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Mid-year report 2022

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 6 October 2022.

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Key developments

The COVID-19 pandemic continued to consume an important portion of the Agency's resources in the first half of 2022 (47 FTEs). Although decreasing from previous year (47 vs 78 FTEs), this still represents a significant overhead for the Agency's capability (~5% of workforce). Short-term positions are therefore very important to continue, ensuring that most of the Agency's public health objectives are delivered, with only a handful of activities delayed. However, in accordance with the Agency's business continuity plans, a number of important public health initiatives continue to be suspended (among others: clinical data publication for non-COVID-19 related products). A short summary of the main activities that took place in Q1/Q2 2022 is presented below.

In the context of the **COVID-19 pandemic,** EMA has granted in Q1/Q2 2022 conditional marketing authorisations for two therapeutics for the treatment of COVID-19, and for one vaccine for the prevention of COVID-19. One additional COVID-19 vaccine has begun the rolling review process with the Agency. In accordance with the COVID-19 pharmacovigilance plan, the Agency continued to collect data on these products after receiving marketing authorisations and is utilising real-world data to monitor the safety and efficacy of approved COVID-19 treatments, vaccines, and other medicines used in patients with COVID-19 in the EU. Through curriculum development and knowledge-sharing initiatives on data science, digital technologies, and artificial intelligence, the Agency has continued its work to build capacity and expertise across the regulatory network. Discussions have also started on topics related to the future of learning, including the implementation of MAWP topics, interactions with external organisations, new areas, and interactions with academia.

Looking into the second half of 2022, the Agency will be increasingly involved in activities related to a second public health emergency stemming from the monkeypox outbreak, which will overlap with the COVID-19 one. This crisis will be a priority for the organisation beyond 2022. The Management Board will be kept regularly informed of the progress on the actions and potential impact of the public health emergency.

With regards to responses to the crisis caused by the **war in Ukraine,** the Agency has established a Core Leadership Team to monitor the situation and to ensure that possible implications for EMA are assessed, so that the Agency is prepared for any such implications in various areas of its work. EMA has regular close engagement with the European Commission, including HERA and other partners, to coordinate actions needed to address the implications of the war: in this context, the Agency has been addressing challenges related to possible medicines shortages in the EU as a result of the war in Ukraine, in close cooperation with NCAs, through the SPOC network and MSSG.

The Agency continued to serve as **ICMRA**'s Chair. One workshop on real-world evidence was held with ICMRA international regulators, and it resulted in a joint statement. Other accomplishments in this area include the development of two pilots on assessment and collaborative hybrid inspections, for which an application call from ICMRA is anticipated for Q3/Q4, and the launch of two ICMRA pilot programmes with a duration of one year for Collaborative Assessment of COVID-19 Related CMC Post-approval changes. Lastly, the Agency is working on rationalisation of ICMRA working groups and ways of working. The Agency devoted significant efforts 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 the FDA and MHRA.

The Agency continued its work on **monitoring and mitigating shortages** and has prepared a draft best-practice guide for industry on prevention/management of shortages of medicinal products, to be presented during a meeting of the HMA/EMA Task Force AAM with industry associations in September

2022. Moreover, the Agency collaborated with international partners on shortages on the level of the Global Regulators Working Group, which has been formally established, while bilateral collaboration is also being set up for the first time in the area of shortages with the US-FDA. In the context of the entry into force of **Regulation (EU) 2021/123 on the EMA extended mandate,** the Agency has formally established the Medicines Shortages Steering Group (MSSG) and the medicines shortages Single Point Of Contact (SPOC) Working Party, which are both fully operational. The group has adopted a list of critical medicines for COVID-19, along with a list of main therapeutic groups. Both lists have been published on the EMA website. The i-SPOC registration was launched on 28 June, so that MAHs of all medicines for human use authorised in the EU can register an i-SPOC by 2 September 2022. Lastly, in scope of the list of critical medicines for COVID-19, MAHs can submit actual or potential shortages of their products from 15 July 2022.

With regards to the **implementation of Regulation (EU) 2019/6** in the first half of the year, the Agency has finalised 12 new or revised guidelines and procedural advice on the application of the new legislation. The Agency also released for public consultation the 'Concept paper on the efficacy of cell therapies: mechanism of action, potency and clinical effects' and the 'Concept paper on quality, safety and efficacy of bacteriophages as veterinary medicines'. The respective working groups of the CVMP reviewed the comments received, and relevant guidelines are being drafted and expected to be presented to the CVMP in October. In the area of **antimicrobials**, the Agency has delivered scientific recommendations to the European Commission on the content of a list of antimicrobials to be reserved for human use, in the context of implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal product. This is the first time worldwide that a robust systematic assessment of all antimicrobials has been carried out, using scientific criteria to recommend which antimicrobials should be banned in animals; these recommendations are a major step forward in global efforts to address antimicrobial resistance. The ensuing implementing measures were published in the Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022. Continuing with **antimicrobials,** the Agency has developed a new list with antimicrobial active substances and respective classes, as per Article 5 of the Commission Delegated Regulation (EU) 2021/578. The list is currently being integrated in the SPOR system. Moreover, the Agency has drafted a mandate, objectives, and rules of procedure for the CVMP Antimicrobials sales and use Working Group, which have been discussed by the VetDomain group in Q2 2022. The final mandate is expected to be adopted by CVMP in Q3 2022. In first half of 2022, the expert group (EMA, EFSA, ECDC) established for the **4th JIACRA** report started their work on the review of the 2019-2021 data. First preliminary results have already been prepared by the statistician group and will be discussed in a meeting in Q3 2022. The results of the report will inform policymakers about decisions on antimicrobial resistance. In June 2022, the Agency also published the EU Veterinary Big Data Strategy 2022-2027; this strategy set up a framework for the EU Veterinary Medicines Regulatory Network to converge traditional regulatory practice with innovative digital solutions to gain efficiency.

