-	-	60	60	0	0%
Number of products removed from the list of additional monitoring	30	-	-	-	-	60	60	0	0%
Number of incident-management plans triggered	3	1	4	4	5	7	7	0	0%
Number of non-urgent information (NUI) or rapid alert (RA) notifications submitted through EPITT	8	26	32	28	25	55	20	-35	-64%

[1] The majority of studies received in the first half of 2020 are classified and accepted by the Committees as Category 3 studies (non-imposed).

Procedure		2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
	Number of external requests for EV analyses	15	7	9	18	24	15	25	+10	67%
	Number of MLM ICSRs created	4,446[1]	5,033	6,378	5,816	3,826	14,000	12,500	-1,500	-11%

Performance indicators

Performance indicators related to core business		Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
	Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%	100%	100%	100%
	Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	95%	100%	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%
	Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	94%	100%	100%	95%	100%	100%
	PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%	100%	100%	100%	100%

[1] The number of MLM ICSRs created is dependent on the number of articles published, which was smaller between January and June 2020. This may have been linked to COVID-19 pandemic.

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 Monthly PRAC interest group impact activities ongoing; guidance on impact/effectiveness evaluation of risk minimisation measures (RMM) finalised; valproate case study on patient/HCP engagement recommendations finalised; EMA funded and collaborative impact research ongoing; updated AR templates and assessors training planned.
	1.4-1	Finalise GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in 2020	30%	MAINTAINED Following Brexit BCP suspension, the activity has been resumed in March 2020. Compilation and review of comments (public consultation ended 28 Feb 2020).
		Prepare for public consultation (2020) and finalise (2021) GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators	60%	MAINTAINED Following Brexit BCP suspension, the activity has been resumed in October 2019. Draft Good pharmacovigilance practice (GVP) XVI Rev.3 part A on RMM tools and part B on effectiveness evaluation (=impact guidance) finalised for PRAC consultation; part C on pregnancy prevention programme (PPP) delayed; public consultation part A+B scheduled Q1/2021.
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through use of high	1.2-4	Build and maintain capacity for EU Network analysis of real world data	10%	REDUCED The activity is reduced to the EMA/HMA task force/steering group on big data and it is planned to fully restart in Q4 2020 The HMA – EMA Joint Big Data Taskforce final report and the top priority recommendations were published on 20 January 2020. Big Data Steering Group was established to take forward the Task Force recommendations and held its first meeting on 4

Objective	MAWP initiative	Activity	% complete	Achievements/results
quality data, information and knowledge				May. Planning has started to establish a sustainable platform to access and analyse healthcare data from across the EU.
		Continue to develop and maintain inventory to facilitate access to data on real-world data in line with recommendations of the Big Data Taskforce	continuous	REDUCED The activity is reduced to maintenance activities and it is planned to fully restart in 2021. The ENCePP database of resources is continuously being updated to include description of disease registries and other real world data sources used for regulatory decision-making. At the end of the first half of 2020 187 centres, 26 networks and 144 data sources were included in the database.
		Conduct of a pilot of rapid analytics of Electronic Health Records to support committee decision-making including increasing the EU healthcare data accessible for analysis. Initiate at least eight in 2020 and twelve in 2021 EMA studies on real world evidence data		MAINTAINED Following Brexit BCP reduction in scope, the activity has been resumed in Q1 2020. During first half of 2020 three pilot analyses were finalised or on-going. Four requests from PRAC were not considered feasible due to the inadequate exposure or outcome frequency in the databases. Progress report will be presented to PRAC in Q3 2020 and the pilot results will be presented and discussed with PRAC in Q4 2020, with a view to judge the utility and practicality of implementing rapid analytics of electronic health records.

Objective	MAWP initiative	Activity	% complete	Achievements/results
	1.2-5	Provide increased support to the use of registries for targeted products on the EU market from learnings including finalised guidance in 2020	continuous	MAINTAINED A SOP providing step by step guidance for real-world evidence input into scientific advice, PRIME and pre-submission meetings has been developed and will be finalised in Q4 2020. The guidance on use of registries for regulatory purposes has been finalised and the consultation process with the EMA scientific committees has started. Public consultation for the guideline on use of registries for regulatory purposes was postponed to Q3 2020 due to BCP and the COVID-19 pandemic (originally scheduled in Q2 2020).
	1.4-1 3.2-3	Based on the analysis of the pilot of MAH signal detection in EudraVigilance implement the decision of the European Commission on extension beyond the pilot phase, including new business process for MAH signals.		REDUCED Activity reduced to pilot phase (pilot extended by EC until December 2021). Business process for MAH signals delivered in November 2019 (post-EC Internal Audit Service audit action).
		Deliver a training curriculum on methodology and Big Data including specific training for assessors on real world data in committee assessment	10%	MAINTAINED The Pharmacoepidemiology training curriculum and Biostatistics training curriculum were adopted in Q2 2020. The Big Data Training signpost document was launched on 30 June 2020.
		Agree on a work plan for the development of guidelines on data, methods and evidence.		SUSPENDED due to COVID-19 BCP The activity is planned to restart in Q3 2020.

6. Other specialised areas and activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Herbal monographs, new	0	0[1]	1	3	6	5	3	-2	-40%
Herbal monographs, reviewed	5	6				12	15	+3	+25%
Herbal monographs, revised	5	0[1]	10	5	3	7	8	+1	+14%
List entries	0	0[1]	0	0	2	1	1	0	0%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
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 Despite activity being suspended, International regulators have completed their review of the prospective study evaluating the degree of concordance between the carcinogenicity assessment documents based on a weight of evidence approach with the data provided by sponsors from the 2 year rat carcinogenicity studies and a regulatory approach proposed.

[1] Cancellation of HMPC March meeting, Brexit BCP related suspension of activities with the Ministry of Health, Labour and Welfare, Japan (MLWP).

Objective	MAWP initiative	Activity	% complete	Achievements/results
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 Despite this activity being SUSPENDED, delivering the "Green Deal" is a priority for the EC, therefore EMA and the Network continued working on the ERA guideline for human medicinal products. The following has been delivered: participation in ad hoc working group of the Pharmaceutical Committee; for the guideline 50% of comments received during the consultation process have been addressed.
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	25%	MAINTAINED COVID-ETF deliberations and approval of Remdesivir (June 2020) and second Ebola vaccine. Lead of the International coalition of medicines regulatory authorities (ICMRA) workshops on vaccines and therapeutics on 18 March, 23 April and 22 June.
Contribute to European and international initiatives and collaborations in the area of AMR	1.1-2	To implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	50%	SUSPENDED due to COVID-19 BCP The activity is planned to restart in Q3/Q4 2020.
	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	30%	MAINTAINED Contribution to the drafting EMA/HMA network strategy to 2025; ICMRA statement, communication ; Drug Information Association (DIA) presentation.

Objective	MAWP initiative	Activity	% complete	Achievements/results
Enhance ability to respond quickly to public-health emergencies	1.1-9	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 R&D of vaccines including dialogue with NITAGs; discussion with EC and ECDC on platform for benefit/risk monitoring of vaccines *Expected to be resumed in 2020 (subject to resource availability)*	50%	MAINTAINED Dialogue on COVID-19 vaccines and advancement of the proposal to the Commission. Second Ebola vaccine has been approved in Q2. COVID-ETF activities in contribution to the EC Pandemic management.
Update guidelines and inspection related procedures in accordance to the new legal requirements	1.3-2	Finalise the new and revised guidelines related to the implementation of the Clinical Trials Regulation, considering as applicable the comments received during public consultation		SUSPENDED due to COVID-19 BCP
		Development of vaccine outreach strategy	10%	MAINTAINED Progress delayed due to COVID-19. Strategy final draft under review and ready to be finalised. Implementation should start in Q3 2020.
		Collaboration with ECDC on European Vaccine Information portal	50%	MAINTAINED European Vaccine Information portal launched successfully in April 2020. Further development and establishment of governance structures to oversee the website on hold due to COVID-19.
Develop Agency approach to implementation of GDPR in relation clinical trial participants/patient data received from 3rd parties		Prepare a paper guiding the Agency approach and where appropriate Q&A or guidance for the Agency and stakeholders	50%	MAINTAINED Draft Q&A will be submitted on 1 July to European Commission for informal consultation.
Strategy on GMP evolution in light of new technologies		Develop strategy paper on GMP evolution and supply chain challenges		SUSPENDED due to COVID-19 BCP The activity is planned to restart in Q3/Q4 2020.

