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Mid-year report 2021

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 7 October 2021.

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Key developments

In the first half of 2021, the COVID-19 pandemic continued to dominate the Agency's activities and substantial resources continue to be allocated to respond to the public health crisis (78 FTEs, equal to almost 9% of EMA workforce). The Agency prioritised key activities and reacted with resilience to prevent the health crisis from severely impacting on its Work Programme and, therefore, only a minor share of its annual actions had to be delayed or suspended. The scope of the 2020 Work Programme had already significantly reduced, with important public health activities either delayed or suspended in line with the business continuity plan (among others: clinical data publication for non-COVID-19 related products; guidelines development; support to working parties; workshop and trainings for stakeholders; support to the translation of ATMPs into patient treatments). A brief summary of the main activities that took place during the first half of 2021 is presented below.

In the context of the **COVID-19 pandemic**, EMA has granted conditional marketing authorisations to three vaccines for the prevention and to one therapeutic for the treatment of COVID-19. The Agency has started the process of rolling review for five more COVID-19 vaccines and is currently reviewing submissions for marketing authorisation for three more COVID-19 treatments. In the first half of 2021, EMA has also worked closely with the EMRN to implement short-term actions to address resourcing needs for COVID-19 applications and to inform supply plans for the authorised vaccines. In accordance with its pharmacovigilance plan for COVID-19, the Agency kept collecting post marketing authorisation information on these products and is making use of real-world data to monitor the safety and effectiveness of authorised COVID-19 treatments and vaccines and other medicines used in patients with COVID-19 in the EU. Moreover, EMA has leveraged collaborations between academia and network scientists to support committee decision making: the Agency collaborated with CHMP, PRAC and the ETF to deliver reports on diagnostics and coagulopathy. EMA led at ICMRA, and through the OPEN initiative, the international collaboration on development approval and monitoring of COVID-19 vaccines and therapeutics. Lastly, EMA has conducted a preliminary lessons-learned exercise on the handling of the COVID-19 pandemic; areas addressed in the lessons learned include: adequacy of the existing (crisis) structures and systems, adequacy of the pharmacovigilance arrangements, striving for the best evidence post-authorisation, availability of clear roles and responsibilities, interaction between EMA and the Member States' Authorities, interaction with international partners, communication related aspects, and safeguarding the sustainability of the Network.

Significant efforts were devoted to tackle **vaccine** hesitancy. The Agency prepared and supported extensive proactive public communication, webinars, meetings and information on the EMA website on COVID-19 vaccines and held regular interactions with ECDC and NITAGs. In addition to this, a pilot started in the second quarter of 2021 in view of establishing a **platform for EU benefit-risk monitoring of vaccines** post-approval.

EMA continued its work also on **medicine shortages** and, in early June 2021, published a reflection paper on forecasting demand data for medicines in the EU/EEA.

Work continued to mitigate the presence of **nitrosamine impurities in medicines**; EMA gave its contribution to the Nitrosamines International Steering Group (NISG), collaborating on new nitrosamines acceptable intakes. In addition, the Nitrosamines Oversight Group has been established, which is a multidisciplinary group with representation from Committees relevant WPs and CMDh ensuring the harmonised implementation of the art 5(3) conclusions across EU, and creating a platform for stakeholder engagement to address emerging science on the topic.

Regarding the **new veterinary legislation**, the Agency is getting ready for the implementation of the Regulation (EU) 2019/6 as of 28 January 2022. Progress was made with the development of new

processes and the required IT systems: the Union product database (UPD) is 70% complete, the Union Pharmacovigilance Database (EVV) is 80% complete, and the Manufacturer and Wholesale Distributors Database (MWD) is 30% complete. The 'go-live' of the three IT systems is scheduled for 28 January 2022.

In April 2021, the Management Board approved the 'go-live' of the **Clinical Trials Information System (CTIS)** for January 2022. Extensive public training material, workshops and training courses in preparation for launch of CTIS have been carried out in the first part of the year.

EMA advanced in the establishment of a **digital innovation lab** to explore, pilot and develop solutions to leverage novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making. The Digital Innovation Lab process, artefacts and governance structure have been designed in June 2021 and a pilot with three innovation proposals is ongoing.

The **EU Collaboration on Artificial Intelligence** (AI) further developed during the first part of the year, and EMA has been one of the leading agencies providing knowledge and support in the area of AI. A consultation process has been triggered to identify, which of the user cases are of utmost importance/relevance to join forces and discuss possible collaboration among agencies.

The **DARWIN EU** project established in December 2020 to deliver a sustainable platform to access and analyse healthcare data from across the EU is on track. As part of the project governance, the DARWIN EU Advisory Board with strategic guidance functions has been established. In June 2021, a tender for a service provider to act as the DARWIN EU Coordinating Centre was published and the dedicated DARWIN EU webpage launched.

In the first half of 2021, the Agency continued to work on antimicrobial resistance (**AMR),** contributing to the enhanced discussions with the World Organisation for Animal Health (OIE) on data collection on antimicrobial use in animals and the option to link EMA and OIE data collection systems. In May, the Agency took part in the EC funded Steering Committee of the project "Working together to combat antimicrobial resistance (AMR)". EMA also contributed to TFAMR and to the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) activities, including leading key action activity 1.1 under the new TATFAR work plan to 2026, and contributing to others, in particular the development to alternatives to antimicrobials.

In addition to this, the Agency (EMA) close collaboration with EFSA and ECDC to analyse the potential relationship between the consumption of antimicrobials by humans and animals and the occurrence of antimicrobial resistance saw the publication of the 3rd **JIACRA report**.

In June 2021, the project for the expansion of the **European Surveillance of Veterinary Antimicrobial Consumption** (ESVAC) was approved. The project aims at collecting information on antimicrobial medicines sales and use in animals across the EU, to obtain reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR.

The **Agency's digitalisation** further progressed in human resources processes (continuous performance management, internal mobility, and career development) and procurement and contract management processes.

The implementation of the **Data protection Regulation for EU institutions and bodies** (EU-DPR) has continued with advice and preparation of records and privacy statements, the organisation of tailored training and awareness sessions.

In the first half of 2021, the Agency has finalised the scope definition and analysis of the **EC Proposal on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.** The exercise has produced a roadmap that, taking into account business process, data requirements, technology and tools, sets out tasks and activities for the implementation of the draft legal text. The roadmap also identifies strategic, tactical and operational priorities that enable the Agency to comply with the challenging timeline for implementation. Following the finalisation of the legislative proposal, expected for the second half of 2021, the roadmap will be further updated to reflect possible differences between the current draft text and the final legal text.

Key figures

This report describes the results and achievements of the Agency, working closely with the national NCAs, during the first six months of 2021, and thus reflects the situation as of 30 June 2021. Here below we highlight the most relevant deviations vs the annual work programme registered in the first half of 2021. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

Protocol assistance reverted the decreasing 3-year trend, growing by more than 20% (80 vs 65 in 2020).

The number of **novel technologies qualification advice/opinions** (14) given was the highest in the last 5 years.

After some years of stabilisation, the number of **orphan medicines applications** grew by almost 10% in the first part of the year, compared to 2020 (134 vs 123).

Only one **marketing authorisation application (MAA) for advanced-therapy medicinal products (ATMP)** was received, as ATMP MAA planned for the first half of 2021 have been postponed to later in 2021 or 2022. The annual forecast was therefore slightly decreased.

Initial evaluation applications of new **orphan medicinal products** and **similar biological products** saw a decrease compared to the first half of 2020, but are expected to largely recover during the second half of the year, leading to a slightly downward revised annual forecast. Equally, a higher-than-forecast level of new **non-orphan medicinal products** is now expected during Q3 and Q4.

The number of type IA variation applications remained substantially stable at 2020 levels, whereas **type II variation applications** received in the first half of the year were marginally lower, compared to the previous year. **Type IB variation application** saw a slight increase in the first half of 2021 (1,393 vs 1,301 in 2020), leading to a 14% upward revised annual forecast.

Article 61(3) applications, as expected, almost doubled (124 vs 66 in 2020), reverting last year trend.

Plasma Master File annual update and variation applications markedly decreased compared to last year (7 vs 18), returning to 2018 levels.

As part of the COVID-19 pandemic effects, in the first half of 2021 EMA received an outstanding number (1,458,522) of **Individual Case Safety Report (ICSR)**, triggering an increased revised annual forecast by more than 50%.

The number of **notifications of withdrawn products** scored a 5-year peak, increasing by almost 40% compared to 2020 (314 vs 230). As a result, the annual forecast has been augmented accordingly.

Assessment activities for veterinary medicines

The **requests for classification as MUMS/limited market** notably decreased in 2021, as expected, due to the upcoming entry into force on 28 January 2022 of the Veterinary Medicines Regulation (Regulation (EU) 2019/6), after which the MUMS policy will cease to be applicable.

Initial evaluation applications decreased by approximately 40%, compared to 2020. This downward trend might be linked to the decision of pharmaceutical companies to submit their applications only when the new provisions foreseen by the new Veterinary Medicines Regulation will become effective.

The number of variation applications continued to increase in the first half of 2021. In particular, **type II variations** reversed the trend compared to 2020 (53 vs 29).

Eight applications for transfers of marketing authorisation were already received in the first half of the year (vs 5 in 2020), the annual forecast has therefore been revised accordingly.

The number of **adverse event reports** (**AER**) saw a slight decrease compared to 2020, both for CAPs and NAPs.

99% of the **periodic safety-update reports (PSUR) received were evaluated within the established timelines**, in line with the previous years and considerably above the expected target.

Inspections and compliance

The number of **good manufacturing practice** (**GMP**) **inspections** was higher than expected. The increase is linked to CHMP requesting several inspections for Covid-19 related vaccines and therapeutics, and pre-approval inspections exceeding expectations. The revised upward annual forecast (from 50 to 160 inspections) takes into account these aspects and the increased expertise acquired by NCAs in performing distant assessments.

Good clinical practice (**GCP**) **inspections** continued to decrease in the first half of 2021 because of the travel limitations related to the COVID-19 pandemic, resulting in the revised annual forecast falling from 90 to 40 inspections. **Plasma Master File** (**PMF**) **inspections** were above target in the first part of the year and are expected to show a significant growth in the second half of 2021, thereby explaining the increased annual forecast.

Standard certificate requests and **urgent certificate requests** increased, compared to the first half of 2020 (respectively 1938 vs 1538 and 987 vs 729).