In the first half of 2022, the **EMA digital innovation lab (DigiLab)** intensified its activities and gathered more than fifty proposals from candidates for digitalisation and automation across the Agency. DigiLab launched five new projects in response to an appraisal of the concepts presented and considering the resources available. These ideas aim to achieve efficiency gains in the administration of the EURD List, the Early Notification System, the evaluation of invented names of medicinal products under evaluation, the accounts receivable mailbox, and the creation of a list with clinical breakpoints for antimicrobial medicines. Moreover, DigiLab worked with the Analytics Centre of Excellence (ACE) to pilot five potential solutions to business challenges. The pilot to adopt the use of QR codes is being finalised, and the following four solutions are being implemented: the Discoverer tool, which helps find

specific scientific information in certain documents faster; two validation tools to compare documents, and a tool to automate registration of applications submitted to EMA.

In the **EU Network Training Centre** area, EMA has set up a new domain for international regulators in the Learning Management System and provided access for a small number of African regulators to Product Information modules. Efforts are ongoing to offer access to certain EU NTC courses to a wider number of international regulators. A contract has been signed with an external consultant for the development of a learning design and development toolkit for curriculum steering groups and course developers.

EMA has continued its work on **EU Collaboration on Artificial Intelligence** (AI), and the AI community has been meeting during the first half of the year, to show different use cases among member Agencies in the network. The Leading Agencies are working on a conference, planned for the end of the year, to present AI projects in each Agency and update on how AI has been implemented across the network.

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. Significant progress has been made in the first half of 2022 as, following an open tender procedure, a contact has been signed in February 2022 with a consortium led by Erasmus Medical Centre, and the onboarding of data partners has started with first studies foreseen for Q4 2022, realising the first benefits for the network and its stakeholders. Similarly, an important step forward was taken in **Metadata, Data Quality Framework and Catalogues Project** to drive up data quality and enable data discoverability: the Agency has performed a comprehensive review of existing data quality frameworks available in the literature or developed by other regulators and organisations, with a view to using it as an input for the drafting of a Data Quality Framework for regulatory purposes. Moreover, the Agency has conducted an in-depth stakeholder consultation. A Real World Metadata list has been adopted and published on the Big Data website. The Agency has developed a methodology to identify databases to include in the EMA Database Catalogue, to engage with database holders, and to collect the metadata required. The first initial set of 24 real-world data sources to be included in the EMA Database Catalogue have been identified.

In addition to the important role performed by the Legal Department's offices in supporting the core business at the Agency, it is worth mentioning an increasing number of **judicial challenges** against EMA's scientific assessments before the Court of Justice of the European Union. During 2022, the Legal Department has worked on 12 court cases, out of which six were directed only against the European Commission. In nearly all cases, EMA's defence was successful. EMA has also intervened in support of Germany and Estonia and their respective appeals against the judgment of the General Court of 28 October 2020 in Pharma Mar v Commission (the 'Aplidin' case). In first instance, the General Court had classified a university hospital as a pharmaceutical company and had considered experts employed by this university hospital to be in a situation of conflict of interest. Germany and Estonia, supported by the Netherlands and EMA, disagree with that interpretation. A hearing will take place at the Court of Justice on 12 October 2022; the CJEU judgment is expected in 2023.The outcome of this case may affect EMA's capacity to use a sufficient number of scientific experts for the preparation of opinions delivered by EMA Committees. In another important case concerning alleged conflicts of interests of EMA scientific experts, in its judgment of 2 March 2022 in D&A Pharma v Commission and EMA, T-556/20, the General Court found that EMA applied correctly its Policy 0044 on the handling of competing interests to two experts providing advice to the Committee for Medicinal Products for Human Use. The Court also noted that EMA's policy contains a detailed examination of all situations of conflict of interest likely to arise from activities of experts in the pharmaceutical industry. This very

favourable judgment has been appealed by D&A Pharma and a final ruling by the Court of Justice is also expected in 2023.

The Agency's implementation of the **Scaled Agile Framework (SAFe)** methodology to improve the software product development process and structure is on track. The new Agile governance is being implemented with 10 (out of 22) projects transitioned to the new approach. All projects (20) will be transferred to agile by the end of 2022 and 2 will be closed.

Key figures

This report describes the results and achievements of the Agency, working closely with the NCAs, during the first six months of 2022, and thus reflects the situation as of 30 June 2022. Here below we highlight the most relevant deviations from the annual work programme, registered in the first half of 2022. Further developments have taken place since, which have not been included in this document.

Assessment activities for human medicines

Pre-authorisation activities

The **total scientific advice and protocol assistance requests** confirmed its 5-year trend for growth, with 470 requests received in Q1/Q2 2022 (10% growth over 2021).

The number of **novel technologies qualification advice/opinions** given matched the 2021 record of 14, which remains a 5-year high.