Objective	MAWP initiative	Activity	% complete	Achievements/results
and medicines and on supply chain challenges				
Implementation of the EU-DPR		Initial implementation of the EU-DPR	98%	MAINTAINED The Agency's Central Register of records of data processing activities has been published in January. IT Security Review has been completed. Internal Guidance on Personal Data Protection and its Annexes have been drafted and submitted for adoption.
Further development of the implementation of the EU-DPR		Full Implementation of the EU-DPR and monitoring of compliance *Expected to continue in 2020 (subject to resource availability)*	Continuous	MAINTAINED Data protection support and continuous consultation is provided in relation to all initiatives and activities involving the processing of personal data. Amongst the more time-consuming activities we can quote the interplay of the EUDPR with the Agency's cloud strategy and workplace digitalisation, the development of Data Protection impact assessment (DPIA) concerning high risk processing activities, the development of privacy statements and records, the data protection checks within procurement procedures (review and drafting of documentation, technical advice for selection, review of vendor compliance).
		Impact assessment, planning and follow-up of the implementation of the recommendations of the report on sartans.		MAINTAINED Lesson learnt based on sartans is finalised and report was published in June 2020 Impact assessment, planning and follow up is an ongoing activity.

Evaluation activities for veterinary medicines

1. Pre-authorisation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	2	3	1	1	3	5	5	0	0%
Scientific advice requests received	14	12	16	14	8	17	21	+4	+24%
Requests for classification as MUMS/limited market of which:	19	20	13	14	11	25	30	+5	+20%
re-classification requests	5	3	1	3		5	7	+2	+40%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
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 report was published in March 2020.
		Revise existing MUMS guidance in line with new veterinary legislation provisions	50%	MAINTAINED Review of the MUMS data requirements guidelines is on-going and drafts for consultations are foreseen to be published in Q4 2020. A reflection paper is being drafted for establishing the

Objective	MAWP initiative	Activity	% complete	Achievements/results
				criteria for eligibility for applications under Art.23 of the Regulation (EU) 2019/6, to be published for consultation by Q4 2020.
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		SUSPENDED due to COVID-19 BCP The activity is planned to restart in 2021.
	2.1-6	Develop regulatory guidance and strategy for technologies that are innovative to veterinary medicine	50%	MAINTAINED The ad hoc expert group on veterinary novel therapies (ADVENT) met once in the first half of the year to progress and finalise the Q&A document on target animal safety for stem cell products, that is to be adopted at the July Committee for Medicinal Products for Veterinary Use (CVMP) and published on the EMA website.
		Finalise a reflection paper including an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials to control infectious disease in animals	60%	MAINTAINED The consultation period for the reflection paper ended on 30 April 2020, comments are under revision and the final document is expected by Q4 2020.
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	50%	REDUCED Promotion of parallel scientific advice in pre-submission phase is an on-going activity. Specific additional activities to increase awareness of this option have been suspended due to BCP.
Support development and availability of veterinary medicines	2.1-2	Review recommendations from the CVMP ad hoc group on veterinary vaccine availability (CADVVA) and agree on CVMP and working parties actions		SUSPENDED
		Develop a reflection paper on promoting		SUSPENDED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		availability of veterinary vaccines in emergency situations		The activity is planned to restart in Q3/Q4 2020.
		Field efficacy trials guidance to be developed as follow up of recommendations from the Field efficacy trials focus group held in 2017		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
	2.1-4	Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities		MAINTAINED Following Brexit BCP suspension, the activity has been resumed in Q1 2020. There were no requests received in the first part of 2020.
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
		Finalise revision of note for guidance on DNA vaccines non amplifiable in eukaryotic cells for veterinary use		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
		Finalise concept paper and start revision of SmPC guideline for anthelmintic		SUSPENDED The activity is planned to restart in Q3/Q4 2020.

2. Initial evaluation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Initial evaluation applications	7	13	7	7	12	18	20	+2	11%
New MRL applications	0	2	1	2	3	3	2	-1	-33%

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
MRL extension and modification applications	1	0	0	3	0	1	2	+1	100%
MRL extrapolations	0	0	0	0	0	0	0	0	0%
Art 10, Biocides	0	0	0	0	0	0	0	0	0%
Review of draft Codex MRLs	3	0	5	0	0	5	3	-2	-40%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
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	Evaluate training material on revised guideline, procedures and templates for CVMP assessment reports and provide training on these with emphasis on benefit-risk		SUSPENDED This activity is now superseded by training needs arising from the new veterinary regulation implementation.
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)	0%	MAINTAINED The European Commission is leading reflections/discussions on the procedure for the establishment of MRLs for biocides, with a particular focus on the workshare between EMA and European Chemicals Agency (ECHA) within the procedure. The reflections/discussions continue at the EC level. The Agency will only progress on this once the EC has concluded on the issue.
		Cooperate with EFSA to harmonise dietary	30%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		exposure assessment methodologies for MRLs [including consideration of international approaches]		The dedicated expert group had four teleconferences from January to June 2020, to compare the models used by CVMP, EFSA for feed additives, and Joint FAO/WHO Expert Committee of Food Additives (JECFA). An intermediate feedback to CVMP is planned in July 2020.

3. Post-authorisation activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Variations applications, of which:	331	252	211	188	132	401	460	+59	+15%
Type IA variations	191	147	106	110	80	206	245	+39	+19%
Type IB variations	111	72	61	47	40	135	155	+20	+15%
Type II variations	29	33	44	31	12	60	60	0	0%
Line extensions of marketing authorisations	1	0	1	4	2	3	3	0	0%
Transfers of marketing authorisations	5	2				5	5	0	0%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%	100%

4. Arbitrations and referrals

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated	1	2	3	0	4	6	6		

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Referral procedures managed within the legal timelines	100%	100%	100%	100%	100%	100%

5. Pharmacovigilance activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	72	71	81	91	88	160	160	0	0%
Total AERs, of which:	31,944	34,491	29,143	20,216	19,168	70,000	70,000	0	0%
Adverse-event reports (AERs) for CAPs	14,195	16,057	14,864	9,838	9,230	35,000	35,000	0	0%
Adverse-event reports (AERs) for NAPs	17,749	18,434	14,279	10,378	9,938	35,000	35,000	0	0%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
PSURs evaluated within the established timelines	90%	100%	95%	95%	97%	95%
AERs for CAPs monitored within the established timelines	95%	95%	96%	99%	96%	98%

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	2.2-5	Organise dedicated focus groups with specialised veterinarians/healthcare professionals to obtain further detailed insight on key aspects to improve pharmacovigilance reporting, and feedback for further development		SUSPENDED The activity has been postponed to 2021 due to the need to redeploy resources to the new veterinary regulation tasks.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	100%	MAINTAINED The Veterinary pharmacovigilance bulletin was published in May 2020.