1,537 parallel distribution initial notifications and **13 parallel distribution notifications of bulk change** were received in the first half of 2021; considerably more than in the first half of the previous years, leading to an upward revised annual forecast

99% of standard certificates were issued within the established timelines, and the **average time to issue standard certificate** reached **16 days**, thereby significantly improving the performances registered in the previous years.

Meetings were still heavily influenced by the COVID-19 pandemic. The number of physical meetings is still lagging compared to the previous years, while the number of virtual meetings show a constant increase (3,220 vs 2,660 in 2020). The number of reimbursed and non-reimbursed delegates is a

noticeable effect of this trend, with no reimbursed Committee or Working Party meetings taking place during Q1 and Q2 2020.

Information and transparency

The consequences of the COVID-19 pandemic have also had an impact on the number of **requests for information,** which increased by 64% (5,915 vs 3,597 in 2020), and in the **completed requests for interviews and comments by media representatives,** which saw an exponential increment (4,057 vs 598 in 2020).

Requests for access to documents (ATD) slightly increased in the first six months of 2021 (342 vs 316 in 2020), while the **number of documents released** substantially grew by almost 50% compared to 2020 levels (568 vs 382 in 2020).

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted EMA work programme 2021.

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 2021'. 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.

1. Human Medicines Division

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Parallel scientific advice with international regulators	3	4	2	3	4	4	4	0	0%
Joint scientific advice with HTA bodies	2	1[1]	10	16	17	4	4	0	0%
Scientific advice for PRIME products	21	19	15	22	12	40	40	0	0%
Protocol assistance	80	65	81	103	79	132	146	+14	11%
Novel technologies qualification advice/opinions	14	9	9	6	11	19	19	0	0%
PRIME eligibility requests received	29	28	24	29	46	55	55	0	0%
Orphan medicines applications	134	123	127	127	127	250	250	0	0%
Submitted applications on the amendment of an existing orphan designation	0	0	5	1	2	2	2	0	0%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	368	339	279	375	310	670	670	0	0%
Finalised procedures for compliance check on PIPs	46	43	40	57	35	80	85	+5	+6%
Requests for classification of ATMPs	46	54	27	27	27	70	70	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.

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	98%	100%	100%		100%
PRIME eligibility requests assessed within regulatory timeframe	100%	100%	100%	100%		
Orphan designation opinions delivered within the legal timeframe	100%	100%	100%	100%	100%	100%
PDCO opinions sent to applicants within legal timelines	99%	99%	100%	99.6%		100%

1.2 Initial evaluation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
New non-orphan medicinal products	23	28	18	20	16	46	68	22	48%
New orphan medicinal products	10	17	17	9	9	29	28	-1	-3%
Similar biological products	4	7	8	5	5	15	13	-2	-13%
Generic, hybrid and abridged applications	12	12	20	13	5	25	23	-2	-8%
Scientific opinions for non-EU markets (Art 58)	0	0	0	0	0	3	3	0	0%
Paediatric-use marketing authorisations	0	1	0	0	1	1	1	0	0%
Number of granted requests for accelerated assessment	7	10	3	1	4	10	10	0	0%
Reviews on the maintenance of the orphan designation criteria at MAA stage	17	21	20	28	17	30	30	0	0%

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast			
						Initial	Revised	Change	
ATMPs applications requests received[1]	1	-	-	-	-	12	9	0	0%
COVID-19 related product applications received[2]	2	-	-	-	-	9	8	-1	-11%
Companion diagnostics opinions	0[3]	-	-	-	-	10	n/a[3]	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of				
		Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Applications evaluated within legal timeframes[4]	100%	100%	100	100%	100%	100%
Average assessment time for new active substances and biosimilars	205	199	198	205	196	180
Average clock-stop for new active substances and biosimilars	180	168	175	214[5]	203	182
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	60%	33%	60%	100%[6]	33%	75%
% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	80%	70%	72%	86%	56%	65%

[1] New indicator introduced in 2021 Work Programme
[2] New indicator introduced in 2021 Work Programme
[3] New indicator introduced in 2021 Work Programme, which is linked to the possible extension of the Agency's mandate following the EC proposal of November 2020. The indicator will not be applicable until 2022.
[4] Includes marketing authorisation and plasma master file applications.
[5] 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).
[6] Value is not representative of longer-term trends as it is based on a single opinion.

1.3 Post-authorisation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Type IA variations	1,961	1,978	1,898[1]	1,604	1,536	4,038	4,046	8	0%
Type IB variations	1,393	1,301	1,011	993	952	2,536	2,888	352	14%
Type II variations[2]	606	630	499	498	533	1,222	1,243	21	2%
Line extensions of marketing authorisations	16	24	9	10	12	25	32	7	28%
PASS scientific advice through SAWP	0	1	1	2	0	1	1	0	0%
Renewal applications	49	44	42	40	25	87	84	-3	-3%
Annual reassessment applications[3]	8	7	7	5	2	29	29	0	0%
Transfer of marketing authorisation applications	30	27	39[4]	232	36	60	60	0	0%
Article 61(3) applications	124	66[5]	157[6]	103	112	300	300	0	0%
Post-authorisation measure data submissions	519	403	446	405	368	900	900	0	0%
Plasma Master File annual update and variation applications	7	18	20	7	17	29	25	-4	-14%

[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] This is a seasonal procedure and 2/3 of these are submitted in second half of the year.
[4] Lower than expected activity as most of Brexit-related transfers were submitted by end of 2018.
[5] The lower result compared to last year is due to a drop in the submissions.
[6] Surge of 61(3) linked to change of local representatives for applicants.

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Post-authorisation applications evaluated within legal timeframes	99%	98%	98%	99%	99%	99%
Average assessment time for variations that include extension of indication	180	162	160	154	152	161

1.4 Referrals

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	2	2	6	2	3	8	5	-3	-38%
Non-pharmacovigilance referrals started	7	5	4	8	2	8	10	+2	+25%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Referral procedures managed within legal timelines	100%	100%	100%	100%	100%	100%

1.5 Pharmacovigilance

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of signals peer-reviewed by EMA	858	1,015	1,063	1,395	1,323	1,900	1,900	0	0%
Number of ICSRs for CAPs (reports received) [1]	1,458,522	-	-	-	-	1,660,000	2,600,000	+940,000	+57%
Number of signals assessed by PRAC (validated by EMA)	33	25	35	44	19	50	50	0	0%
PSURs (standalone CAPs only) started	265	243	278	256	309	569	573	+4	+1%
PSUSAs started	142	141	138	161	178	327	327	0	0%
Number of imposed PASS protocol procedures started	4	0[2]	6	7	8	6	4	-2	-33%
Number of imposed PASS result procedures started	6	3	1	5	1	5	6	+1	+20%
Number of notifications of withdrawn products received	314	230	187	217	138	400	500	+100	+25%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Periodic safety update reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%	100%	100%	100%

[1] New indicator introduced in 2021 Work Programme.
[2] The majority of studies received in the first half of 2020 are classified and accepted by the Committees as Category 3 studies (non-imposed).

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Periodic safety assessment reports (PSUSAs result procedures) assessed within the legal timeframe	95%	95%	100%	100%	100%	100%
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%	100%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%	100%	100%	100%	100%

1.6 Inspections and compliance

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
GMP inspections	77	127[1]	247[2]	162	226[3]	50	160	+110	+220%
GLP inspections	0	0	0	0	0	1	1	0	0%
GCP inspections	15	39[1]	79	74	69	90	40	-50	-56%
Pharmacovigilance inspections	10	3[1]	3	13	9	16	15	-1	-6%
PMF inspections	20	16[4]	66	87	40[5]	20	76	+56	+280%
Notifications of suspected quality defects	87	87	93	69	98	250	250	0	0%
Notifications of GMP non-compliances[6]	2	6	3	10	44	20	20	0	0%

[1] The result has been affected by travel restrictions due to the COVID-19 pandemic. The resources have been redirected to activities granting a 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] The result has been affected by travel restrictions due to the COVID-19 pandemic.
[5] Large part of PMF inspections' requests are usually received in the first half of the year.
[6] Other GMP inspections-related notifications previously included under suspected quality defects.

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Medicinal products included in the sampling and testing programme	94	70	67[1]	55	1[2]	88	94	6	7%
Standard certificate requests received	1,938	1538	1,284[3]	1,961	2,057	3,720	3,585	-135	-4%
Urgent certificate requests received	987	729	1,349	365	230	1,485	1,654	+169	+11%
Parallel distribution initial notifications received	1,537	1,141	1,265	1,264	1,414	2,450	2,800	+350	+14%
Parallel distribution notifications of bulk change received	13	5	8	4	4	10	20	+10	+100%
Parallel distribution annual updates received	2,331	7778[4]	1,369[5]	46[6]	2,938	5,500	5,000	-500	-9%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Inspections conducted within established regulatory timeframes	100%	100%	-[7]	100%	100%	100%
Standard certificates issued within the established timelines (30 working days)	90%	99%	97%	14%	0%	93%
Average days to issue standard certificate	10[8]	16	26	65.0	21.5	8.4
Urgent certificates issued within established timelines (2 working days)	100%	99%	98%	99%	99%	100%

[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] 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.
[5] To allow for IRIS implementation annual update, submissions were frozen for 3 months.
[6] 3,175 annual updates were estimated to have been received but not processed at that time.
[7] Inspections are being re-planned according to travel restrictions and likely availability.
[8] 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 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Parallel distribution notifications checked for compliance within the established timeline	90%	98.8%	98%	27%[1]	98%	94%
Impact of GCP confidentiality arrangements: Additional GCP inspections addressed through information exchange on inspections carried out by international partners	35%	35%	44%	73%[2]	31%	37%

1.7 Committees and working parties

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of reimbursed meetings	0	52[3]	143	213	261	512	91	-421	-82%
Committees and Management Board meetings	51	15[1]	38	35	40	77	38	-39	-51%
Trainings	2	1	12	8	10	33	2	-31	-94%
Workshops	1	0	0	28	20	20	2	-18	-90%
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	93	36[1]	93	142	191	382	49	-333	-87%

[1] The significantly lower result is due to the 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] The significant variation in the figures is due to the COVID-19 outbreak.