The first half of 2022 also saw a continued increase in applications **for orphan medicinal product designation,** which peaked at 157 - the highest in the last 5 years and a 17% increase over first half of 2021.

After two years of growth, the **requests for classification of ATMPs** returned to Q1/Q2 2019 level, marking a decrease of 45% compared to Q1/Q2 2021 (46 in 2021 vs 25 in 2022).

Initial evaluation activities

The number of **COVID-19 related product applications received** has also dropped, with five applications received in the first half of 2022, compared to the 14 in 2021.

New non-orphan medicinal products applications have seen a 39% drop from 2021 (14 vs 23), with a revised annual forecast for 2022 down by 31% (61 to 42).

Generic, hybrid and abridged applications also saw a 25% decrease from 2021 (9 compared to 12), and a forecast revised downwards by 27% (19 expected in 2022 from initial 26).

Post authorisation activities

The number of **type IA variation applications** decreased by 9% compared to 2021, whereas **type IB variation applications** saw a 15% increase compared to 2021 (1,606 vs 1,393). **Type II variation applications** remained substantially stable compared to previous years.

In the first half of 2022, **line extensions of marketing authorisations** continued to decrease (11), returning to 2019 levels.

Article 61(3) applications marked a 16% decrease compared to 2021 (104 vs 124), in line with the annual forecast for 2022 (200).

In Q1/Q2 2022**, Plasma Master File annual update and variation applications** confirmed 2021 levels, with 8 applications received.

The COVID-19 pandemic effects continue to remain visible in the exceptionally high cumulative number (1,348,258) of **Individual Case Safety Reports (ICSR)**. Though declining slightly compared to 2021, these levels remain unprecedented and triggered an increased revised annual forecast of 8% (to 2,700,000).

Assessment activities for veterinary medicines

Requests for classification as limited market under Article 4(29) and eligibility under Article 23 (new indicator introduced to reflect changes brought by Regulation (EU) 2019/6) is showing a positive trend, which led to an upwards revision of the initial forecast for 2022 (initial forecast 20, revised 25) and volumes aligned with those registered in previous years under **MUMS/limited market requests** (indicator removed).

Initial evaluation applications have more than doubled compared to 2021 (9 vs 4), marking an increase of 225%. However, this remains lower than forecasted at the beginning of 2022, leading to a revised downward forecast for the whole year (initial forecast 32, revised 27, -16%).

The number of **variation applications** indicator refers only to applications submitted under the Directive 2001/82/EC, in force until 28 January 2022, hence the discrepancy between 2021 and 2022 volumes. These indicators will be reviewed during the 2022 planning cycle, to take into account the entry into force of Regulation (EU) 2019/6 and the new framework for veterinary variations.

The number of **adverse event reports** (**AER**) saw a significant increase related to the voluntary (no legal requirement) and one-off submission of non-serious AERs by MAHs of reports obtained prior to the implementation date of Regulation 2019/06, hence the figures are higher than average for mid-year reporting, leading to an upwards-revised forecast for 2022.

There were three **Arbitrations and Community referral procedures** initiated in the first half of 2022, two of them under the Veterinary Medicinal Products Regulation - an increase compared to the previous year.

Inspections and compliance

The number of **good manufacturing practice** (**GMP**) **inspections** was higher than 2021, following the lifting of travel limitations previously imposed due to the COVID-19 pandemic (from 77 in 2021 to 89 in 2022). However, the annual forecast has been revised to 205 (-24%).

Good clinical practice (**GCP**) **inspections** have grown compared to the past two years, with 38 more inspections carried out in the first half of 2022 compared to the previous year.

Plasma Master File (**PMF**) **inspections** were below target in the first part of the year but are expected to show a notable growth in the second half of 2022, thereby explaining the increased annual forecast of 126%.

Standard certificate requests marked a slight increase compared to the previous year, while **urgent certificate requests** decreased substantially compared to 2021(respectively 2,012 vs 1,938 and 591 vs 987).

1,012 parallel distribution initial notifications were received in the first half of 2022, marking a decrease from the previous year and returning to the 2020 level, with a downwards revised forecast of -27%; **parallel distribution annual updates** showed an increase compared to 2021, up at 2,851, leading to a revised forecast of +27% for 2022 (4,160 initial forecast vs 5,300 final forecast).

100% of standard certificates were issued within the established timelines, and the **average time to issue a standard certificate** reached **3 days**, thereby remarkably improving performance compared to previous years.

With regards to **meetings,** the Agency has launched a pilot to re-introduce face-to-face meetings in the first half of Q2 2022. With this pilot, the Agency aimed at leveraging lessons learned during the 'virtual only' meeting period imposed by the COVID-19 pandemic, to test new ways of working, by introducing an alternation between face-to-face and virtual meetings for all Committees and one physical meeting a year for Working Parties. In the long term, this new way of working will also significantly reduce the Agency's carbon footprint. For this reason, the number of reimbursed meetings shows a slight increase in 2022 compared to zero reimbursed meetings in 2021. However, in view of the above-mentioned approach that the Agency is currently testing, the number of face-to-face meetings will most likely not go back to previous years' level.

Information and transparency

The consequences of the COVID-19 pandemic are still visible in the number of **requests for information,** which is significantly higher compared to pre-pandemic years (4,559 vs 3,597 in 2020). **Completed requests for interviews and comments by media representatives** remain at a high level compared to pre-pandemic years (996 in 2022 vs 598 in 2020); however, requests have declined compared to 2021 (996 in 2022 vs 4,057 in 2021).