6. Other specialised areas and activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast		
						Initial	Revised	Change
n/a								

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Plan for and implement the revised veterinary legislation	2.2-2	Revise business processes to fit the new veterinary legislation provisions	10%	MAINTAINED Preparatory discussions are ongoing, the main part of the activity will be developed in 2021.
		Develop new guidance and revised existing one to support new procedures and processes for the new veterinary legislation	10%	MAINTAINED Coordination activities to distribute the tasks are ongoing and priorities have been assigned.
		Develop and implement new IT systems required by the new veterinary legislation	50%	MAINTAINED The projects concerning the Union Product Database and the Union Pharmacovigilance Database have been initiated including establishment of the governance structure and are progressing on time and on scope using agile development methodology.
	2.2-9	Provide technical support to the European Commission in drafting delegated and implementing acts specified in the new veterinary legislation	70%	MAINTAINED The following recommendations were submitted to the European Commission in the first part of 2020: - Format for collection of data on antimicrobial medicinal products used in animals; - Implementing measures on veterinary medicinal products regarding Good Pharmacovigilance Practice; - Format and content of Pharmacovigilance System Master File and its summary; - Measures on Good Distribution Practice for veterinary

Objective	MAWP initiative	Activity	% complete	Achievements/results
				medicinal products; - Measures on Good Distribution Practice for active substances used as starting materials in veterinary medicinal products.
Support increased availability of veterinary medicines	2.1-3	Consider regulatory tools to implement recommendations of pilot project on the harmonisation of old veterinary antimicrobials (PPHOVA)	75%	SUSPENDED The activity is planned to restart in Q3/Q4 2020. The reflection paper on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics (SmPC) harmonisation was published in July 2018 for public consultation ending in January 2019, comments were received from 5 stakeholders. After a period of suspension due to redeployment of resources to priority matters, the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) authors are starting the revision of the reflection paper which is foreseen to be finalised in Q3/Q4 2020.
	2.1-11	Finalise a reflection paper on resistance in ectoparasites		SUSPENDED The activity is planned to restart in Q3/Q4 2020
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	75%	MAINTAINED EU comments on the draft guidelines were provided in March 2020, the revised versions of the guidelines are expected in Q3 2020 and finalisation is planned for 2021.
		Follow up on recommendations of the reflection paper on anthelmintics resistance		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	50%	MAINTAINED The task force met three times in the first half of 2020 to supervise and progress the actions of the thematic working groups.

Objective	MAWP initiative	Activity	% complete	Achievements/results
	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	25%	MAINTAINED The Terms of Reference of the pilot for the implementation of the guidance for MAHs on product shortage detection and notification and the Terms of Reference of the pilot for NCAs for the use of product shortage metrics are being prepared and are expected to be finalised by Q4 2020. The guidance on withdrawal applications is progressing and is expected to be finalised in 2021. The second phase of the pilot on the SPOC system for products availability has been currently delayed due to the COVID-19 outbreak; however, the newly created SPOC network was activated by the COVID-19 crisis.
Provide high-quality and consistent scientific outputs	3.2-15	Finalise revision of guideline on summary of product characteristics for antimicrobials		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
	2.2-7	Revise training needs of the veterinary network and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity	50%	MAINTAINED The veterinary training coordination group met in January 2020. The training needs were assessed and training courses have been developed (or started being developed). Due to the COVID-19 crisis all veterinary face-to-face training courses in 2020 have been postponed. Decision on when to run the planned courses will be made later in 2020.
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	50%	MAINTAINED EMA contributed to the review of training slides on International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL39 and to a training document on setting withdrawal periods, both are to be made available on the VICH website. A training on VICH GL27 is also planned for November 2020.
	4.2-5	Continue dialogue with international risk	0%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		assessment bodies with a view to increasing harmonisation of scientific approaches and methodologies for the establishment of MRLs		No further topics for discussion were identified for this year.
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 extended-spectrum penicillins	75%	MAINTAINED The activity has been resumed in Q2 2020 The reflection paper was discussed by the Antimicrobial working party in two meetings (May and June 2020) and it is expected to be finalised by the end of this year.
	2.4-3	Finalise report on 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	25%	SUSPENDED The activity is planned to restart in Q3/Q4 2020. Despite the activity being suspended due to limited available resources, the first draft of the report has been prepared. The final report, subject to availability of resources, is expected to be finalised by Q4 2020.
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	50%	MAINTAINED The "Reflection paper on the harmonisation of the reporting of consumption of antimicrobials" is carried over for delivery under the draft Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) strategic plan for 2021-2025 and is to be finalised in 2021. The Agency organised one TATFAR meeting in the first part of 2020, and participated in two other TATFAR meetings.
	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 The One Health Network meeting, due to take place in March 2020, was cancelled because of the COVID-19 crisis and no virtual alternative was organised. EMA participated virtually to two meetings of the OIE AMR working group, which met in April and June 2020, its subgroup on poultry met as well virtually in June 2020. EMA also attended the One Health EJP Stakeholder Committee

Objective	MAWP initiative	Activity	% complete	Achievements/results
				meeting that met virtually in May 2020.
	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	50%	MAINTAINED 2018 data have been submitted and their validation is to be finalised by end of June 2020. The 10th ESVAC report is being drafted, consultation with Member States is expected in mid-July and publication in October 2020.
	2.4-5	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	50%	MAINTAINED The JIACRA group met several times virtually in 2020 to progress the work on its third report. One more meeting is foreseen Q3 2020. However, due to the ongoing COVID-19 crisis and its impact on resources, ECDC, EMA and EFSA requested to the EC an extension of 6 months of the original deadline for the submission of the report.
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	Finalise reflection paper on higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
		Draft a concept paper as starting point for a guideline development on the potential risks associated with the use of veterinary medicinal products in aquaculture		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
	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 implementation of their strategy on managing pharmaceuticals in environment	50%	MAINTAINED Advice to EC is provided as needed.

Horizontal activities and other areas

1. Committees and working parties

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Number of reimbursed meetings	52[1]	143	213	261	238[2]	493	88[1]	-405	-82%
Committees and Management Board meetings	15[1]	38	35	40	-[2]	76	36[1]	-40	-53%
Trainings	1	12	8	10	-[2]	14	2	-12	-86%
Workshops	0	0	28	20	-[2]	15	2	-13	-87%
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	36[1]	93	142	191	-[2]	388	48[1]	-340	-88%
Number of virtual meetings (audio-, video- and web conferences)	2,660	1,659	2,524	2,460	2,665	5,000	5,000	0	0%
Number of reimbursed delegates	1,003	2,856	3,969	4,159	4,277	9,182	3,000	-6,182	-67%
Number of non-reimbursed delegates	60	227	564	1,464	1,724	1,500	120	-1,380	-92%

[1] The significant variation in the figures is due to the COVID-19 outbreak.
[2] 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 2020	Outcome at the end of				
			Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
	Delegate satisfaction with meeting support services	85%	-[1]	-[2]	n/a[3]	n/a	n/a
	Up-to-date electronic declarations of interests submitted by committee members prior to participating in a scientific committee meeting	100%	99%	99%[4]	100%	99.5%[5]	98%
	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%

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 Regulatory operations		SUSPENDED The activity is planned to restart in 2021.
Ensure 'fit-for-purpose'	3.1-1	Finalise the regulatory science strategy,		SUSPENDED

[1] Survey cancelled in 2020 due to COVID-19 outbreak.
[2] No survey due to BCP
[3] As of 2017, delegate survey has been aligned with the annual delegate survey conducted by the Scientific Committees Service of the Agency. However, as this service will was not conducting a survey in 2017, no delegate satisfaction survey took place in 2017.
[4] Members who did not submit an up-to-date declaration of interest prior to the meeting did not participate in the meeting.
[5] Nine committee members did not submit their up-to-date declaration of interests on time.

Objective	MAWP initiative	Activity	% complete	Achievements/results
scientific capability of the network		addressing evolution in science, technology and regulatory tools for human and veterinary medicines and translate to implementation phase		The activity is planned to restart in Q3/Q4 2020 for the implementation of the Regulatory Science Strategy.

2. Inspections and compliance

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
GMP inspections	127[1]	247[2]	162	226[3]	374[4]	220	365[5]	+145	+66%
GLP inspections	0	0	0	0	0	1	1	0	0%
GCP inspections	39[1]	79	74	69	56	135	44	-91	-67%
Pharmacovigilance inspections	3[1]	3	13	9	3	14	10	-4	-29%
PMF inspections	16[6]	66	87	40[7]	-[8]	65	40	-25	-38%
Notifications of suspected quality defects	87	93	69	98	90	200	250[9]	+50	+25%
Notifications of GMP non-compliances[10]	6	3	10	44	36	20	20	0	0%

[1] The result has been affected by travel restrictions due to COVID-19 pandemic. The resources have been redirected to activities granting the high level of responsiveness of the Agency to the pandemic.
[2] Higher than previously forecast results due to further additions to the EMA inspection programme, for example re-inspections after short interval.
[3] Significantly higher result 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 US sites manufacturing biological APIs.
[4] Includes PMF inspections.
[5] The figure is based on the total fees of inspections to be requested, or that have been finalised and initiated, in 2020
[6] The result has been affected by travel restrictions due to COVID-19 pandemic.
[7] Large part of PMF inspections' requests are usually received in the first half of the year.
[8] Included in GMP inspections results.
[9] The revised forecast anticipates the impact of nitrosamines.
[10] Other GMP inspections-related notifications previously included under suspected quality defects.