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of virtual meetings (audio-, video- and web conferences)	3,220	2,660	1,659	2,524	2,460	4,600	6,400	+1,800	+39%
Number of reimbursed delegates	0	1,003	2,856	3,969	4,159	9,358	0	-9,358	-100%
Number of non-reimbursed delegates	7,129	60	227	564	1,464	1,500	7,129	5,629	375%
Herbal monographs, new	2	0	0[1]	1	3	4	4	0	0%
Herbal monographs, reviewed	8	5	6			15	15	0	0%
Herbal monographs, revised	0	5	0[1]	10	5	4	3	-1	-25%
List entries	0	0	0[1]	0	0	1	1	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%	100%	100%	100%

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Support the STAMP scientific advice pilot for repurposing established medicines	1.1	A number of prioritised established medicines are enlisted in the pilot	Delayed	The project was delayed due to COVID-19 and BCP and will restart in Q4 2021.

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

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
SPM&S - Substances and products management services	Implementation of ISO Identification of Medicinal Products standards to apply interoperability and consistency to the information shared across the regulatory authorities within the EU and internationally	Merge for delivery optimisation into the Regulatory Business Process Optimisation Programme (RBPOP) in Q2 2020 - EU Implementation Guide V2.1 published on June 2021

2. Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests (Vet)	4	2	3	1	1	5	5	0	0%
Scientific advice requests received	11	14	12	16	14	22	22	0	0%
Requests for classification as MUMS/limited market of which:	7	19	20	13	14	25	25	0	0%
re-classification requests	3	5	3	1	3	5	5	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100%	100%

2.2 Initial evaluation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Initial evaluation applications	4	7	13	7	7	18	11	-7	-39%
New MRL applications	0	0	2	1	2	2	2	0	0%
MRL extension and modification applications	1	1	0	0	3	2	2	0	0%
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	0	3	0	5	0	0	0	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Procedures completed within legal timeframes	100%	100%	100%	100%	100%	100%

2.3 Post-authorisation activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Variations applications, of which:	381	331	252	211	188	425	649	+224	+53%
Type IA variations	212	191	147	106	110	217	366	+149	+69%

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Type IB variations	116	111	72	61	47	145	205	+60	+41%
Type II variations	53	29	33	44	31	63	78	+15	+24%
Line extensions of marketing authorisations	0	1	0	1	4	3	3	0	0%
Transfers of marketing authorisations	8	5	2			5	8	+3	+60%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%	100%

2.4 Arbitrations and referrals

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated	0	1	2	3	0	6	3	-3	-50%

Performance indicators

Performance indicators related to core business	Target 2020	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Referral procedures managed within the legal timelines	100%	100%	100%	100%	100%	100%

2.5 Pharmacovigilance activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	87	72	71	81	91	160	160	+0	+0%
Total AERs, of which:	31,000	31,944	34,491	29,143	20,216	75,000	75,000	+0	+0%
Adverse-event reports (AERs) for CAPs	15,000	14,195	16,057	14,864	9,838	37,500	37,500	+0	+0%
Adverse-event reports (AERs) for NAPs	16,000	17,749	18,434	14,279	10,378	37,500	37,500	+0	+0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
PSURs evaluated within the established timelines	90%	99%	100%	95%	95%	97%
AERs for CAPs monitored within the established timelines	95%	95%	95%	96%	99%	96%

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals.	3.1	Guidance for novel therapies and biologicals developed	On track	The CVMP Novel therapies and Technologies working party (NTWP) has been established in April 2021. During the May NTWP meeting, two operational expert groups were created to work on guidance for cell therapies and bacteriophages

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				respectively. The release of concept papers for public consultation is planned for Q1 2022.
Engage with EU and international risk-assessment bodies with a view to aligning methodology for estimating consumer exposure to residues, including dual-use substances.	3.1	Analysis of existing models Evaluation of finding and recommendation on harmonised approach	**On track**	The experts group met four times in 2021, progressing the work on the recommendation to be sent to the EC by 30 November 2022 (EMA/EFSA joint final report). An intermediate report including the analysis of currently available models is planned for the end 2021.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database;	3.1	Guidance for surveillance and signal detection developed Enhanced communication with the network	**On track**	Specific guidance and system specifications were developed with the expert groups and discussed at several stakeholder meetings during the first part of the year. Signal management process development and work share proposals are ongoing.
Using data on the sales of veterinary products, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use.	3.1	Methodology established and guidance developed	**On track**	System specifications to collect and store sales data have been discussed with stakeholders and system development is ongoing.
Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label.	3.1	Expert group established with mandate and objectives	**On track**	A concept paper was drafted and published for consultation in 2020. Drafting of the guideline is ongoing, expected to be published for consultation in Q4 2021.
Improve communication of veterinary pharmacovigilance to the general public.	3.1	Establish PhV communication framework	**On track**	Systems specifications have been developed for the systems set-up to ensure transparent and continuous communication. EMA participated to webinars on pharmacovigilance topics

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				organised by the Federation of Veterinarians of Europe (FVE) and the European Association for Porcine Health Management (EAPHM) in Q2 2021.
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required.	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	**On track**	EMA provided input in 2020 to the consortium tasked by EC to perform the feasibility study for the monograph system.
Develop further guidance on when the use of persistent, bio accumulative and toxic substances in animals can be justified.	3 (additional RSS recommendation)	PBT guidance developed and published	**Delayed**	Development of a reflection paper on the interpretation of Art.37(2)(j) of regulation 2019/6 was initiated in Q1 2021.
Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish cooperation with international institutions, academic organisations and relevant initiatives.	3 (additional RSS recommendation)	Establish ERA framework with EU and international partners	**On track**	Ad hoc cooperation on identified topics for discussions is ongoing (e.g. AMR in the environment with EFSA). Generally, cooperation with other Agencies and academia is being initiated on a case-by-case basis.
Provide scientific support to the European Commission and the EU network to ensure that a "One Health" approach is applied to ERA.	3 (additional RSS recommendation)		**On track**	EMA provides input to EC/other Agencies when requested on ERA "One Health" topics. No specific request was received in the first half of 2021.
Expand current ESVAC system to include other antimicrobials.	4.1	Collection of data expanded to include all antimicrobials	**On track**	In line with the Commission Delegated Regulation (EU) 2021/578, the work on development of the new antimicrobial sale and use data system to receive extended list of antimicrobials is ongoing.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight.	4.1	Establish and implement new process for JIACRA report to be led by EMA and CVMP in cooperation with EU MSs	On track	The 3rd JIACRA report was published in June 2021. Preparation for CVMP's oversight as provided by Regulation (EU) 2019/6 will start in the second half of 2021.
Adjust the methodology for analysis of antimicrobial data, by considering approaches developed internationally.	4.1	Analyse international approaches and integrate where possible in methodology	On track	A concept paper was drafted and published for consultation in 2020. Drafting of the guideline is ongoing, expected to be published for consultation in Q4 2021.
Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals.	4.1	Define new requirements Develop guidance on new requirements	On track	A concept paper was drafted and published for consultation in 2020. Drafting of the guideline is ongoing, expected to be published for consultation in Q4 2021.
Inform policy decisions via enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food.	4.1	Actively participating to policy development	Delayed	The activity has been deprioritised due to more urgent work on establishing the antimicrobial sales and use data collection system in line with the requirements of the Regulation (EU) 2019/6.
Participate in international initiatives to reduce the risk of AMR.	4.1	Actively participating in international fora	On track	EMA participated to the OIE AMR WG in April and to the PAHO-led EC funded Steering Committee of the project "Working together to combat antimicrobial resistance (AMR)" in May. Participation in TFAMR activities in January, May, June and July. EMA contributes to the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) activities throughout the year, including leading key action activity 1.1

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				under the new TATFAR work plan to 2026, and contributing to others, in particular the development to alternatives to antimicrobials. EMA contributed to enhanced discussions with OIE on the data collection on antimicrobial use in animals and the option to link EMA and OIE data collection systems.
Update existing guidelines, and initiate new guidance as needed.	4.3	Develop relevant guidance	**On track**	The following guidance has been finalised and published in the first half of 2021: "Reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health"; and "Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances".
Finalise the CVMP reflection paper on antimicrobial resistance in the environment, in the light of comments received. Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper.	4.3	Reflection paper finalised and published	**On track**	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms.	4.3	Framework developed Communication with stakeholders	**On track**	A reflection paper on promoting the authorisation of alternative to antimicrobials (ATAm) has been finalised and will be adopted by CVMP in July 2021.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				In addition, discussion on possible regulatory approaches to alternatives are being discussed in the context of TAFTAR work plan (action 3.3).
Enhance the promotion of responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion.	4.3	Guidance development Communication with stakeholders	**On track**	Concept paper on update to the CVMP's reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health is being drafted for finalisation Q3 2021. Reflection paper on criteria to determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted in regard to Article 107(3) of Regulation (EU) 2019/6 is being drafted for finalisation Q4 2021.
Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health.	4.3	Guidance development	**On track**	A reflection paper on promoting the authorisation of ATAm has been finalised and will be adopted by CVMP in July 2021. Prioritisation of the relevant guidance to be developed is on-going. Development of guidance on bacteriophage therapy has been already included in the work plan of NTWP, to be adopted in July 2021.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives.	4.3	Cooperation at EU and International level for events Common approach agreed	**On track**	See the activity on reflection on alternatives to antimicrobials and the TATFAR activities.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances).	4 (additional RSS recommendation)	Identify different benefit-risk approaches per type of vaccines Guidance on benefit-risk	**On track**	Guideline on limited market data requirement will be adopted at CVMP in July 2021 and a guideline on exceptional circumstances data requirements will be adopted by CVMP in July 2021 for consultation; both guidelines will be instrumental for establishing benefit-risk of these products. The IWP-V will discuss further actions in Q4 2021 in the context of the development of the new work plan for the working party.
Develop a regulatory framework for authorisation, under exceptional circumstances, of vaccines for emerging health threats and benefit-risk monitoring post-approval.	4 (additional RSS recommendation)	Guidance developed and implemented	**On track**	A concept paper on exceptional circumstances was published for consultation in January 2021. The draft guideline on data requirements will be adopted by CVMP and released for consultation at the July CVMP meeting. Finalisation of the guideline expected in January 2022.
Develop appropriate and proportionate guidance to maximise opportunities offered by Regulation (EU) 2019/6 for promoting availability of vaccines (vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers).	4 (additional RSS recommendation)	Guidance developed and implemented	**On track**	Concept papers for all the three topics were published in January 2021 for consultation. Drafts of a "Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines" and a "Guideline on data requirements for vaccine antigen master files (VAMF)" were published for consultation in June 2021, both guidelines took into consideration the comments submitted during the concept papers consultation. Guideline on vaccine platform