Requests for access to documents (ATD) slightly increased in the first six months of 2022 (375 vs 342 in 2021).

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted EMA work programme 2022.

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 2022'. For performance indicators that are expressed as a percentage, the mid-year target is assumed to be equivalent to the annual target. The forecasts of the indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

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.

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

Human Medicines Division

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Total scientific-advice and protocol-assistance requests	470	427	392	337	317	885	865	-20	-2%
Parallel scientific advice with international regulators	4	3	4	2	3	4	6	+2	+50%
Joint scientific advice with HTA bodies	3	2	1	10	16	3	8	+5	+166 %
Scientific advice for PRIME products	16	21	19	15	22	42	30	-10	-25%
Protocol assistance	75	80	65	81	103	154	146	-8	-5%
Novel technologies qualification advice/opinions	14	14	9	9	6	21	22	+1	+5%
PRIME eligibility requests received	25	29	28	24	29	55	50	-50	-9%
Applications for orphan medicinal product designation	157	134	123	127	127	250	280	+30	+12%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	346	368	339	279	375	801	801	0	0%
Requests for classification of ATMPs	25	46	54	27	27	60	60	0	0%

1.2 Initial evaluation activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
New non-orphan medicinal products	14	23	28	18	20	61	42	19	-31%
New orphan medicinal products	12	10	17	17	9	28	29	+1	+3%
Similar biological products	4	4	7	8	5	15	15	0	0%
Generic, hybrid and abridged applications	9	12	12	20	13	26	19	-6	-27%
Scientific opinions for non-EU markets (Art 58)	0	0	0	0	0	1	1	0	0%
Paediatric-use marketing authorisations	0	0	1	0	0	1	1	0	0%
Number of granted requests for accelerated assessment	0	7	10	3	1	12	10	0	0%
ATMP marketing application authorisation requests received[1]	1	3	6	-	-	8	9	0	0%
COVID-19 related product applications received[2]	5	14	6	-	-	11	8	-1	-11%

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Average assessment time for new active substances and biosimilars	205	199	199	198	205	196
Average clock-stop for new active substances and biosimilars	180	229	168	175	214	203

[1] New indicator introduced in 2021 Work Programme
[2] New indicator introduced in 2021 Work Programme

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	60%	33%	33%	60%	100%	33%
	% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	80%	60%	70%	72%	86%	56%

1.3 Post-authorisation activities

Workload indicators

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Type IA variations	1,778	1,961	1,978	1,898	1,604	4,078	3,870	208	-5%
	Type IB variations	1,606	1,393	1,301	1,011	993	3,016	3,013	-3	0%
	Type II variations[1]	617	606	630	499	498	1,245	1,319	+74	+6%
	Line extensions of marketing authorisations	11	16	24	9	10	38	28	-10	-26%
	Renewal applications	58	49	44	42	40	75	73	-2	-3%
	Annual reassessment applications[2]	9	8	7	7	5	31	31	0	0%
	Transfer of marketing authorisation applications	25	30	27	39	232	60	60	0	0%
	Article 61(3) applications	104	124	66	157	103	200	175	-25	-12%
	Post-authorisation measure data submissions	680	519	403	446	405	925	925	0	0%
	Plasma Master File annual update and variation applications	8	7	18	20	7	25	25	0	0%

[1] First half of the year normally sees lower volume of type II variations than the second half.
[2] This is a seasonal procedure and 2/3 of these are submitted in second half of the year.

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Average assessment time for variations that include extension of indication	180	171	162	160	154	152

1.4 Referrals

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Pharmacovigilance referrals started	4	2	2	6	2	6	5	-1	-16%
Non-pharmacovigilance referrals started	0	7	5	4	8	8	8	0	0%

1.5 Pharmacovigilance

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Number of signals peer-reviewed by EMA	1,126	858	1,015	1,063	1,395	1,900	1,900	0	0%
Number of ICSRs for CAPs (reports received) [1]	1,348,258	1,458,522	-	-	-	1,500,000/ 2,500,000	2,700,000	+200,000	+8%
Number of signals assessed by PRAC (validated by EMA)	26	33	25	35	44	40	40	0	0%
PSURs (standalone CAPs only) started	247	265	243	278	256	560	546	-14	-25%

[1] New indicator introduced in 2021 Work Programme.

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
PSUSAs started	142	142	141	138	161	358	331	-27	-8%
Number of imposed PASS protocol procedures started	6	4	0	6	7	6	4	-2	-33%
Number of imposed PASS result procedures started	2	6	3	1	5	8	6	-2	-25%

1.6 Inspections and compliance

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
GMP inspections	89	77	127[1]	247[2]	162	270	205	-65	-24%
GLP inspections	1	0	0	0	0	1	1	0	0%
GCP inspections	53	15	39[1]	79	74	87	87	0	0%
Pharmacovigilance inspections	10	10	3[1]	3	13	10	11	+1	+10%
PMF inspections	20	20	16[3]	66	87	54	122	+68	+126%
Notifications of suspected quality defects	131	87	87	93	69	250	250	0	0%
Medicinal products included in the sampling and testing programme	94	94	70	67[4]	55	81	94	+13	+16%
Standard certificate requests received	2,012	1,938	1538	1,284[5]	1,961	3,641	3,928	+287	+8%

[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] The result has been affected by travel restrictions due to the COVID-19 pandemic.
[4] Several products were not on the market at the time of sampling and had to be removed.
[5] 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.