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Medicinal products included in the sampling and testing programme	70	67[1]	55	1[2]	48	70	85	+15	+21%
Standard certificate requests received	1538	1,284[3]	1,961	2,057	2,042	3,500	3,525	+25	+1%
Urgent certificate requests received	729	1,349	365	230	273	1,500	1,485	-15	-1%
Parallel distribution initial notifications received	1,141	1,265	1,264	1,414	1,629	2,300	2,450	+150	+7%
Parallel distribution notifications of change received	-[4]	1,038	840	832	1,211		-[4]	-[4]	-[1]
Parallel distribution notifications of bulk change received	5	8	4	4	4	15	10	-5	-33%
Parallel distribution annual updates received	7778[5]	1,369[6]	46[7]	2,938	2,202	5,500	10,535[5]	+5035	92%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Inspections conducted within established regulatory timeframes	100%	-[8]	100%	100%	100%	100%
Standard certificates issued within the established timelines	90%	97%	14%	0%	93%	85%
Average days to issue standard certificate	~~10~~[9] 30	26	65.0	21.5	8.4	7.9

[1] Several products were not on the market at the time of sampling and had to be removed.
[2] Reports from the sampling and testing programme are usually expected starting in June. One report was received before the end of reporting period.
[3] 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.
[4] Included in parallel distribution annual update.
[5] The higher figure is due to the inclusion of notifications of change as well as the backlog of 2018-2019 annual updates which have been processed as of December 2019.
[6] To allow for IRIS implementation annual update submission were frozen for 3 months.
[7] 3,175 annual updates were estimated to have been received but not processed at that time.
[8] Inspections are being re-planned according to travel restrictions and likely availability.
[9] The target handling time of 10 working days for certificates requested through the standard procedure has been temporarily extended to 30 working days.

Performance indicators related to core business	Target 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Urgent certificates issued within established timelines (2 working days)	100%	98%	99%	99%	100%	100%
Parallel distribution notifications checked for compliance within the established timeline	90%	98%	27%[1]	98%	94%	98%
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	35%	44%	73%[2]	31%	37%	31%
Outcome reports of the sampling and testing programme for centrally authorised products followed up with the MAH within one month of receipt	100%	n/a[3]	n/a[3]	n/a[3]	n/a[3]	100%

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	4.3-2	Strengthen collaboration with trusted 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	continuous	REDUCED The activity is limited to exchange on product specific issues. Collaborative exchanges with GCP inspections ongoing.
	4.1-5	Enhance the co-operation with member states in co-ordinating third country inspections	continuous	MAINTAINED Collaborative exchanges on active pharmaceutical ingredient (API) and finished product inspection
Minimise risk and impact of shortages due to	1.1-14	Provide regulatory support to the work of the EU Observatory, to facilitate the transition	continuous	REDUCED This activity is limited to exchange on product specific issues

[1] The significantly lower result is 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.

Objective	MAWP initiative	Activity	% complete	Achievements/results
manufacturing problems and quality defects		from high enriched uranium to low enriched uranium		Participation to EU Observatory meetings.
	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	continuous	MAINTAINED Establishment of EU Executive Steering Group on shortages caused by major events.
		Support the implementation of the agreed Work Plan of the EMA/HMA task force on the availability of authorised human and veterinary medicines and provide the secretariat for the task force	continuous	SUSPENDED due to COVID-19 BCP During the December 2019 meeting HMA agreed to extend the mandate of the group for a further 3 years; Workplan has been reviewed and some of the plan output have been postponed to Q3/Q4 2020 and Q1/Q2 2021 due to COVID-19 impact and lack of EMA resources.
		Support the operation of the Single Point of Contact system and provide the secretariat for the system	continuous	SUSPENDED due to COVID-19 BCP Phase 2 is planned to restart in Q3/Q4 2020 (escalation to Scientific Committees) due to lack of resources and conflicting priorities (COVID-19)
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 The activity is planned to restart in Q3/Q4 2020.
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors from international regulators		SUSPENDED Training missions to India and China have been currently suspended due to the COVID-19 pandemic. However, the planning for next years has been initiated.
Expand work-sharing and mutual-reliance initiatives	4.3-1	Coordination of Joint Audit Programme in support to the implementation and extension	Continuous	MAINTAINED Ongoing but partially delayed due to COVID-19 outbreak. A JAP

Objective	MAWP initiative	Activity	% complete	Achievements/results
		of the EU US MRA		concerning veterinary agency of Romania was performed in January 2020 as planned. Two audits, of the veterinary agencies of Cyprus and Slovakia, and two audits of the agencies of Serbia and Montenegro were planned for the first half of 2020, but were postponed due the outbreak of the COVID-19 pandemic.

3. Partners and stakeholders

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Requests for SME qualification	303	328	254	312	357	597	597	0	0%
SME status renewal requests	178[1]	134	163	392	260	1,613	1,613	0	0%
Number of cases of patient/consumer engagement[2] in EMA (medicines-related) activities	358	333[3]	200[3]	350	302	550	550	0	0%
Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	64[4]	110	102	450	399	200	150	-50	-25%
Interaction with Membership organisations	-[5]	-[5]				-[5]	-[5]	-	-

[1] SME renewal applications typically submitted towards year-end.
[2] 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.
[3] Due to a change in methodology as a result of BCP, only engagements related to products are counted
[4] Numbers depend on related-product activities
[5] The tracking had been suspended in 2019 due to BCP.

Procedure		2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
	Number of Membership organisations' speaker requests answered	235[1]	-	-	-	-	100	400[6]	+300	+300%
	New scientific, regulatory and telematics curricula developed	3	1	0	0	-[2]	2	3	+1	+50%
	Number of training events advertised to the EU Network	20[3]	27	25[4]	69	-[2]	60	30	-30	-50%
	Number of reimbursed training events to the EU Network	1[5]	7	1[9]	11	-[2]	15	1	-14	-93%
	Number of messages circulated via 'Early Notification System'	373[6]	215	217	198	-[2]	440	700	+260	59%
	Number of EMA communications pro-actively sent to stakeholders	101[7]	68	100	63	-[2]	175	200	+25	+14%
	Number of EPAR summaries and EPAR summaries updates published	164	144	149	145	-[2]	300	300	0	0%
	Number of summaries of orphan designation published	64	55	87	87	-[2]	150	150	0	0%
	Access to documents, requests received	316	362	462	464	418	900	632	-268	-30%
	Access to documents, documents released	382	792	1,364	1,411	1,179	2,700	764	-1936	-72%
	Requests for information received	3,597	3,677	3,651	3,241	2,441	7,500	7,200	-300	-4%
	Number of documents published on EMA website	3,628	3,533	3,871	3,713	4,416	7,000	7,000	0	0%

[1] The actual figure deviates largely from the original forecast due to COVID-19 pandemic. In fact, most events of Membership organisations were rescheduled and transformed into virtual meetings which allowed wider involvement of Agency topic experts, thus doubling the effort of responding to speaker requests.
[2] New indicators introduced in the 2017 work programme.
[3] Lower results due to COVID-19 pandemic.
[4] Limited number of courses being developed and offered to Network-
[5] Several courses have been postponed because of COVID-19 pandemic.
[6] Higher results due to the increase in communications concerning COVID19-
[7] The increase is due to COVID-19 related communications.