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				technology master files (vPTMF) will be adopted and released for consultation at the July CVMP meeting. Finalisation of guidelines is expected in January 2022.
Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best practices on the use of veterinary antiparasitic medicines.	4 (additional RSS recommendation)	Improve interaction with International organisations Best practices embedded in guidance	**On track**	EMA is part of the OIE Electronic Expert Group (EEG) on Antiparasitic Resistance (APR). The group met once in the first part of the year and otherwise had email exchanges, to progress the work on the "Prudent use of antiparasitic agents to help control antiparasitic resistance in grazing livestock species" document. EMA provided input into the regulatory requirements in the EU.
Promote responsible use of antiparasitics in the EU.	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	A "Concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics" was published in April 2021 for consultation. The draft revised guideline is for adoption at the July CVMP meeting for public consultation.
Veterinary Medicines Regulation: Preparation phase – 2021; Implementation phase from 2022.	6.1	Prioritised guidance, processes and IT systems in place in time for implementation	**On track**	Work on the prioritised guidance is on-going and veterinary processes and procedures are being aligned with the new requirements of Regulation (EU) 2019/6. The development of required IT system is on track:

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- Union product database (UPD) go live scheduled for 28 January 2022 (70% complete); - Union Pharmacovigilance Database (EVV) go live scheduled for 28 January 2022 (80% complete); - Antimicrobial Sales and Use (ASU); MVP go live scheduled for end 2022; post-MVP improvements Q2 2023 (25% complete); - Manufacturer and Wholesale Distributors Database (MWD) go live scheduled for 28 January 2022 (30% complete). Two recommendations are under development: - List of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans; - List of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))."
Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision-making.	6.2	Analysis of current methodologies, development of harmonised approach and guidance	**On track**	A drafting group of the CVMP is working on a revision of the "CVMP recommendation on the evaluation of the benefit-risk balance", with the aim to improve the current benefit-risk methodology and align with the Regulation (EU) 2019/6 provisions. A concept paper for consultation will be circulated in Q4 2021.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies.	6.2	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	On track	The newly formed NTWP is starting to develop guidance for new technologies like bacteriophages and cell therapies products.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	The EVVet3 project aims to provide a "Union veterinary pharmacovigilance system", by implementing any remaining requirements from Directive 2001/82/EC (as applicable, in relation to veterinary pharmacovigilance reporting), as well as the VICH guidelines relating to pharmacovigilance reporting	- Go Live planned for January 2022
UPD - Union Product Database [continues]	Providing a Union Product Database system regarding Veterinary products according to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018	- Go live planned for January 2022 - UPD V1.02 already live for NCAs to be able to test
ESVAC - Collection of Antimicrobials Sales and Use Data [new]	The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project collects information on how antimicrobial medicines are used in animals across the European Union (EU). The objective is to obtain reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR.	- Project approved June 2021 and work has started for a 'go-live' in January 2022
EudraGMDP - Union Manufacturers and Wholesale Distributors Database	The EudraGMDP database is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates.	- Analysis/impact assessment of amendments and needed improvements to EudraGMDP

3. Task forces

3.1. Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
New scientific, regulatory and telematics curricula developed	0	3	1	0	0	2	2	0	0%
Number of training events advertised to the EU Network	36	20[1]	27	25[2]	69	40	40	0	0%
Number of reimbursed training events to the EU Network	0	1[3]	7	1[9]	11	12	12	0	0%
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	10	6	6	4	6	10	10	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Number of users registered to the EU NTC Learning Management System	5,400	5,514	5,213	4,842	4,020	2,850
Number of NCA experts[4] registered to the EU NTC Learning Management System	4,500	4,511	4,236	3,888	3,060	1,950

[1] Lower results due to the COVID-19 pandemic.
[2] Limited number of courses being developed and offered to Network.
[3] Several courses have been postponed because of the COVID-19 pandemic.

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Establish a digital innovation lab to explore, pilot and develop solutions and processes, across the drug regulation spectrum, that leverage novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making.	2.2	Review and implement digital business transformation, using analytics, artificial intelligence and automation methodologies, across selected business functions supporting medicines' development, evaluation, supervision and administrative processes Set up an innovation lab	**On track**	The Digital Innovation Lab process, artefacts and governance structure have been designed as of June 2021 and a pilot with three innovation proposals is ongoing. These include exploring application of analytics and novel technologies.
Establish an EU collaboration on AI with other Agencies in the EU Network.	2.2	Develop and promote AI community Share knowledge and increase maturity Collaborate for the implementation of common AI initiatives and projects	**On track**	The EU Collaboration on AI is ongoing on a monthly basis, where the EU agencies meet to discuss specific topics on AI. EMA is represented by colleagues in the TDT, TDA and Veterinary division. EMA is one of the leading agencies proving knowledge and support in the area of AI. As the next step, a consultation process has been triggered to identify which of the use cases are of utmost importance/relevance to join forces and discuss possible collaborations among agencies.
Develop capacity and expertise across the regulatory network through curriculum development and knowledge-sharing initiatives on data science, digital technologies and artificial intelligence-related solutions, products and endpoints, and their applications in the regulatory system.	2.3	Develop a future state learning delivery model and landscape that serves new and existing audiences,in co creation with the EU-NTC Deliver training on AI	**On track**	A draft roadmap for an updated service model and related technology ecosystem has been developed, with the aim of expanding the current ecosystem and allowing extension of training to external audiences.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop the integrated evaluation pathways for the assessment of combination products / companion diagnostics.	3.4	Facilitate the regulatory pathway between notified bodies and medicines' regulators	Delayed	In view of resource constraints and MDR/IVDR coming into application this year and next year respectively, the priority is currently on the implementation of the MDR/IVDR. Also, although not yet a formal integrated pathway in place, EMA has established regular collaborative interactions for notified bodied working groups for the MDR/IVDR implementation (e.g. Art 117 workshop, Companion diagnostics Consultation Working Group, notified body opinion template) and also through product-specific procedures (via scientific advice or pre-submission meeting).
Identify and enable access to the best expertise across Europe and internationally.	3.4	Map all current working groups (i.e. at EMA, HMA/CAMD, NCA, EC) working on medical devices and in vitro diagnostic where there is a connection to medicinal products and identify common tasks/topics. Establish a more formal link between the current groups and the experts at the NCA's facilitating systematic interaction.	On track	EMA activities are mapped. Ongoing bilateral meetings with the EC taking place with the aim of raising upfront awareness and better interplay of deliverables and priorities on both sides, identify groups to be involved and consulted in respective deliverables.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
ECTD4: Implementation and adoption of eCTD v4.0 standard	The project aims at implementing the next generation standard defining the message for exchanging regulatory submission	- Impact analysis delivered - More details on project initiation planned in the context of 2022 prioritisation exercise

Project title	Long term objective	Achievements/results in Q1/Q2 2021
	information electronically between applicants and Regulatory Authorities.	
IRIS: Platform to support regulatory business processes of the Agency	The IRIS platform will provide a single space for applicants and EMA to submit requests, communicate, share information and deliver documents concerning regulatory and scientific procedures.	- Marketing status ready to go live in July 2021 - eAF proof of concept ongoing - Inspections GMP 90% completed

3.2. Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of MLM ICSRs created	4,896	4,446[1]	5,033	6,378	5,816	15,000	10,000	-5000	-33%
Number of healthcare data sets to which EMA has access and therefore its committees can integrate analyses into assessments	3	3[2]	-[3]	-[3]	-[3]	6	6	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	90%	95%	100%	100%	95%	100%

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Progress the development, construction and delivery of the Data Analytics and Real World Interrogation Network.	2.1	To initiate a project to deliver DARWIN EU, including the sourcing of an external	On track	EMA activities are mapped. Ongoing bilateral meetings with the EC taking place with the aim of raising upfront awareness

[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.
[2] New indicator included in 2020 Work Programme

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		technical coordinator. A pilot with the European Health Data Space initiated.		and better interplay of deliverables and priorities on both sides, identify groups to be involved and consulted in respective deliverables.
Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network - DARWIN). Build the business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare.	2.1	To initiate a project to deliver DARWIN EU, including the sourcing of an external technical coordinator. A pilot with the European Health Data Space initiated.	**On track**	The DARWIN EU project was established in Q4 2020. As part of the DARWIN EU project governance, the DARWIN EU Advisory Board has been established and held its first meeting in June 2021. The Advisory Board will provide strategic guidance to the DARWIN EU project. In June 2021, a tender for a service provider to act as the DARWIN EU Coordinating Centre was published, and the dedicated DARWIN EU webpage launched. The EC has postponed European Health Data Space (EHDS) pilots to 2022.
Launch and carry out CHMP pilot for individual patient-level data from clinical trials.	2.1	Pre-pilot of at least one marketing authorisation application in 2021	**On track**	The DARWIN EU project was established in Q4 2020. As part of the DARWIN EU project governance, the DARWIN EU Advisory Board has been established and held its first meeting in June 2021. The Advisory Board will provide strategic guidance to the DARWIN EU project. In June 2021, a tender for a service provider to act as the DARWIN EU Coordinating Centre was published, and the dedicated DARWIN EU webpage launched. The EC