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Urgent certificate requests received	591	987	729	1,349	365	1,737	1,260	-477	-27%
	Parallel distribution initial notifications received	1,012	1,537	1,141	1,265	1,264	2,900	2,100	-800	-28%
	Parallel distribution annual updates received	2,851	2,331	7778[1]	1,369[2]	46[3]	4,160	5,300	+1140	+27%

Performance indicators

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Standard certificates issued within the established timelines (30 working days)	90%	100%	99%	97%	14%	0%
	Average days to issue standard certificate	15[4]	3	16	26	65.0	21.5
	Urgent certificates issued within established timelines (2 working days)	98%	100%	99%	98%	99%	99%
	Parallel distribution notifications checked for compliance within the established timeline	98%	98.8%	98.8%	98%	27%	98%

[1] 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.
[2] To allow for IRIS implementation annual update, submissions were frozen for 3 months.
[3] 3,175 annual updates were estimated to have been received but not processed at that time.
[4] The target handling time of 10 working days for certificates requested through the standard procedure has been temporarily extended to 30 working days.

1.7 Committees and working parties

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Number of reimbursed meetings[1]	24	0	52[2]	143	213	420	94	-326	-77%
Committees and Management Board meetings	11	51	15[1]	38	35	75	31	-44	-59%
Trainings	1	2	1	12	8	22	1	-21	-95%
Workshops	1	1	0	0	28	13	1	-12	-92%
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	11	93	36[1]	93	142	310	61	-249	-80%
Number of virtual meetings (audio-, video- and web conferences)	3,000	3,220	2,660	1,659	2,524	6,500	6,500	0	0%
Number of reimbursed delegates	309	0	1,003	2,856	3,969	8,500	2,500	-6,000	-71%
Number of non-reimbursed delegates	44[1]	7,129	60	227	564	1,500	250	-1,250	-83%
Herbal monographs, new	2	2	0	0[3]	1	5	3	-2	+40%
Herbal monographs, reviewed	19	8	5	6		22	28	+6	+27%
Herbal monographs, revised	1	0	5	0[1]	10	6	3	-3-	-50%
EU herbal List entries	0	0	0	0[1]	0	1	1	0	0%

[1] COVID had an impact on face-to-face meetings. So far most of meetings have been cancelled or organised virtually. For Q3 and Q4, it is anticipated an increase in the number of face-to-face meetings. However, the initial number of planned face to face meetings will not be reached.
[2] The significant variation in the figures is due to the COVID-19 outbreak.
[3] Cancellation of HMPC March meeting, Brexit BCP related suspension of activities with the Ministry of Health, Labour and Welfare, Japan (MLWP).

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
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
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1, ECP4)	Increased awareness to facilitate the uptake of biosimilars	**On track**	EMA statement on interchangeability under review.
Support the STAMP scientific advice pilot for repurposing established medicines	1.1	A number of prioritised established medicines are enlisted in the pilot	**On track**	Project submissions have been reviewed by EMA and a short list of selected projects have been identified by end of Q2 2022. ED decision has been developed to provide SA fee reductions for the selected projects.
• Provide parallel/joint EMA/HTA scientific advice, also in anticipation of and with the new HTA Regulation • Progress with the HTA consortium the objectives of and tools for post-licensing evidence generation • Launch a pilot for prospective evidence planning with payer's	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	**On track**	Parallel Joint Scientific Consultations (JSC) initiated for the developments identified in the 1st Open call by EUnetHTA21; Experience with the procedure reviewed jointly between EMA and EUnetHTA21; 2nd Open call launched for identification of additional developments for parallel JSC; Agreement with payer community to have prospective evidence planning as priority topic.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
representative, to explore potential scope and feasibility				
• Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers • Conduct product-specific reviews with HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes	1.2 (ECP 1)	Stakeholder communication about regulatory assessment is enhanced	**On track**	Analysis of learnings completed and proposals established for guidance update to optimise the CHMP assessment report as reference for HTA, in line with CHMP work plan item; Product-specific discussions agreed as priority as part of the EMA/EUnetHTA21 work plan; Regular debriefings of payers on regulatory outcomes in the context of MEDEV meetings.
• Set up and operate a Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative methods • Deliver on International activities relating to Pharmaceutical Quality Knowledge Management System (PQKMS) • Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	3.1 (ECP 1)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	**On track**	QIG: Industry survey conducted (Feb 22), Mandate and membership criteria of QIG developed (April 22), roadmap for implementation developed (May 22), stakeholders (SciCoBo, PROM, WPs, IWG, CAT) informed call for expression of interest launched (closed on 27 May), status: election of members ongoing (target adoption of MS by July 22) PQKMS: Two pilots on assessment and collaborative hybrid inspections have been developed through ICMRA and a call from ICMRA for applications is imminent. A pilot on reliance in inspection has been presented at GMDP IWG with a view to adoption in Q3 Enable use of risk-based approaches to manufacturing and control strategies by