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Number of pages published and updated on EMA website	1,681	1,821	2,534	2,261	2,824	4,000	3,500	-500	-13%
Number of press releases and news items published	86	63	99	63	88	150	150	0	0%
Requests for interviews and comments by media representatives	598	564	732	927	1,110	1,000	1,100	+100	10%
Number of reports, brochures, leaflets laid out or printed	214[1]	33	28	20	5	30	400	+370	1233%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Satisfaction level of patient and consumers' organisations	95%	n/a[2]	n/a[3]	n/a	n/a	97%
Satisfaction level of healthcare professionals' organisation	95%	n/a[2]	n/a[3]			
Satisfaction level of SMEs	80%	88%	88%[4]	n/a	98%	93%
Responses to ATD within set timelines	92%	86%	92%	97%	96%	90%
Responses to RFI within set timelines	97%	92%	96%	97%	99%	97%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	80%	82%	89%	90%	85%	68%
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	10	6	6	4	6	-[5]
Number of users registered to the EU NTC Learning Management	5,100	5,213	4,842	4,020	2,850	-[5]

[1] Higher figure due to the intensified use of visuals on EMA website/presentations, preparation of images for press releases/news items/social media and preparation of several videos.
[2] Questionnaire to be sent at the end of the year
[3] No survey due to BCP
[4] Indicator from 2018 info day
[5] New indicators introduced in the 2017 work programme.

Performance indicators related to core business		Target 2020	Outcome at the end of				
			Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
	System						
	Number of NCA experts[4] registered to the EU NTC Learning Management System	4,100	4,236	3,888	3,060	1,950	-[1]
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	80%	-[2]	n/a[3]	n/a	79%	n/a
	Average rating of pages on corporate website during the year	3.3	3.7	3.2	3	4	3.6

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Strengthen stakeholder relation focusing on patients and consumers, healthcare professionals, industry associations and academia	1.3-3 3.1-7	Implement a framework for collaboration with academia with respect to human medicines and consider the need for any specific adaptations to the framework with respect to veterinary medicines		SUSPENDED The activity is planned to restart in Q3/Q4 2020 Proposal for internal academia collaboration matrix finished and preparations for restart are already in place.
	3.4-6	Publish annual report on EMA interactions with industry associations	30%	SUSPENDED The activity is planned to restart in Q4 2020. Despite the activity being suspended, the first draft of the report has been prepared.
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals and their organisations	65%	SUSPENDED The activity is planned to restart in Q3/Q4 2020. Despite the activity being suspended, all data have been collected and analysed. First draft has been reviewed. New format is being discussed with graphic designer.
	3.4-5	Participation in CIOMS Working Group XI-on		MAINTAINED

[1] New indicators introduced in the 2017 work programme.
[2] Survey planned for Q3 2020
[3] No survey due to BCP

Objective	MAWP initiative	Activity	% complete	Achievements/results
		patient involvement in clinical development and safe use of medicines		Draft Council for international Organisation of Medical Sciences (CIOMS) guidance has been prepared. Publication expected in Q4 2020.
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	94%	MAINTAINED The implementation of the action plan has continued in the first half of 2020, with 15 out of 16 actions currently delivered. Work on the final action (n°5, "Expanding outreach of the EU Network Training Centre EU-NTC in relevant areas") will be carried out in Q3/Q4 2020.
Further strengthen Agency's transparency and open data commitments	1.4-5	Plan the relaunch of clinical data publication		SUSPENDED The activity remains suspended in 2020 with exception for products targeting COVID-19.
		Hold regular discussions in the technical group on anonymisation of clinical data		SUSPENDED The activity remains suspended in 2020, subject to BCP.
	1.4-5 1.4-6 1.4-7	Agree draft principles of transparency		SUSPENDED The activity remains suspended in 2020, subject to BCP.
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		MAINTAINED In the urgent timeline of the REMDESIVR assessment, CHMP used the MNAT approach for the quality part of the assessment.
	3.1-6	Implement the second phase (2020) and launch the third phase (2021) of the multinational assessment team approach post-authorisation		SUSPENDED due to COVID-19 BCP The second phase implementation is planned to restart in 2021, unless required earlier in context of COVID-19 assessment (situation is being monitored through COVID-19 WS3).
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 Ongoing activity in collaboration with EU NTC.
		Develop in collaboration with the Network, the	75%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		EU Medicines Agencies Network Strategy to 2025		Draft strategy completed in the first half of 2020 ready to be sent out for consultation in early July.
		Develop the Regulatory science observatory with a collaborative methodology to contribute to the EU Medicines Agencies Network Strategy to 2025		SUSPENDED The activity is planned to restart in Q3/Q4 2020.
	3.1-3	Work with the Network to prioritise training needs	20%	MAINTAINED Work in the first 6 months of 2020 have focused on making available online training materials from previous face to face events: Risk assessment - sampling and testing, 3 Rs, Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) training material to wider audience. In addition to this, work focussed on progressing development of training to meet identified needs in areas of Non-Clinical, Internal Audits, Assessment of Herbal Medicinal Products. In view of Covid-19 crisis and competing priorities in the Network, it was agreed that the timing was not optimal to engage in surveys with the network relating to identification of future training needs. This work will restart in Q3 - Q4 with view to looking at identifying training needs for 2021. Work has also slowed on the development of training to meet identified needs with two face to face training events in veterinary area postponed and plans for a webinar in ATMPs not progressed.
	3.1-2	Review and update existing curricula to ensure provision of up-to-date training	40%	MAINTAINED In the first half of 2020 Work continued the review of recommended areas of training in existing curricula to ensure that these reflect prioritised needs and with the Network to develop training in these areas - as well as instigating curricula in new areas to deal with emerging challenges from advances in science and technology. This included discussion on:

Objective	MAWP initiative	Activity	% complete	Achievements/results
				i) the development of training in the GCP and Bioequivalence Inspections areas; ii) curricula in the area of Big Data (including Data Literacy and Biostatistics); iii) Regulatory Science Strategy topics; iv) involvement in clinical trials information systems (CTIS) training; v) Roadmap for Digital Academy.
	1.3-8	Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency		REDUCED The activity is reduced to observer status and it is planned to fully restart in Q4 2020.
		Foster the visibility and activities of the EU Innovation office network to ensure effective and harmonised support to early innovators at local and European level		SUSPENDED The activity is planned to restart in 2021.
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.		REDUCED The activity is reduced to observer status and it is planned to fully restart in Q4 2020.
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency .work, outputs and	3.3-10	Improve EMA's crisis communication by drafting and testing a crisis communication plan	50%	SUSPENDED Despite the activity being suspended, in the context of the COVID-19 pandemic, crisis plan has been developed and adjusted on an ongoing basis.
	3.3-7	Carry out an EMA perception survey to better understand communication opportunities and		SUSPENDED The activity is planned to restart in Q3/Q4 2020

Objective	MAWP initiative	Activity	% complete	Achievements/results
medicinal products		challenges, and review the Agency's communication products and tools as per the results of the survey		
	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	25%	SUSPENDED The activity is planned to restart in Q3/Q4 2020 Despite the activity being suspended, the request to EMA Architecture board for purchase of website accessibility and quality-management tool was drafted and website search feature was adjusted to improve the relevance of search results.
	3.3-1	Develop and implement a five-year EMA Communication Strategy	20%	SUSPENDED The activity is planned to restart in Q3/Q4 2020. Despite the activity being suspended, in Q1 2020 a plan for collection of necessary background information was developed and building blocks for the framework strategy identified. Workshop on new brand narrative was carried out in June 2020.
		Develop and implement an annual communication plan, in line with the framework strategy for external communication	50%	MAINTAINED An annual communication plan has been developed and is adapted as needed and implemented throughout the year.
	3.3-4	Continue development and implementation of a social media strategy, including consolidate social media channels and grow followership	50%	SUSPENDED The activity remains suspended in 2020, subject to BCP.
	3.3-5	Develop new digital and multimedia communication tools	10%	SUSPENDED The activity is planned to restart in 2021. Despite the activity being suspended, a new digital format for the annual report has been developed.
	3.3	Support open access publication of relevant scientific articles	50%	MAINTAINED 12 articles provided as open access.