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				has postponed European Health Data Space (EHDS) pilots to 2022.
Work with international partners to develop roadmap and guidance.	2.1	Agreement of roadmap for international regulatory collaboration on real world evidence.	**On track**	The interim lessons learned from the MAA application pre-pilot for analysis of raw data was presented at CHMP strategic and learning meeting in May. An ad-hoc advisory group on raw data will be established in July 2021 to design the full pilot and examine the practical aspects of raw data analysis.
Collaborate with international initiatives on Big Data. Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners.	2.1	Develop a set of documents to describe and establish a data standards development Strategy followed by a roadmap. Develop international guidelines to improve innovative drug development.	**On track**	A Data Standardisation Strategy for the Network is under development and was the subject of a workshop with stakeholders held on 18 May 2021. ICH E20 members reviewed the impact of adaptive designs on ICH M11 standard trial protocol in April 2021. The ICH MIDD (model-informed drug development) working group drafted an updated proposal on MIDD guideline topics and a road map prioritisation in the first half of 2021.
Work to develop and implement EU framework.	2.1	Consult stakeholders on data elements to be used as real world meta-data for regulatory purposes.	**Completed**	The technical workshop on real-world metadata for regulatory purposes was held on 12 April 2021 to gather stakeholder's feedback on: the list of metadata; options for metadata collection and maintenance processes; proof-of-concept catalogue of data sources and metadata.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Establish an EU framework for data quality and representativeness. Develop guidelines, a strengthened process for data qualification through Scientific Advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability.	2.1	The final guidance on studies from registries published.	**On track**	Procurement process was launched in Q2 2021 for an academic consortium to deliver a data quality framework strengthening the use of real-world data in medicines development. The draft guideline on registry-based studies has been revised, following the public consultation that took place from September to December 2020. The consultation with the EMA committees on the final draft guide will start in Q3 2021, with a view to publish the guidance at the end of 2021.
Enable data discoverability. Identify key meta-data for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable).	2.1	Initiate a project to enhance the EU database of real world data resources (ENCePP database).	**On track**	The Real-World Metadata project was initiated in December 2020. The enhancement and delivery of a catalogue of real-world data and upgrade of the register of observational studies are within the project scope and are planned for 2022. The external consortium developing real world metadata and maintenance process work started in January 2021. The technical workshop on real-world metadata for regulatory purposes was held on 12 April 2021.
Develop EU Network skills in Big Data. Develop a Big Data training curriculum and strategy based on a skills analysis across the Network,	2.2	Training curricula finalised on pharmacoepidemiology, biostatistics and data science.	**On track**	The survey on Big Data skills in the EU Regulatory Network was completed in Q2 2021, with clear training priorities

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
collaborate with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI.		Integrate curriculum on modelling and simulation.		identified for each training curriculum. The pharmacoepidemiology and biostatistics training curricula were finalised in 2020. The Data Science curriculum is on track to be adopted by the Big Data Steering Group in September 2021. The drafting of the Modelling and Simulation curriculum is delayed due to COVID-19 related activities.
Create and maintain a Health Data Science and AI forum to engage with a diverse set of stakeholders in novel digital technologies and artificial intelligence. This will include the technical, ethical, legal, regulatory and scientific perspectives of the use of digital technologies, and AI-powered applications.	2.2	Stakeholder workshop on AI held.	**Completed**	The joint HMA/EMA workshop on artificial intelligence (AI) in medicines regulation was held on 19-20 April 2021. The workshop report was published in June 2021, summarising the workshop outputs and the list of prioritised recommendations on AI.
Develop Big Data learning initiative with a view to developing guidelines and processes that learn from applications.	2.2	Review of real-world data in marketing authorisation applications from 2018 and 2019 completed and learnings presented to CHMP and Big Data Steering Group. Hold a workshop with stakeholders to learn from Big data in regulatory submissions.	**On track**	The retrospective analysis of centralised marketing authorisation applications (MAA) and extensions of indications (EoI) submissions, involving RWD/RWE in 2018-2019, was completed. Preliminary results were presented to Big Data Steering Group, PRAC, SAWP and CHMP meetings in April 2021. The Big Data learnings initiative workshop is planned for Q4 2021.
Strengthen EU Network processes for Big Data submissions. Launch a 'Big Data learnings initiative' where submissions that include Big Data	2.2	Initiate project to upgrade the EU Post-Authorisation Studies Register with agreed meta-data and functionalities to	**On track**	The Real-World Metadata project was initiated in December 2020. The enhancement and delivery of a catalogue

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
are tracked and outcomes reviewed, with learnings fed into reflection papers and guidelines. Enhance the existing EU PAS register to increase transparency on study methods.		enable posting of protocols and results and complex searches.		of real-world data and upgrade of the register of observational studies are within the project scope and are planned for 2022. Stakeholder consultation on the EU PAS register will start in Q3 2021.
Create an EU Big Data 'stakeholder implementation forum'. Dialogue actively with key EU stakeholders, including patients, healthcare professionals, industry, HTA bodies, payers, device regulators and technology companies. Establish key communication points in each agency and build a resource of key messages and communication materials on regulation and Big Data.	2.4	Multi-stakeholder forum on Big Data held.	**On track**	Preparations for the second multi-stakeholder forum have started. The forum is planned for December 2021.
The actions in this Regulatory Science Strategy relating to RWD are included within the 10 actions listed under Big Data. In addition, specific pilots of RWD analytics will be conducted and the work on pharmacovigilance methods will continue: - Conduct a pilot of using rapid analytics of real-world data (including electronic health records) to support decision-making at the PRAC and CHMP; - Review of the utility of using electronic health records for detecting drug safety issues (including drug interactions).	2.4	The final report of PRAC rapid analytics pilot and initiate pilot with one other committee.	**On track**	The PRAC pilot of rapid analytics of real-world data was completed in January 2021. The survey to collect PRAC feedback on the pilot results was launched in May 2021. The executive summary and recommendations from the final report will be published on the EU PAS register in Q3 2021. The rapid data analytics project was presented to PRAC, PDCO, COMP, CAT and SAWP. Members of these Committees have been identified to help define use cases for the proof of concept studies. Piloting is on track to start with at least

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				two committees Q4 2021 (PDCO and COMP).
Develop the regulatory framework for emerging clinical data generation.	3.2	Over a three-year period, compile a review of current experience of novel trial design concepts or statistical methods related to: estimands, master protocols, Bayesian, single arm trials, indirect comparison. To include considerations for special populations. Plan guidance drafting or revision where necessary. Implement recommendations, including via training.	**On track**	ICH E20 Sections on principles, need for adaptation and Bayesian aspects were partly or fully drafted up until June 2021. ICH E11A sections on modelling and simulation have been drafted and extensively redrafted and commented upon. Sections on the extrapolation of safety and the inclusion of adolescents in adult trials were fully drafted. Questions on complex clinical trials were written in April 2021 by a cross-Agency drafting group in collaboration with the European Commission and the Clinical Trials Facilitation Group for a question and answer. Answers were drafted in June 2021.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
- Lifecycle Regulatory Submission Raw Data	- Report on review of experience with IPD at EMA and other international regulatory agencies and develop protocol for IPD	- Review of experience with IPD delivered
- Lifecycle Regulatory Submission Metadata	- Identify relevant data sources; by defining and standardising the structure of the information (i.e. defining the 'metadata'	- Data standard strategy finalized

Project title	Long term objective	Achievements/results in Q1/Q2 2021
	and supported through relevant standards), the scientific information will become more accessible	
- Real-world Metadata, Quality Framework and Catalogues	- Conduct external studies to identify data sources of real-world data, define and collect metadata and deliver a data quality framework.	- Final list of Metadata of the Minerva study delivered
- Observational Studies Rapid Analytics	- Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	- Instant Health Data (IHD, i.e. a Rapid Analytics software) live and training delivered.
- Observational Studies DARWIN EU	- Establish a network of data, expertise, and services to support better decision-making by EMA and NCA scientific committees on the benefits and risks of products via rapid access and analysis and increased reliability, validity and representativeness of EU health data	- Tender procedure launched. - DARWIN web page published on EMA corporate website.
- Signal and Safety Analytics	- Increase saleability and efficiency in processing of signals & safety data	- The project is planned to start in Q4 2021

3.3. Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests	21	15	11	10	12	35	35	0	0%
Innovation Task Force Art 57 CHMP opinion requests	0	0	0	0	0	3	3	0	0%
Business Pipeline briefing meetings[1]	6	-	-	-	-	22	18	-4	-18%
Regulatory assistance, including SME briefing meetings[2]	105	-	-	-	-	223	223	0	0%
Requests for SME qualification	312	303	328	254	312	532	532	0	0%
Requests for SME status renewal	131	178[3]	134	163	392	1,362	1,362	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Satisfaction level of SMEs	80%	89%	88%[4]	n/a	98%	93%

[1] New indicator introduced in Work Programme 2021
[2] New indicator introduced in Work Programme 2021
[3] SME renewal applications typically submitted towards year-end.
[4] Indicator from 2018 info day

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1	New technologies identified and integrated within EU-NTC	**On track**	No new technologies identified yet.
Leverage collaboration between academia and network scientists to address the rapidly emerging regulatory science research questions.	3.3	Emerging regulatory science research questions addressed in support of committee decision-making	**On track**	Support to COVID-19 activities and delivery of reports on diagnostics and coagulopathy; engagement with SAWP and TDA on use of RWE in advice procedures; collaboration with PRAC and CHMP and ETF.
Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients.	3.3	Regulatory training modules developed	**On track**	The Agency is currently developing proposal for ICH training in collaboration with ICH coordinator, EU NTC and TDA.
Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.	3.4	Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	**On track**	Exchanges identified, platform to be investigated: expansion of the scope of business pipeline meetings; Academic newsletters; lunch time talks (EIT health); establishment of collaboration with C-Path (Duke) and EIC.
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre;	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	**Delayed**	EXB progressed discussion of the prioritisation exercise across the 6 thematic areas. Tracking of RSS delivery is linked to the MAWP 2022-2023 cycle and annual report for 2021.

3.4. Clinical Studies and Manufacturing (TCS)

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop data-sharing principles with stakeholders and provide regulatory guidance.	2.4	Questions and Answers (Q&As) on the GDPR and the Secondary Use of Data for Medicines and Public Health Purposes. Prepare a high-level paper, guiding the Agency and the stakeholders with respect to the use of clinical trial and other health data for the purpose of the development, authorisation and safety monitoring of medicines.	**Delayed**	Finalisation of Q&As put on hold as instructed by EC to await EDPB guidance on scientific research and secondary use of health data, which is expected by the end of 2021.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual.	3.2	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**Delayed**	Draft Principles of ICH E6 published for transparency in April 2021. Annex 1 drafting progressing but step 2 will be in 2022.
Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level.	3.2	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**Delayed**	Draft Principles of ICH E6 published for transparency in April 2021. Annex 1 drafting progressing but step 2 will be in 2022.
Establish a multi-stakeholder, neutral platform, to enable new approaches to clinical studies and to position the EU as a preferred location for innovative clinical research.	3.2	Establish a framework, mandate and objectives for a multi-stakeholder platform for discussion of new approaches for Clinical Studies.	**On track**	Discussion ongoing. In the context of ICH GCP renovation, stakeholder engagement is being implemented. Large webinars conducted worldwide with patient and academia representation to discuss ICH E6 Principles and progress.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				On complex clinical trials, Clinical Trials Facilitation and Coordination Group (CTFG), EMA and Commission drafting Q&A participation in public workshop is anticipated in Q4. Extensive public training material, workshops and training courses in preparation for launch of the Clinical Trials regulation and CTIS.
Work with stakeholders, the EU Medicines Regulatory Network and the European Commission to promote and facilitate the conduct of complex clinical trials and other innovative clinical trial designs.	3.2	Using the multi-stakeholder framework from 3.2.1.11, develop action plan and workstreams on complex clinical trials.	**On track**	On complex clinical trials, CTFG, EMA and Commission drafting Q&A participation in public workshop is anticipated in Q4. Extensive public training material, workshops and training courses in preparation for launch of the CT regulation and CTIS.
Promote the inclusion of neglected populations, such as pregnant and lactating women, the elderly, and those of diverse ethnicity in clinical trials.	3.2	Use the revision of ICH E8 and E6 to remove barriers and to encourage the inclusion of neglected populations in clinical trials.	**On track**	ICH E8 to reach step 4 in second part of 2021; incorporates wording to facilitate inclusion of these population. ICH E6 Draft Principles include general wording.
Define approaches for review of data with international regulator.	4.6	Build on the experience acquired with COVID-19 to establish the approach for future emergencies.	**On track**	The reflection paper on variants has been issued and the discussion with stakeholders and other developers is progressing.
Communicate proactively with key stakeholders on benefit-risk, using evidence-based tools to tackle vaccine hesitancy.	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA	**On track**	Extensive proactive public communication, webinars and information on EMA website on COVID-19 vaccines. Support to EVIP and EC. Public stakeholder meetings on COVID-19