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				implementing ICH Q12 (e.g. trainings on Pharmaceutical Quality System (PQS) effectiveness) and participation in the ICH Q9 revision [continues through 2023]
• Develop guidance on information required to implement decentralised manufacturing and batch release for ATMPs • Deliver tailored engagement with academics and the community of ATMP developers • Strengthen support to development of ATMPs	3.1 (ECP 1)	Increased support to the integration of scientific and technological progress in the development of ATMPs	**On track**	Decentralised manufacturing: The concepts on decentralised manufacture/personalised medicines developed and proposed as modification to legislation and development of complementary guidance as part of EC Pharma strategy (as part of paper on new manufacturing methods). We have developed and delivered several training activities, with quality issues very well covered; Strengthen support to ATMP development: survey performed for SMEs to complement existing data. Discussions with EC for funding of ATMP-related research on-going. Feedback for pharma strategy ongoing (concept papers and in liaison with Innovation TF). Training sessions for ATMP developers prepared and recorded (collaboration with EATRIS-ADVANCE); Pilot for academic development support initiated: ATMP Academic Support Pilot agreed at EXB and selection of candidate products ongoing
• Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/convergence of practices and training with the Pharmaceutical	5.3	Reinforced responsibility for product quality by harmonising and reinforcing guidance	**On track**	Adaptation of GMP guidance: Several GMP guidance are under revision at IWG in collaboration with PIC/s for convergence at different stages of finalisation. To note the finalisation of the revision

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Inspection Co-operation Scheme, extend EU-US mutual recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA				Annex 1 and Annex 21, as well as start of revision of Annex 11/Chapter 4. Training collaboration with PIC/s: Ongoing discussion with PIC/s on collaboration on the PIC/s Inspector Academy training platform. In June 2022, the IWG has agreed to set up a group to leverage ongoing initiative on training from the HMA MAWP, the EU4Health initiative and the EU NTC collaboration with PIC/s. EU-US MRA: ongoing work on MRA expansion on vaccines and plasma derived products and veterinary products and recognition of third country inspections.
• Develop guidance for MAH's to undertake a risk assessment of supply chain and have a 'resilience plan' including shortage prevention and management • Start a pilot for key medicines including training	5.4	Promoted supply chain resilience and reliability of supply of APIs and medicinal products	**On track**	Draft Best practice guide for industry on prevention/management of shortages of medicinal products to be presented during the meeting of the HMA/EMA TF AAM with industry associations on 12 September 2022.
• Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	6.2 (ECP 2)	Improved benefit/risk communication	**On track**	Presentation of pilot project at CAT in September 2022 for a decision conference with assessors, looking at several examples of preference elicitations in the context of a hypothetical advisory group alongside traditional advice. Similar activities planned with CHMP.
• Draw lessons from COVID-19 evaluations	6.2 (ECP 2)	Regulatory innovations and flexibilities to accelerate the availability of medicines are	**On track**	Covid lessons learnt conducted. Reflections on optimisation of rolling reviews are ongoing. As part of the pharma strategy, proposals to optimise the

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
• Develop simplifications/reductions of post-authorisation procedures • Review of the scientific advice offering to provide more agility • Analyse experiences gained to allow exceptions to the use of paper Package leaflets		identified, and where feasible, are progressed for implementation		labelling, the post-authorisation procedures and other elements of the regulatory framework.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
Meeting secretariat improvement	Implementation of a new operating model for working parties, of the support to medical devices expert panels (EMA extended mandate), and meeting secretariat operating improvements	Merge for delivery optimisation into the Regulatory Business Process Optimisation Programme (RBPOP) in Q2 2020

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Innovation Task Force briefing requests (Vet)	0	4	2	3	1	5	5	0	0%
Scientific advice requests received	18	11	14	12	16	22	30	+8	+36%
Requests for classification as MUMS/limited market of which:	n/a	7	19	20	13	n/a	n/a	0	0%
re-classification requests	n/a	3	5	3	1	n/a	n/a	0	0%
Requests for classification as limited market under article 4(29) and eligibility under article 23	11	n/a	n/a	n/a	n/a	20	25	+5	+25%

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Scientific advice procedures completed within set timeframes	100%	100%	100%	100%	100%	100%

2.2 Initial evaluation activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Initial evaluation applications	9	4	7	13	7	32	27	-5	-16%
New MRL applications	0	0	0	2	1	2	2	0	0%
MRL extension and modification applications	0	1	1	0	0	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	0	3	0	5	0	0	0	0%

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Procedures completed within legal timeframes	100%	100%	100%	100%	100%	100%

2.3 Post-authorisation activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Variations applications, of which:	102[1]	381	331	252	211	n/a[2]	n/a	n/a	n/a

[1] These actuals refer only to the variations submitted under the old Directive 2001/82/EC.
[2] Regulation (EU) 2019/6 defines post-authorisation variations differently from currently applicable rules, therefore detailed forecast was not possible at the time of 2022 planning.

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Type IA variations	54	212	191	147	106	n/a	n/a	n/a	n/a
	Type IB variations	25	116	111	72	61	n/a	n/a	n/a	n/a
	Type II variations	23	53	29	33	44	n/a	n/a	n/a	n/a
	Line extensions of marketing authorisations	0[1]	0	1	0	1	n/a	n/a	n/a	n/a
	Transfers of marketing authorisations	0	8	5	2		5	5	n/a	n/a

Performance indicators

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Post-authorisation applications evaluated within legal timeframes	100%	100%	100%	100%	100%	100%

2.4 Arbitrations and referrals

Workload indicators

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Arbitrations and Community referral procedures initiated	3	0	1	2	3	6	4	-2	-33%

[1] These actuals refer only to the variations submitted under the old directive 2001/82/EC.