4. International activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Interactions with FDA	368	-[1]		-[2]	-[2]	700	700	0	0%
Interactions with PMDA/MHLW	60[3]	-[1]		-[2]	-[2]	200	150[3]	-50	-25%
Interactions with Health Canada	93	-[1]		-[2]	-[2]	200	200	0	0%
Interactions with any other stakeholders	390	-[1]		-[2]	-[2]	700	700	0	0%
Number of information and/or document exchanges	498	-[1]		-[2]	-[2]	900	900	0	0%
Number of teleconferences organised	97[4]	-[1]		-[2]	-[2]	150	250[4]	+100	+66%
ICMRA executive committee and full membership TC	21[5]	-[6]	-[6]	-[6]	-[6]	10	35[5]	+25	+250%
International stakeholders' visits (fellowships, experts, observers	1[7]	-[6]	-[6]	-[6]	-[6]	25	1[7]	-24	-96%
Organisation of International awareness sessions	0[8]	-[6]	-[6]	-[6]	-[6]	2	0[8]	-2	-100%

[1] Data not available as tracking of activities was not a priority for Q1/Q2 in 2019
[2] New indicators introduced in 2018 work programme.
[3] The direct interactions with EMA have decreased due to COVID-19 pandemic, hence the lower revised forecast. Other platforms such as ICMRA have been used by Pharmaceuticals and Medical Devices Agency (PMDA)/MHLW for communication.
[4] Higher result and revised forecast are linked to COVID-19 pandemic and the need to arrange online conferences.
[5] The high result and revised forecast reflect the increased ICMRA work related to COVID-19.
[6] New indicators introduced in 2020 work programme
[7] The very low result and revised forecast are mainly due to COVID-19 restrictions to travelling and accessing the EMA building.
[8] Veterinary awareness session has been postponed to 2021 and no other awareness session is planned to be organised in 2020.

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
n/a						

Achievements

Objective	MAWP initiative	Activity	% complete	Achievements/results
Reliance: 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	45%	REDUCED The activity is limited to product specific issues. -WHO Workshop on the European Union (EU) Article 58 procedure and the Swissmedic Procedure for Marketing Authorisation for Global Health Products (MAGHP) taking place 11 March 2020 (Geneve). -Follow-up EU-M4all products (liaising with experts, WHO, Applicants): Dapivirine vaginal ring, Dengue vaccine, Dolutegravir, Bivalent oral poliomielitis vaccine and arpraziquantel (SA). -Parallel application for EU-M4all (Article 58) opinion and centralised procedure Marketing Authorisation (in progress).
Communication: 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 Active participation in international fora and communication to stakeholder, including but not limited to ICDRA, DIA, ICH, IPRP.	40%	REDUCED Presentations at DIA; participation in International Pharmaceutical Regulators Programme (IPRP) and ICH Nitrosamines M7 discussion at ICH; COVID activities at DIA.
		Support ICH GCP Renovation process by	40%	MAINTAINED

Objective	MAWP initiative	Activity	% complete	Achievements/results
		participation in ICH E8 and ICH E6 revisions as Regulatory chair		ICH principles drafted. ICH Stakeholder engagement plan adopted.
		Establish platform for EU expert governance in conjunction with EC		SUSPENDED The activity is planned to restart in Q3/Q4 and to be progressed with DG SANTE B4.
Collaboration/supply chain: Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	4.2-2	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	50%	REDUCED 'EU and FDA compiling catalogue of GMP training involving or regarding India, including scientific and regulatory conferences. EMA reaching out to MS on events, priorities, also to Japan, WHO, European Directorate for the Quality of Medicines & HealthCare (EDQM) and Pharmaceutical Inspection Co-operation Scheme (PIC/S). BCP on hold.
Collaboration/supply chain: 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	50%	REDUCED The activity is limited to support the topic lead. The working group has finalised a draft document on technical recommendations to allow interoperability of Track&Trace systems globally, which will be forwarded to ICMRA at the beginning of July, for final adoption and publication. A public consultation on the document will be likely carried out during the second half of 2020, subject to ICMRA plenary agreement.
Collaboration/capacity building: 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
		A meeting/training related to IPA will be organised at EMA in November 2020.	50%	MAINTAINED - Contact points in candidate countries and potentially candidates have been established. - 2 tele-conferences with contact points to discuss organisation

Objective	MAWP initiative	Activity	% complete	Achievements/results
				of virtual trainings in 2020. - Draft programme for the virtual trainings proposed to beneficiaries of the Instrument for Pre-accession Assistance (IPA) program. - Survey of training needs and responses analysed
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU		REDUCED Training webpages with update
		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		Completed
Collaboration/capacity building:		Re-start of the International awareness sessions for regulators; Organisation of the Veterinary awareness session in April 2020		SUSPENDED due to COVID-19 BCP The activity is planned to restart in 2021. Veterinary awareness session postponed to 2021, but preparatory work completed
		Collaborating with EC/EMA to develop a joint long-term strategy for targeted and effective training programs on pharmaceutical GMP/GCP in China and India.		SUSPENDED Activity planned to restart in 2021
Communication:		ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA face to face meetings.	75%	MAINTAINED Regular activities: Executive Committee - 4 meetings, Communication group meetings, Statement on Vaccines Confidence COVID-19 dedicated ICMRA meetings: 1) ICMRA SARS-CoV-2 Vaccines workshop - 2 meetings; 2) ICMRA COVID-19 Therapeutics workshop - 1 meeting 3) ICMRA COVID-19 Real Word Evidence workshop - 2 meetings 4) ICMRA COVID-19 Policy Bi-weekly TCs - 6 meetings; ICMRA

Objective	MAWP initiative	Activity	% complete	Achievements/results
				COVID-19 Working Group - 4 meetings; ICMRA Executive Committee COVID-19 dedicated meeting; Development and implementation of 3-year ICMRA communication strategy, Production and dissemination of ICMRA Statements led by EMA
Core business:		Communication of information, answer to queries, internal coordination. Monitoring of the matrix of the tracking of interactions. Organisation of cluster meetings, teleconferences and preparations of visits, missions' preparation, support to FDA, Health Canada, PMDA and other international partners fellowships and expert visits	60%	MAINTAINED - Update of 5 guidance, including the International guidance for sharing documents and the one on Parellel Scientific Advice; - Relaunch and publication of the 'International affairs highlights' newsletter, after the BCP period covering 18 months of AF-IA activities; - initial preparatory work for the Veterinary awareness session planned to take place in April, but cancelled due to COVID-19 crisis; - Work programme report on the overall 2019 activities; - organisation of 64 cluster meetings, teleconferences; - organisation of 6 missions (decrease due to COVID-19 crisis) - 34 documents redacted; - Support to the organisation of 5 global teleconferences related to COVID-19,
Reliance:		support EU and EU/MRA team meetings	50%	MAINTAINED - Progress with capability assessments for veterinary products; - Ongoing support to Member States, EMA Mutual Recognition Agreement (MRA) and FDA teams; - ongoing support to EMA change in leadership - ongoing capacity building support to EC for establishment of a veterinary timeline
Collaboration/capacity building:		Collaboration in the establishment of the African Medicines Agency (AMA)	50%	MAINTAINED -participation in:

Objective	MAWP initiative	Activity	% complete	Achievements/results
				1) the African Medicines Regulatory Harmonisation Partnership Platform Virtual Meeting i.a. on the AMA update (Feb.) and submission of B22 the proposal to further support harmonisation processes in Africa. 2) African Medicines Regulatory Harmonisation – Innovation in Regulatory Science – capacity building, the Role of National Regulatory Agencies in informing the African Union policy organs and update on AMA (June).

During the first half of 2020 activities have been repurposed to support COVID19 activities, among others, vaccines, shortages, paediatrics and pharmacovigilance, and to facilitate exchanges and ad hoc meetings for vaccines and therapeutics, in particular the development program for remdesivir. In addition to the above, other activities carried out in the first half of 2020 were related to the WHO Collaborative Registration, the WHO Prequalification Programme; the preparation to the CAPs ARs sharing with the South African Health Products Regulatory Authority; the international collaboration and contribution to the nitrosamines taskforce.