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				vaccines. Product-related communications and safety updates issued. Lancet publication on COVID-19 vaccines. User-testing of COVID-19 information materials. Visual risk contextualisation for Vaxzevria Art 5.3.
Engage with public health authorities and NITAGs to better inform vaccine decisions.	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute.	**On track**	Regular interactions with NITAG, including bi-weekly teleconferences in the context of the pandemic.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval;	4 (additional RSS recommendation)	Set up the platform and conduct first studies.	**On track**	Pilot started Q2 in context of the pandemic.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database; renamed including a merger with SUSAR)	The project aims at delivering Clinical Trials Information System (CTIS) to support the harmonisation of the assessment and supervision processes for clinical trials throughout the EU.	- April Management Board approved 'go-live' in January 2022 - Training materials and user trainings reached 75% and will continue after 'go-live' - Safety reports added to the scope for 'go-live'

4. Deputy Executive Director Division

Performance indicators

Performance indicators related to core business	Forecast 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Energy consumption (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-2%	-9%
Water consumption (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-7%	+22%
Paper consumption (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-18%	-13%
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-12%	+25%
Recyclable waste produced (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-21%	-3%
Recycling rate (change in % per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-1%	-4%
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-11%	+8%
Overall net CO_2 emissions (per workstation)	n/a[1]	n/a[1]	n/a[1]	n/a[1]	-12%	+7%

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop a common framework/methodology for forecasting demand data for medicines in the EU/EEA	1.1	Common Framework methodology for forecasting demand data for medicines in the EU/EEA developed and adopted by the network	Completed	Reflection Paper on forecasting demand data in the EU/EEA published in early June 2021.

[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.

5. Advisory functions (International affairs, Internal audit, Legal department)

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast			
						Initial	Revised	Change	
Interactions with FDA	377	368	-[1]		-[2]	700	700	0	0%
Interactions with PMDA/MHLW	72	60[3]	-[1]		-[2]	200	150	-50	-25%
Interactions with Health Canada	91	93	-[1]		-[2]	200	200	0	0%
Interactions with any other stakeholders	384	390	-[1]		-[2]	700	700	0	0%
Number of information and/or document exchanges	512	498	-[1]		-[2]	900	900	0	0%
Number of teleconferences organised	112	97[4]	-[1]		-[2]	150	150	0	0%
ICMRA executive committee and full membership TC	48	21[5]	-[6]	-[6]	-[6]	10	10	0	0%
International stakeholders' visits (fellowships, experts, observers	0	1[7]	-[6]	-[6]	-[6]	25	25	0	0%
Organisation of International awareness sessions	0	0[8]	-[6]	-[6]	-[6]	2	2	0	0%

[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 the 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.

Pillar 2 – Public health activities and Business Services

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
COVID-19 and ICMRA secretariat	1.1	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication	**On track**	Significant effort devoted to COVID-19 response, including a wide range of projects, 7 ongoing collaborative workstreams, 2 support workstreams for governance & membership, and communications; 2 key public statements on COVID-19 vaccine confidence were issued (on transparency and data integrity, and on product quality knowledge management system); 4 major COVID-19 technical workshops (on vaccine safety, pregnancy & lactation, and two on vaccine development)
Nitrosamines	1.1 5.5	Participation in Nitrosamines International Steering Group (NISG)	**On track**	Collaboration on new Nitrosamines acceptable intakes and under sharing of Safety Working Party report.
Extension of US MRA	1.1 5.5	Extension to vaccines and vet medicines	**On track**	SUPPORT TO THE EXTENSION OF THE MRA FOR VETERINARY PRODUCTS: - Progress with capability assessments for single (veterinary only) Competent Authorities (some delays in finalising audit reports or sending capability assessment packages to FDA, 3 audits delayed from last year to Q4 2021 due to COVID-19

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				situation; however, not expected to impact on MRA potential implementation date - Q1 2022); - FDA Center for Veterinary Medicine (CVM) not yet recognised by EU due to pending corrective and preventive action (CAPA) plans from EU audit; - Technical and strategic discussions between EU (EU auditors and EC), FDA CVM and other FDA concerned divisions regarding implementation of key corrective actions (cross contamination and notification of manufacturing of a new substance) from CVM/CAPA plan; - Input to EC on establishment of timeline/conditions for implementation of MRA for veterinary products SUPPORT TO THE EXTENSION OF MRA TO VACCINES AND PLASMA DERIVED PRODUCTS: - No progress on this (COVID-19 prevented joint inspections). Internally agreed to push for technical engagement with FDA. SUPPORT TO MRA HUMAN RELATED ACTIVITIES: - Internal discussions, with GMDP IWG and with FDA on (proposals for) improvement of functioning of MRA Human regarding exchange of GMP documents;

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- Discussions with GMDP IWG and informal discussions with FDA on recognition of third country inspections; - Discussion on pre-authorisation inspections put on hold at EMA request;
Article 58 – EU-M4all	1.2	Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	Follow-up of 9 EU-M4all products~~: Dengue Qdenga vaccine, Novo Nordisk human insulin, diabetes Polypill, Sanaria's malaria vaccine, Yellow fever virus vaccine, Acoziborole, Arpraziquantel, Dapivirine and Mycobacterium T Vaccine.~~ Interacting with WHO (e.g. in the process of expert/observer's nomination), with concerned regulators from different NRAs and internally; -Participation in monthly Tier 2 meeting to improve EU-M4all process (revision of templates, guidance, etc.); -Creation and publication (after public consultation) of Public guidance on Parallel application for EU-M4all (Article 58) opinion and Centralised Marketing Authorisation procedure; -Promotion of parallel applications for EU-M4all scientific opinion and centralised marketing authorisation procedure. First parallel application procedure (Dengue Qdenga vaccine) started in March2021

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- 1 training to WHO experts/NRA observers organised (Feb 2021). -Promotion at EFPIA workshop of EU-M4all in May 2021.
Develop international collaboration and reliance, including through Confidentiality Arrangements.	6.5	Update existing and putting in place new confidentiality arrangements	**On track**	Confidentiality arrangement with Brazil signed in 2021. 6 ad-hoc Confidentiality Arrangements (COVID-19) signed with Argentina (ANMAT), Chile (ISPCH), Peru (INS), Colombia (INVIMA), South Africa and Saudi Arabia. 1 ad-hoc Confidentiality Arrangement (Dengue) signed with Dominican Republic - CONABIOS.
Capacity building Provide assistance to candidate countries (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process.	6.1	- Increased visibility of EMA - Training on acquis Communautaire of candidate and accessing countries	**Delayed**	-1 advanced training with 7 sessions attracting 300+ participants - 2/3 from IPA -3 contact points teleconferences - Further training postponed to September due to lack of speakers
Supply chain	5.2	Work with project on shortages, on API with priority countries China project on API	**On track**	Regular participation and input to Global Shortages teleconferences/discussions. Support to the EC for China API project.
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	**Delayed**	- Russia application to PIC/S ongoing
OPEN project	6.5	Active collaboration of selected regulatory authorities in CHMP and European Task Force for COVID-19 MEDICINES	**On track**	- 5 authorities involved (Health Canada, Swissmedic, PMDA/MHLW, WHO, Therapeutic Goods Administration) - 4 vaccines (Zorecimeran, Nuvaxovid, CoronoVac, Gam-COVID-Vac)

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- 5 therapeutics (Etesivimab, Bamlanivimab, REGN-COV2, VIR-7831, Regdanvimab) and 42 experts participating.
Active participation in WHO activities, international fora and communication to stakeholders, including but not limited to ICDRA, DIA, ICH, IPRP.	1.1	Promote convergence of global standards and contribution to international fora	**On track**	Participation in IPRP, ICH meetings. 6 ICH meetings: 2 Feb, 25 Feb, 15-16 March, 29-30 March, 26 April, 11 May 1 IPRP meetings: 20 April Chairing and presenting at DIA (7 sessions)
Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	5.3	Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	**On track**	Joint WHO/EMA inspection in Russia. Sharing inspection reports with number of authorities and discussion with Brazil Joint SAHPRA/Health Canada/EMA in the US.
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.	5.1	Assure product supply chain and data integrity	**On track**	Public consultation of Track & Trace interoperability recommendations closed on time. Working Group completed revision of all comments and finalised draft recommendations ready for adoption by ICMRA membership and publication. Pharmaceutical Quality Knowledge Management System (PQKMS) group created and agenda for the workshop created - workshop took place on 6-7 July.
Increase the number of opportunities for non-EU regulators, in particular those of candidate and	6.1	Support training and capacity building of non-EU regulators	**On track**	Contribution to the project on Expansion of the EU NTC learning Ecosystem (internal discussions and input to consultants regarding extension to International Regulators).