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Referral procedures managed within the legal timelines	100%	n/a[1]	100%	100%	100%	100%

2.5 Pharmacovigilance activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Periodic safety-update reports (PSURs)	n/a	87	72	71	81	160	160	+0	+0%
Total AERs, of which:[2]	91,939	31,000	31,944	34,491	29,143	75,000	120,000	+45,000	+160%
Adverse-event reports (AERs) for CAPs	57,211	15,000	14,195	16,057	14,864	37,500	60,000	+22,500	+160%
Adverse-event reports (AERs) for NAPs	34,728	16,000	17,749	18,434	14,279	37,500	60,000	+22,500	+160%

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
PSURs evaluated within the established timelines	n/a	n/a	99%	100%	95%	95%
AERs for CAPs monitored within the established timelines	95%	n/a[3]	95%	95%	96%	99%

[1] No procedures were concluded in the first half of 2022.
[2] Please note that a large backlog was received this year, hence the figures are higher than average for mid-year reporting.
[3] The new systems are not yet 100% up and running and several products have not yet been migrated, therefore, at the moment is not possible to calculate the percentage of AERs monitored by the established timeline.

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 "Concept paper on the efficacy of cell therapies: mechanism of action, potency and clinical effects" and the "Concept paper on quality, safety and efficacy of bacteriophages as veterinary medicines" have been released for public consultation in January 2022 for three months, the operational experts groups (OEGs) reviewed the comments received and the relevant guidelines are being drafted and expected to be presented to CVMP in October.
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 3 times in the first half of 2022 progressing the work on the recommendation to be sent to the EC (EMA/EFSA joint final report). In April 2022 the CVMP adopted and the EFSA Scientific Committee endorsed for two month public consultation the "Draft report on development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin". The draft report was also reviewed by EC. The public consultation started on

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				30 June. This was advertised in news announcement and posted on LinkedIn and Twitter, in cooperation with EFSA. The public consultation may be extended by two weeks upon request from Animalhealth Europe (AhE). The comments received will be reviewed in Q3-Q4 2022 and the final recommendation sent to EC in Q4 2022.
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**	The Pilot Signal Management experts group (P-SMEG) is developing a process document, to be adopted in October 2022. The P-SMEG is currently testing different strategies on signal management, which might lead to additional updates of existing guidelines. The P-SMEG report on its activity including recommendations on lesson learned is planned for end of 2023 (end of pilot phase).
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**	The topic is to be discussed at the P-SMEG level, guidance will be developed and provided in 2023.
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	**Delayed**	It is considered that such expert meetings should take place in face-to-face settings, hence the further delay while facing continued Covid related measures. The set up of the 2 initial groups (related to

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				poultry and aquatic animals) has now been postponed to 2023
Improve communication of veterinary pharmacovigilance.	3.1	Establish PhV communication framework	**On track**	EMA organised follow-up webinars in January 2022 on the 'Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Collection and recording of suspected adverse events for veterinary medicinal products', the 'Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management' in terms of the implementation of the Regulation (EU) 2019/6 with target audience: NCAs, Industry Stakeholders and FVE.
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	**Suspended**	This activity is suspended until further input will be provided by the EC.
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	**On track**	The "Reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6" has been released for three months public consultation in February 2022. The final reflection paper is expected in Q3-Q4 2022.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
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 6 months of 2022.
Expand current ESVAC system to include other antimicrobials.	4.1	Collection of data expanded to include all antimicrobials	**On track**	A new list with the antimicrobial active substances and respective classes was created, as per Article 5 the of the Commission Delegated Regulation (EU) 2021/578. This list includes not only antibacterial (as in ESVAC), but also antivirals, antifungals, antiprotozoals, antimycobacterial and anti-infective. The list was developed and peer-reviewed internally and agreed with the ASU Product Owners Group in June 2022. The list was sent to the Substance Management Services (SMS) colleagues in June 2022 and is currently being integrated in the SPOR system.
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**	Mandate, objectives and rules of procedure for the CVMP Antimicrobials sales and use working group have been drafted and discussed by CVMP in Q2

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				2022. This WG will have oversight of future JIACRA reports. The final mandate is expected to be adopted by CVMP in Q4 2022
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**	In May 2022 a Manual for reporting data to the Agency on the use of on antimicrobials in animals per species and categories was published. The Manual was thoroughly discussed with Member States within the ESVAC Change Liaison Network for ASU and was discussed and adopted by CVMP at its meeting in May 2022. A guideline on denominators and indicators is being drafted with the ESVAC ad hoc expert group on revision of indicators and denominators. This guideline will include the new methodology for analysis of antimicrobial data for ASU and during the discussions, the methodologies used in other regions (e.g. FDA, Canada, WHOA) are being taken into consideration.
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**	In May 2022 a Manual for reporting data to the Agency on the use of on antimicrobials in animals per species and categories was published. The Manual was thoroughly discussed with Member States within the ESVAC Change Liaison Network for ASU and was discussed and adopted by CVMP during at its May 2022 meeting.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				The Manual defines the requirements for a harmonised collection of data on the use of antimicrobials per species and categories. The ASU Protocol is being drafted and prepared together with the ASU Product Owner group. The Protocol will include all the necessary requirements for reporting data to the Agency and therefore, shall also be used by Member States when developing their national data collection systems. A period of consultation with the Network is expected for Q3 2022.
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 in policy development	**Delayed**	The technical estimates used for the JIACRA report were updated for the years 2014-2020 in 2021. In 2022 the experts group (EMA, EFSA, ECDC) working on the 4th JIACRA report started their on-going meetings to review the 2019-2021 data, the first preliminary results are already prepared by the statisticians group. The results of the report will inform policy-makers from about decisions on AMR.
Participate in international initiatives to reduce the risk of AMR.	4.1	Actively participating in international fora	**On track**	EMA participated in the first 6 months of 2022 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,