5. Information management

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
Number of Telematics information services provided by EMA	25[1]	25	23	23	21	25	25	0	0%
Number of ongoing Telematics IT projects where EMA is the delivery organisation	4[2]	3	7	11	7	7	4	-3	-43%
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	8	5	7	10	5	7	10	+3	+43%
Number of healthcare data sets to which EMA access and therefore its committees can integrate	3[3]	-[3]	-[3]	-[3]	-[3]	4	6	+2	+50%

[1] Annual forecast equivalent to midyear expectation, as the figure represents number of services continuously provided throughout the year
[2] EudraCT is now integrated under CTIS.
[3] New indicator included in 2020 Work Programme

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020 annual forecast Initial	Revised	Change	
analyses into assessments									

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Satisfaction of EMA internal and external users	80%	88.17	84%	-	93.9%	90.4%
Availability of corporate/Telematics IT systems and corporate website	98%	99.06	98%	99%	99%	99.9%

Support and governance activities

Workload indicators

Procedure	2020 Q1-Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2016 Q1–Q2	2020nnual forecast Initial	Revised	Change	
n/a									

Performance indicators

Performance indicators related to core business	Forecast 2020	Outcome at the end of Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Posts on the Agency establishment plan filled	97%	98%	99%	99%	98%	98%
Total TA staff recruited against vacant posts	24	13	23			
Staff turnover rate (staff leaving against total no. of staff TA & CA)	8%	2%	4%			
Time to fill position from vacancy notice to establishment of reserve list						

Performance indicators related to core business	Forecast 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Standard procedure	<3 months	<3 months	3 months[1]			
Medium procedure	<3 months	n/a[2]	n/a[2]			
Large procedure	<6 months	n/a[2]	n/a[2]			
Revenue appropriations implemented	97%	50%[3]	41%	40%	42%	55%
Expenditure appropriations implemented	97%[4]	75%	67%[5]	71%	73%	
Payments against appropriations carried over from year N-1	97%	87%	71%[6]	68%	76%	83%
The maximum rate of carryover to year N+1, of total commitments within the title:						
Title 1	1%	n/a[7]	2.19 %	1.0%	0.86%	1.0%
Title 2	15%	n/a[7]	10.79%	11.8%	7.93%	8.0%
Title 3	25%	n/a[7]	29.16%	31.1%	25.86%	27.0%
Payments made within 30 days' time	98%	94%	96.13%	97%	97.26%	98.98%[4]
Receivable overdue for more than 30 days (including provision for bad debts)	<10%	8.47%[8]	-[8]	-[8]	-[8]	-[8]
Energy consumption (change in % per workstation)	n/a[9]	n/a[9]	n/a[9]	-2%	-9%	-[10]

[1] No medium or large selection procedures were done. 4 standard procedures took place in Q2.
[2] The distinction between medium and large procedure no longer applies.
[3] Annual target to be reached at year-end.
[4] The annual implementation rate is expected to be lower for some expenditure due to the impact of COVID-19.
[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] Annual target to be reached at year-end
[8] New indicator included in 2020 Work Programme
[9] Due to EMA's two-stage relocation to Amsterdam the environmental performance indicators cannot be estimated. During 2019-2021 EMA will occupy 3 buildings; 30 Churchill Place in London (Jan-Feb 2019), Spark building in Amsterdam (Mar-Dec 2019) and EMA building in Amsterdam (Jan 2020 to 2021 and beyond). 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.
[10] New indicators included in 2017 work programme.

Performance indicators related to core business	Forecast 2020	Outcome at the end of				
		Q2 2020	Q2 2019	Q2 2018	Q2 2017	Q2 2016
Water consumption (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	-7%	+22%	-[3]
Paper consumption (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	-18%	-13%	-[3]
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	-12%	+25%	-[3]
Recyclable waste produced (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	-21%	-3%	-[3]
Recycling rate (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	-1%	-4%	-[3]
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	n/a[1]	n/a[1]	n/a[1]	-11%	+8%	-[3]
Overall net CO_2 emissions (per workstation)	n/a[1]	n/a[1]	n/a[1]	-12%	+7%	-[3]

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	30%	MAINTAINED Revised draft of the multiannual planning documents aiming at streamlining the activities; several presentations given to senior management in order to calibrate the grouping of activities and to define the next steps in terms of resources allocation; support to H division to create a time vs capacity model; agreement with H division to jointly run a pilot project with external advisors to test a capacity vs time model; no specific delays linked to the BCP but the speed of development impaired by telework.
	3.2-5	Implement a competency management	30%	MAINTAINED

[1] Due to EMA's two-stage relocation to Amsterdam the environmental performance indicators cannot be estimated. During 2019-2021 EMA will occupy 3 buildings; 30 Churchill Place in London (Jan-Feb 2019), Spark building in Amsterdam (Mar-Dec 2019) and EMA building in Amsterdam (Jan 2020 to 2021 and beyond). 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.

Objective	MAWP initiative	Activity	% complete	Achievements/results
		framework		Internal competency analysis based on Job Profile Builder (JPB, SAP tool); 1st draft of the competency framework; consultation with a group of senior managers; onboarding consultants; initial meetings with senior managers and HRBPs on competencies and job descriptions; job profile template finalised, incl. in JPB; work in progress with regards to aligning Learning Management System and other modules from a competency and Learning & Development perspective.
		Digitalise HR-related processes (on-boarding tool, appraisal, career development) and gradually replace the overall HR management system	50%	MAINTAINED **On-boarding project:** - Business requirements signed off; - On-boarding tool was launched on 20th May for TA, CA and SNEs launched; - On-boarding tool was launched for interims and contractors on 1st June; - To-be processes completed; - Training guidance updated; - On-boarding portal published; - Cross-boarding analysis and configuration in staging finalised; - On-boarding for trainees was configured for testing; Activity completed: 90% **Performance and Development programme:** - Business requirements signed off; - Goals and Performance module has been configured in staging for testing; - Succession and Development module has been configured in staging for testing; - Change management and communication strategy have been signed off;

Objective	MAWP initiative	Activity	% complete	Achievements/results
				Activity completed: 50% **E-signatures design:** - Stakeholders identification; - Business requirements completed; - Technology selection done; - POC launched for two final vendors; Activity completed: 70%
		Digitalise procurement and some reporting processes		MAINTAINED **Procure to Pay achievements**: - AS-IS process workflow; - Business consultancy contract signed, - Phase 0 completed: 2 weeks phase to prepare the rest of phases, - Data extraction from Jira and SAP; - Analysis of the AS-IS process, - Activity completed: 10% **Registration Process**: - Recurrent process to extract electronic application forms information; - App development, - Email workflow implemented - Technical Validation implemented - Initiating of the SIAMED data integration development - Activity completed: 30% **Business Intelligence**: - Business case agreed by Administration Division transformation Steering Committee; - Plan on a page agreed by sponsor(s); - High level requirements documented;

Objective	MAWP initiative	Activity	% complete	Achievements/results
				- Intermediate (mock) report produced and agreed; - Pilot (Proof of concept) planned and resourced, detailed requirement drafted; pending approval by sponsor and senior management; Activity completed: 7%
		Review project governance in line with Agile development approach		SUSPENDED due to COVID-19 BCP The activity is planned to restart Q3 2020
		Implement improved delegate reimbursement, travel and accommodation booking process and tools		SUSPENDED The project to introduce an integrated booking and automated expense reimbursement functionality is discontinued due to project and operational reasons i.e. after analysis and design phase the benefits no longer outweigh project complexity and effort; this is also significantly affected by current COVID situation which has changed travel and meeting environment but also introduced a high level of uncertainty for the future. This changes the project's business case which was set up before COVID. Nevertheless, in order to streamline the hotel and travel booking process for delegates attending EMA's meetings and staff members going on missions, the Agency has developed through its travel agent an online booking tool. The system is called Cytric and will go live in Q4 2020. At the beginning, due to COVID-19, only a restricted number of members of the scientific committees will be allowed to organise their journey to Amsterdam through Cytric. As soon as the COVID-19 outbreak will cease, all delegates will have access to the new platform.
Maintain high level of independence, integrity and transparency in all aspects	3.1-8	Conduct the annual review of the Agency's handling of independence		MAINTAINED Yearly review of the Agency's handling of independence (2018 and 2019): Yearly review report endorsed by EXB, on time