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
potential candidate countries, to participate in scientific and regulatory training activities[1].				Internal discussions on proposal to have International Regulators as the pilot project for the extension of EU NTC to other stakeholders, including development of the International Regulators Curriculum Framework.
Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU.	6.1	Support training and capacity building of non-EU regulators	**Suspended**	The action is currently suspended due to resource constraints linked to the COVID-19 pandemic.
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	**Suspended**	The action is currently suspended due to resource constraints linked to the COVID-19 pandemic.
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.	6.1	Capacity building through training	**Suspended**	The project has been suspended.
ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA meetings.	1.1	Communication	**On track**	1 Plenary Meeting of all ICMRA members organised on 28 April 2021. Active engagement with members maintained through written procedures for approval of documents, e.g. joint ICMRA-WHO statement on transparency, PQKMS, vaccine confidence, etc. In addition, active communication assured through the introduction of new weekly update email to wide ICMRA distribution list

[1] Including contributing to the IPA activities of the European Commission (Instrument for Pre-accession Assistance) and a virtual meeting/training related to IPA will be organised in Q1 2021.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				with updates on ICMRA activities and information of general interest.
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. Selected redaction of documents.	1.1	Support to the International Affairs Division and its specific activities	**On track**	- Update of 4 guidance documents, including the International guidance for sharing documents and on Parallel Scientific Advice; - Relaunch and publication of the 'International affairs highlights' newsletter, after one year following the BCP period related to the COVID-19 crisis. - Organisation of the 2nd IPA training; - Work programme report on the overall 2020 activities; - Organisation of 52 cluster meetings, teleconferences -14 documents redacted -350+ interactions with FDA -90+ interactions with Health Canada -70+ interactions with PMDA/MHLW -350+ interactions with other stakholders Contribution to meetings, such as the bilateral PMDA-EMA on 25 January. Presentation by ED prepared by AF-IA: Russia, BMGF, IFPMA, WHO manufacturing capacity. Presentation to Health Canada, training to Tunisia, EDCTP grant evaluation
Support EU and EU/MRA team meetings	5.2	Reliance and supply chain integrity	**On track**	Participation and support to all MRA meetings.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building through providing adequate guidance	**Delayed**	In May, the EC announced the intention to back with 1 billion euro the Team Europe initiative on manufacturing and access to vaccines, medicine and health technologies in Africa. The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) contacted EMA in the context of their BACKUP programme commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ), to support local vaccine manufacturing in Africa and the future AMA. EMA asked to consider providing support to this initiative by: conducting joint assessments of vaccines (involving CHMP Rapporteurs), training, and providing experience with the EU collaborative model.
Initial implementation of the EU-DPR	6.2	Assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, privacy statements, DPIA reports, joint controllership agreements; adopt instruments for international data transfers; conclude appropriate contracts with data processors)	**On track**	Draft Joint Controllership Arrangement and related privacy statement for CTIS prepared and finalised internally. Consultation process with EC, MSs and sponsor representatives on track. Draft Joint Controllership Arrangement and related privacy statement for CTIS prepared, internal consultation ongoing. Administrative Arrangement for personal data sharing with Health Canada prepared and negotiated; submitted for EDPS

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				authorisation, which resulted in authorisation with conditions. Advice regarding the tender procedure for DARWIN EU Network provided, participation in evaluation committee. Preparation of preliminary DPIA regarding the project. Advice regarding handling of personal data breach caused by the cyberattack, participation and support provided to Steering Committee and Risk Assessment Subcommittee. Ongoing consultation and advice on A-Div Data Protection Impact Assessment for Talent Hub and BI@Admin project. Review of CCTV policy update.
Full Implementation of the EU-DPR and monitoring of compliance	6.2	As necessary, update and adopt further annexes to 0055-2020 Internal Guidance of Personal Data Protection. Update, develop and deliver data protection trainings on request or upon own initiative.	**On track**	Advice and preparation of records and privacy statements (e.g. https://www.ema.europa.eu/en/about-us/legal/privacy-statement/central-register-data-processing-records). Preparation of adapted training and awareness sessions are on track. Draft training syllabuses are under consultation with Data Protection Coordinators.

Significant efforts by the International affairs division were also devoted to the development of international collaboration and reliance (including through Confidentiality Arrangements), to the collaboration with WHO and EAU on tuberculosis and to the development and implementation of pregnancy strategy with FDA and MHRA.

6. Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of cases of patient/consumer engagement[1] in EMA (medicines-related) activities	289	358	333[2]	200	350	600	600	0	0%
Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	105	64	110[2]	102	450	200	200	0	0%
Number of professional membership organisation events attended by participating Agency staff[3]	10					40	30	-10	-25%
Number of sessions with Agency representatives[4]	92					150	136	-14	-9%
Number of messages circulated via 'Early Notification System'	635	373[5]	215	217	198	440	1,100	+660	+150%
Number of EMA communications pro-actively sent to stakeholders	110	101[6]	68	100	63	200	200	0	0%
Number of EPAR summaries and EPAR summaries updates published	118	164	144	149	145	300	250	-50	-17%
Number of summaries of orphan designation published	0[7]	64	55	87	87	120	120	0	0%

[1] These include any interaction a healthcare professional may have with EMA, in addition to those occurring with healthcare professionals nominated by the national agencies.
[2] Due to a change in methodology as a result of BCP, only engagements related to products are counted as of 2019
[3] New indicator introduced in 2021 Work Programme
[4] New indicator introduced in 2021 Work Programme
[5] Higher results due to the increase in communications concerning COVID-19
[6] The increase is due to COVID-19 related communications.
[7] Activity put on hold because of BCP

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Access to documents, requests received	342	316	362	462	464	820	650	-170	-21%
Access to documents, documents released	568	382	792	1,364	1,411	1,500	1,300	-200	-13%
Requests for information received	5,915	3,597	3,677	3,651	3,241	7,500	9,000	+1,500	+20%
Number of documents published on EMA website	4,071	3,628	3,533	3,871	3,713	7,500	7,500	0	0%
Number of pages published and updated on EMA website	1,883	1,681	1,821	2,534	2,261	3,500	3,500	0	0%
Number of press releases and news items published	122	86	63	99	63	170	170	0	0%
Completed requests for interviews and comments by media representatives	4,057	598	564	732	927	1,200	7000	+5,800	+483%
Number of reports, brochures, leaflets laid out or printed, social media visuals	300	214[1]	33	28	20	500	500	0	0%

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Satisfaction level of patient and consumers' organisations	90%	92%	n/a[2]	n/a[3]	n/a	n/a
Satisfaction level of healthcare professionals' organisation	90%	90%	n/a[2]	n/a[3]		
Triage of incoming requests received via AskEMA within set timelines[4]	100%	99%		-	-	-
Responses to ATD within set timelines	90%	92%	86%	92%	97%	96%

[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] New indicator introduced in 2021 Work Programme

Performance indicators related to core business		Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
	Responses to RFI within set timelines	95%	85%	92%	96%	97%	99%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	80%	82%	82%	89%	90%	85%
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	n/a	n/a	-[1]	n/a[2]	n/a	79%
	Average rating of pages on corporate website during the year	3.4	3.5	3.7	3.2	3	4

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop content strategy in key public health areas and hot topics: - Design communication materials and campaigns in collaboration with relevant stakeholders to proactively approach to key public-health areas (e.g. COVID-19 vaccines) - Improve communications for patients, healthcare professionals and other stakeholders including HTAs and payers - Enhance professional outreach through scientific publications & conferences - Embed best practices in key areas, such as audience research, user-experience design, user	1 (additional RSS recommendation)	Effective delivery of communication materials and campaigns on key topics, with focus on COVID-19	**On track**	Production, publication and evaluation of COVID-19 content on a daily basis, including regular reporting. Update of information material on COVID-19 vaccines and user testing. Consolidated approach to scientific publication strategy approved internally. Key communications on COVID-19 vaccines developed and disseminated to key EMA stakeholders. User research and interface design activities completed for two high-profile EMA-run websites.

[1] Survey planned for Q3 2020
[2] No survey due to BCP

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
and usability testing, social-media strategy and evaluation of communication activities				Interface improvements to corporate website search and medicine-related pages (e.g. orphan designation, EUM4ALL).

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
e-PI set up	This e-PI set-up project for human medicines (CAPs and NAPs) will provide the initial building blocks towards creation of electronic product information (summary of product characteristics, package leaflet and labelling) for EU medicines. Product information is currently only provided in PDF format.	- EU common standard for ePI published for comments as part of the public consultation. - First prototype and PoC delivered.

7. Information Management Division

Workload indicators

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of Telematics information services provided by EMA	13	25[1]	25	23	23	26	26	0	0%
Number of ongoing Telematics IT projects where EMA is the delivery organisation	7	4[2]	3	7	11	7	10	+3	+43%

[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.

Procedure	2021 Q1-Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2017 Q1–Q2	2021 annual forecast Initial	Revised	Change	
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	10	8	5	7	10	6	12	+6	+100 %

Performance indicators

Performance indicators related to core business	Target 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Satisfaction of EMA internal and external users	80%	96%	88.17	84%	-	93.9%
Availability of corporate/Telematics IT systems and corporate website	98%	99.5%	99.06	98%	99%	99%

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
DREAM Replacement Agency Document: Management system end of lifecycle and need to be replaced.	The objective is to replace the Agency Document Management System, which is at end of lifecycle, with a modern, flexible, collaborative solution	- First impact assessment reviewed, and project plan ongoing.

8. Administration Division

Performance indicators/Forecast activity

Performance indicators related to core business	Forecast 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Posts on the Agency establishment plan filled	99%	97%[1]	98%	99%	99%	98%
Total TA staff recruited against vacant posts	90	40	13	23		
Staff turnover rate (staff leaving against total no. of staff TA & CA)	6%	3%	2%	4%		
Time to run selection procedures from vacancy notice to establishment of reserve list	100% <3 months	66%[2] < 3 months	<3 months	3 months		
Revenue appropriations implemented	97%	45%[3]	50%	41%	40%	42%
Expenditure appropriations implemented	97%	67%[1]	75%	67%[4]	71%	73%
Payments against appropriations carried over from year N-1	97%	70%	87%	71%[5]	68%	76%
The maximum rate of carryover to year N+1, of total commitments within the title:						
Title 1	1%	n/a[6]	n/a[4]	2.19 %	1.0%	0.86%
Title 2	15%	n/a[4]	n/a[4]	10.79%	11.8%	7.93%
Title 3	25%	n/a[4]	n/a[4]	29.16%	31.1%	25.86%
Payments made within 30 days' time	98%	97%	94%	96.13%	97%	97.26%

[1] The figure does not include the posts linked to the new mandate, which are subject to the development of the legislative process.
[2] The current average selection procedure time is 2.53 months. Specifically, 11% of selection procedures were standard (single post) and their average completion time was 1.4 months; 66% of selection procedures were medium selections (a few posts for multiple requirements) and their average completion time was 2.6 months; 23% were large selection procedures (multiple requirements across the Agency) and their average completion time was 2.8 months.
[3] Annual target to be reached at year-end.
[4] The higher commitment rate is due to administrative expenditure being committed for the whole year.
[5] Includes C8 and C2 - at acceptable level at the end of Q2.
[6] Annual target to be reached at year-end.

Performance indicators related to core business	Forecast 2021	Outcome at the end of Q2 2021	Q2 2020	Q2 2019	Q2 2018	Q2 2017
Receivable overdue for more than 30 days (including provision for bad debts)	<10%	2%	8.47%[1]	-[5]	-[5]	-[5]

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Develop and implement a framework for integrated planning and monitoring activities	6.2	Finalisation of the Human Medicines Division business processes and full implementation of the time& capacity model.	Delayed	The time and capacity model was supposed to be applied to the Paediatrics activities, but the project will only start in the last quarter of the year, as the procurement process was unable to find a suitable advisor. However, in the context of the planning exercise, the activities will be mapped with a template developed and tested in the A division.
Consolidate the human resource and talent management strategy	6.2	The strategy will consolidate practices into a coherent system and practices and will lead to continuously improving approaches in domains of staff wellbeing, leadership and management, talent management and culture.	On track	A plan has been agreed within HR on the development of the strategy. Initial meeting with ED and DED held. An HR workshop, to progress work planned, to be held on 6 July 2021.
Implement a competency management framework	6.2	Competency framework (behavioural and technical competencies); revised role descriptions with embedded competency profiles and proficiency levels of competencies leading to higher effectiveness, contributing to job	On track	The competencies detailed in the framework have been identified through a wide consultation process with staff, managers, HR and the Staff Committee, to ensure each staff member has a competency profile that is fit for purpose,

[1] New indicator included in 2020 Work Programme

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		satisfaction and development opportunities.		is transparent and development-focused. The consultation took place in three steps: • First consultation on competency definitions and job architecture (completed in May 2021): surveys to all staff to help identify the core behavioural competencies and core managerial competencies. As another outcome, 'priority' competencies will be periodically selected among all competencies to help focus our attention on what the Agency needs to achieve its strategic objectives and be future-proof. • Second consultation on proficiency level and nomenclature (completed in June 2021): targeted invitation to relevant job holders on the proficiency levels needed for the core competencies and grade-specific behavioural competencies. In addition, we consulted on job titles nomenclature, to ensure they best describe the job staff members do. • Third consultation on role descriptions and remaining competencies (ongoing, July-

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				October 2021): targeted written consultations and workshops are organised to gather input on the role descriptions for each profile, to continue building the competency profile with sub-family competencies and role-specific competencies.
Digitalise HR-related processes (recruitment, onboarding, appraisal, continuous performance management, internal mobility, career development, succession planning)	6.4	Key HR processes are digitalised and automated to better support the HR teams and enable them to provide a better service with more active and added value tasks to performance and development of our staff members.	**On track**	The launch of Goals and Performance and Development modules took place in February 2021. Team went live with new processes and features related to objective setting, continuous performance management, Performance Support Plan, probation, internal mobility and mentoring activities. A big effort was made by colleagues across the A Division to achieve this objective on time and successfully, as well as for the EMA staff members to learn and embed it within their performance and development activities.
Digitalise procurement, contract management, risk management and some reporting processes.	6.4	Almost real-time information is available for managers for decision making across contract management, budget, human resource domains. Introducing updated procurement, contract management and risk management processes that reduce	**On track**	Specifications for the risk management process review are being drafted to progress to the contractor selection process. Short term JIRA improvements: • Specific contract for JIRA consultant set up

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		processing times and enable automating processes easier access to information.		• Most relevant processes and templates in JIRA have been updated in test environment New long-term tooling (Procurement & Contract management): • Market research conducted • Identification of possible solutions/vendors • Preliminary questions to identified vendors raised and analysed • Requirements of a tooling solution elaborated
Review project governance in line with Agile development approach	6.2	Put in place a more agile governance by implementing a project planning tool and the SAFE methodology across programmes and projects in the organisation in collaboration with the I Division.	**On track**	New terms of reference have been drafted and will be finalised in Q3, when the new boards will meet for the pilot.
New Fee Regulation: optimisation and review of revenue and expenditure process.	6.3	Implementation of the New fee regulation with an optimised and more efficient revenue and expenditure process.	**On track**	EC consultation launched in July 2021, implementation shifted to 2022.

Annex 2: Project progress and delivery

Project progress and delivery as of 30 June 2021 against what was planned in the work programme 2021 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 2021, in comparison to what was planned and approved at the end of 2020 (i.e. as noted in the work programme 2021). Notes explaining the changes are added.

In cases where the project start or end dates foreseen in the work programme 2021 were revised during Q1 and Q2 2021, the current dates are added in the relevant cells, with the original date from the work programme 2021 shown as crossed out.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2021
				Time	Budget	Scope	
Clinical trials programme							
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR) [continues]	• Regulation (EC) 536/2014, art.80-82	Q3 2014	2023				- April Management Board approved 'go-live' for January 2022. - Training materials and user trainings reached 75% and will continue after 'go-live' - Safety reports added to the scope for 'go-live'
e-Submission programme							
ECTD4: Implementation and adoption of eCTD v4.0 standard [restart]	n/a	2021	2023				- Impact analysis delivered. - More details on project initiation planned in the context of 2022 prioritisation exercise.
Single Submission Portal: (eAF replacement): NCA led initiative to develop a single submission gateway and portal for the European Medicines Regulatory Network [cancelled]	n/a	-	-				- Part of this scope will be delivered by the Regulatory Business Process Optimisation Programme (**RBPOP**), i.e. eAF replacement. - Agree approach to other Common European Submission Platform (CESP) activities outside the eAF scope.
New Veterinary Medicine Regulation Programme - VMP-Reg							
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0 [continues]	• Regulation (EC) 726/2004, art.57(d) • Regulation (EU) 2019/6; associated implementing acts	2017	2022				- 'go-live' planned for January 2022
UPD - Union Product Database [continues]	• Regulation (EU) 2019/6; associated implementing act	Q1 2020	Q3 2022				- 'go-live' planned for January 2022 - UPD V1.02 already live for NCAs to be able to test

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2021
				Time	Budget	Scope	
ESVAC - Collection of Antimicrobials Sales and Use Data [new]	• Regulation (EU) 2019/6; associated implementing act and delegated act	Q1 2021	2023				- Project approved in June 2021 and work has started for a 'go-live' in January 2022.
EudraGMDP - Union Manufacturers and Wholesale Distributors Database [new]	• Regulation (EU) 2019/6; associated implementing act and delegated act	2021	2022				- Analysis/impact assessment of amendments and needed improvements to EudraGMDP
Online programme							
European Medicines web portal [restart in 2022]	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	2022	2023				- Suspended until 2022 but there are common elements with the Union Product Database project from the VMP-Reg programme supporting some of the future developments, as well as interdependencies with SPM&S and e-PI projects.
Data integration programme							
SPM&S - Substances and products management services [merged]	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26 • Draft veterinary regulation, art.51 • Clinical trials regulation 536/2014, art.8193)	2017	-				- Merge for delivery optimisation into the Regulatory Business Process Optimisation Programme (**RBPOP**) in Q2 2020.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2021
				Time	Budget	Scope	
	• 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						
Regulatory Business Process Optimisation Programme - RBPOP (new)							
IRIS: Platform to support regulatory business processes of the Agency [continues]	n/a	2019	2025				- Marketing status ready to go live in July 2021 - eAF proof of concept on going - Inspections GMP 90% completed
SPM&S - Substances and products management services [continues]	• Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU • Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26	2017	2024				- EU Implementation Guide V2.1 published on June 2021

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2021
				Time	Budget	Scope	
	• Clinical trials regulation 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						
Data Analytics Programme (new)							
- Lifecycle Regulatory Submissions Raw Data	n/a	2021	2024				- Review of experience with IPD delivered.
- Lifecycle Regulatory Submissions Meta Data	n/a	2020	2022				- Data standard strategy finalized.
- Real-world Metadata, Quality Framework and Catalogues	n/a	2021	2025				- Final list of Metadata of the Minerva study delivered.
- Observational Studies Rapid Analytics	n/a	2020	2022				- Instant Health Data (IHD, i.e. a Rapid Analytics software) live and training delivered.
- Observational Studies DARWIN EU	n/a	2021	2025				- Tender procedure launched. - DARWIN web page published on EMA corporate website.
- Signal and Safety Analytics	n/a	2021	2023				- The project is planned to start in Q4 2021.

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2021
				Time	Budget	Scope	
IRIS: S-REPS Phase 3 SIAMED with Knowledge Management [merged]	n/a	2019	2020				- Merged into the Regulatory Business Process Optimisation Programme (RBPOP).
e-PI set up [new]	n/a	2020	2021				- EU common standard for ePI published for comments as part of the public consultation. - First prototype and PoC delivered.
DREAM Replacement Agency Document: Management system end of lifecycle and need to be replaced [new]	n/a	2021	2023				- First impact assessment reviewed, and project plan ongoing.
Administration Digitalisation: Optimisation of the Administration supporting tools [continues]	n/a	2019	2022				- New Goals and performance system delivered. - New succession planning system delivered. - Digital personal file migration started. - Procurement, Budget and Finance dashboards in User Acceptance Testing.

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
CAPA	Corrective and preventive action
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
CTFG	Clinical Trials Facilitation and Coordination Group
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

Term/abbreviation	Definition
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
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
FDA CVM	FDA Center for Veterinary Medicine
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
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
IPD	Individual patient data
IPRP	International Pharmaceutical Regulators Programme
IRIS	Regulatory & Scientific Information Management platform
IT	Information technology

Term/abbreviation	Definition
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
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
NTWP	CVMP Novel therapies and Technologies working party
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
PQKMS	Pharmaceutical Quality Knowledge Management System
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

Term/abbreviation	Definition
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
RMM	Risk minimisation measures
ROG	Regulatory Optimisation Group
RWE	Real world evidence
SA	Scientific advice
SAG	Scientific Advisory Group
SAHPRA	South African Health Products Regulatory Authority
SAWP	Scientific Advice Working Party
SC	Scientific committee
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
S-REPS	Scientific and regulatory evaluation procedure support
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TC	Teleconference
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