Objective	MAWP initiative	Activity	% complete	Achievements/results
of Agency's work				endorsed 2/20 and Yearly review 2018 and 2019 presented to MB on time, endorsed by MB 11/3/20
		Implement the action plan of the anti-fraud strategy		SUSPENDED As for the COVID BCP impact, the random verifications action has been impacted as it proves extremely difficult to be performed remotely. As for the permanent actions performed every year as part of the anti-fraud strategy action plan, by their nature they are typically performed in the 2nd half of the year.
Subletting arrangements of London premises		Manage subletting arrangements of London premises		MAINTAINED The agency continued to manage the sub-let premises: - Analysed and approved architectural modifications to the building - Monitored construction and unrelease matters - Ran a system to manage payment from the sub-tenant and to the landlord - Managed VAT matters - Managed procured contracts

Annex 2: Project progress and delivery

Project progress and delivery as of 30 June 2020 against what was planned in the work programme 2020 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
	No activity/result to report

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)
	No activity/result to report

The traffic lights reflect the change to the overall project timeline, budget and scope that has taken place during Q1 and Q2 2020, in comparison to what was planned and approved at the end of 2019 (i.e. as noted in the work programme 2020). Notes explaining the changes are added.

In cases where the project start or end dates foreseen in the work programme 2020 were revised during Q1 and Q2 2020, the current dates are added in the relevant cells, with the original date from the work programme 2020 shown as crossed out.

In line with the BCP implemented at the Agency, delivery of some of the projects in the adopted work programme was reduced or postponed. To reflect the current impact of the COVID-19 crisis, the status of the projects is indicated in the report under 'Results 2020' as *continues*, *reduced* or *suspended*, according to the decisions taken on these projects by 1st September, this status indication is not linked to the results delivered in 2020, but only reflects the BCP status of a given project.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2020
				Time	Budget	Scope	
Clinical trials programme							
• CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR)	• Regulation (EC) 536/2014, art.80-82	Q3 2014	2021-2022				CONTINUES • Continued development of CTIS version for audit in Dec 2020 as agreed at MB 06/2020 and also agreed as working assumption a go live for December 2021 • Ongoing user testing of intermediate CTIS versions • Ongoing delivery of training to stakeholders • Communication plan fully implemented
• EudraCT linked to CTIS (EudraCT legacy)	• Regulation (EC) 536/2014, Art. 80-82,98	2018	2021-2023				CONTINUES • This project has been integrated under the CTIS new way of working and we will be delivered under the CTIS project.
e-Submission programme							
eCTD4 pre-project	n/a	2021	2022				SUSPENDED UNTIL 2021
Single Submission Portal	n/a	2021	2022				SUSPENDED UNTIL 2021
Veterinary change programme							
EudraVigilance veterinary v3.0	• Regulation (EC) 726/2004, art.57(d)	2017	2022				CONTINUES, subject to budget availability • Status amber as additional budget was required in 2020; and delivery scope continues to be dependent on the drafting and finalising of pharmacovigilance-related implementing acts. • Initiation of system implementation as a first step towards a Union veterinary pharmacovigilance system • Initiation of testing of 1st release
New Veterinary Legislation	• New veterinary	Q1 2019	2022				CONTINUES, subject to budget availability

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2020
				Time	Budget	Scope	
	legislation						• Status amber as additional budget for the delivery of the Union Product Database was required in 2020; and delivery scope continues to be dependent on the finalisation of the Union Product Database -related implementing act • Project initiation and analysis of requirements for the Union Product Database • Preliminary business case has been delivered • Revised internal governance within the Veterinary division of EMA delivered
Online programme							
European medicines web porta	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	2021	2022				SUSPENDED UNTIL 2021
EMA Intranet	n/a	2021	2022				SUSPENDED UNTIL 2021
EMA Extranet	n/a	2021	2022				SUSPENDED UNTIL 2021
Data integration programme							
Substances and products management services	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26 • Draft veterinary regulation, art.51 • Clinical trials regulation	2017	2024				CONTINUED: • Resources have been redirected under the New Veterinary Legislation programme in order to support the delivery of the Union Product Database. • MB decision from December 2019, allowed the project team to restart the activities • Re-planning of the activities and re-baselining of the project plan to be able to resume fully the activities

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2020
				Time	Budget	Scope	
	536/2014, art.8193) • Pharmacovigilance fees regulation 658/2014, art.7 • Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU						by Q3 2020
Administration digitalisation	n/a	2019	2021				CONTINUES • Provide better tools to overcome manual processing and repetitive tasks: onboarding tool launched in Q2 2020; onboarding portal published in Q2 2020 • E-recruitment and Learning Management System has been closed Q2 2020 • New Goals and Performance system and Succession Planning have been started in Q2 2020 • New Time & Attendance Management system and the start of the migration of SAP HR to Employee Central to be reviewed for 2021
IRIS Scientific advice SIAMED with Knowledge Management	n/a	2019	2021				CONTINUES • Roadmap to capture the scientific knowledge has been drafted • Process and system analysis and design has been carried out in Q2 2020 • ITF has been integrated in IRIS Q2 2020
Data centre refresh	n/a	2020	2020				• Project started Q2 2020 and will also update the Agency cloud strategy

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2020
				Time	Budget	Scope	
Application Maintenance and Development (AM&D) sourcing project	n/a	2019	2020				CONTINUES • The first tender for IT Framework Contract out of 4 has been completed Q2 2020.
Knowledge Transfer to the new DIMSIS contractor	n/a	2020	2020				• Project may start Q3/Q4 2020 if the contractor changes

Annex 3: Terms and abbreviations

Term/abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ACE	Analytics Centre of Excellence
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
AMR	Antimicrobial resistance
API	Active pharmaceutical ingredient
Art	Article
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
BCP	Business continuity plan
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
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CIOMS	Council for international Organisation of Medical Sciences
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
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
COVID-ETF	COVID-19 EMA Pandemic Task Force
CTIS	Clinical trials information systems
CVMP	Committee for Medicinal Products for Veterinary Use
DDC	Drug-device combination
DG	Directorate-General of the European Commission
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
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
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Term/abbreviation	Definition
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
ERA	Environmental risk assessment
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU-DPR	Data protection Regulation for EU institutions and bodies
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
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
FTE	Full time equivalent
DIA	Drug Information Association
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
GxP	Generic good practice
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
HMPC	Committee on Herbal Medicinal Products
Horizon 2020	EU Research and Innovation programme
HR	Human resources
HTA	Health technology assessment
HTAN	HTA network
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
IMI	Innovative Medicines Initiative
IMI PREFER	Patient Preferences in Benefit-Risk Assessment during the Drug Life Cycle
INC	International Neonatal Consortium
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme
IRIS	Regulatory & Scientific Information Management platform
IT	Information technology
ITF	EMA Innovation Task Force
IVD	In Vitro Diagnostics
JECFA	Joint FAO/WHO Expert Committee of Food Additives
JIACRA	Joint interagency antimicrobial consumption and resistance and analysis report
KPI	Key performance indicator

Term/abbreviation	Definition
LEU	Low enriched uranium
LMS	Learning management system
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
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
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
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
NRG	(Invented) Name Review Group
NTC	EU Network training centre
NUI	Non-urgent information
NVR	New veterinary legislation
OIE	World Organisation for Animal Health
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
PhV	Pharmacovigilance
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PLD	Patient level data
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
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
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
QRD-WG	Working Group on Quality Review of Documents
QWP	Quality Working Party
R&D	Research and development
RA	Rapid alert
REA	Relative effectiveness assessment
RFI	Request for information

Term/abbreviation	Definition
RMM	Risk minimisation measures
ROG	Regulatory Optimisation Group
RWE	Real world evidence
SA	Scientific advice
SAG	Scientific Advisory Group
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
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
WHO	World Health Organization
WP	Working party
WS	Work stream