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				in particular the development to alternatives to antimicrobials. EMA actively participated or presented in the following AMR related events or groups in the first six months of 2022: - PAHO-led EC funded Steering Committee of the project "Working together to combat antimicrobial resistance (AMR)" in March 2022, as member of the group; - DIAmond session on AMR in March 2022, at DIA Europe 2022; - AMR WG in April 2022, as member and in several subgroup meetings to revise chapter 6.10 of the Terrestrial Animal Health Code and to refine the list of antimicrobials of veterinary importance with respect to use in pigs; - OneHealth EJP 9th Stakeholder meeting in April 2022; - EFSA One Health conference in June 2022 as co-chair and rapporteur for the international session 'Tackling antimicrobial resistance in food producing environments' - EMA also contributed to enhanced discussions with World Organisation for Animal Health (WOAH) on the data collection on antimicrobial use in animals and the option to link EMA and OIE data collection systems.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Update existing guidelines, and initiate new guidance as needed.	4.3	Develop relevant guidance	**On track**	No new guidance has been initiated in the first 6 months of 2022, however, work is progressing on a number of guidelines expected to be finalised in Q3 and Q4 2022.
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	**Delayed**	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**	See also item 22 and 23 with regard to activities relevant to establishing a regulatory framework for alternatives to antimicrobials. Internal discussions have been held to monitor implementation of the recommendations given in the Reflection Paper on promoting the authorisation of alternatives to antimicrobial VMPs. Preparations are ongoing to organise an event with stakeholders in 2023.
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	**Delayed**	'The consultation phase on the "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" ended in January 2022, the comments

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				received are being reviewed and the final document is expected to be published in September 2023. The "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" has been released for three months public consultation in January 2022. The comments received were reviewed in Q2 2022, comments are currently awaited from EC.
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 ATAm	**On track**	A concept paper for the development of a guideline on data requirements and potential claims for alternatives to antimicrobial veterinary medicinal products is being drafted by CVMP Efficacy working party with an estimated completion date by December 2022.
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**	EMA has continued participation in TATFAR meetings under Action 3.3, aimed at discussing approaches and challenges related to the authorisation of novel therapies as alternatives to antimicrobials. Discussion on bacteriophage products has been completed, probiotics will be discussed next.

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**	A Guideline on exceptional circumstances data requirements was published in January 2022; the guideline will be instrumental for establishing benefit-risk of these products.
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	**Completed**	The Guideline on data requirements for authorisation of immunological veterinary medicinal products (IVMPs) in exceptional circumstances has been finalised and published 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**	The revised Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines, the Guideline on data requirements for vaccine antigen master files (VAMF) and the Guideline on data requirements for vaccine platform technology master files (vPTMF) have been finalised and published in January 2022. In addition to the guidance, a Procedural advice for veterinary vaccine antigen master file (VAMF) certification has been adopted in April 2022. A Procedural advice for vaccine platform technology master file (vPTMF) certification is being developed with an expected completion date by Q4 2022.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
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**	Following the publication of the OIE document on antiparasitic resistance in grazing livestock species, the OIE, since June 2022 WOAH, expert group are now planning the future activities to which EMA is also invited to contribute. A mapping exercise has been launched in order to identify and agree the next topics to be addressed by the group. No meeting took place in the first half of 2022.
Promote responsible use of antiparasitics in the EU.	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	The revised VICH guidelines on efficacy of anthelmintics have been published in June 2022 for public consultation. A training/webinar on the revised CVMP "Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products" was held on 29 June 2022. CVMP Efficacy working party is currently contributing to several CVMP GLs/RPs addressing issues for antiparasitics (resistance): Reflection paper on resistance in ectoparasites; Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (which also addresses reduction in the antiparasitic resistance).

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Prepare for and implement Veterinary Medicines Regulation	6.1	Prioritised guidance, processes and IT systems in place in time for implementation	On track	The Veterinary Medicines Regulation became applicable on 28 January 2022. Procedures have been aligned with the changed requirements. The development of required IT system is on track: - Union product database (UPD): MVP completed and live as of 28 January 2022, work post-MVP improvements is ongoing; - Union Pharmacovigilance Database (EVV): MVP completed and live as of 28 January 2022, work on post-MVP improvements is ongoing; - Antimicrobial Sales and Use (ASU); Submission component go live scheduled for end 2022; analytics component scheduled for go live in Q2 2023 (30% complete); - Manufacturer and Wholesale Distributors Database (MWD): MVP completed and live as of 28 January 2022, work on post-MVP improvements is ongoing. Project closure is scheduled for Q4 2022. Recommendation to EC: - The "Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				veterinary medicinal products" has been published in May 2022; - The "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))" is under drafting and expected to be finalised by Q4 2022.
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", to improve the current benefit-risk methodology and align with the Regulation (EU) 2019/6 provisions. A concept paper for consultation was published in Q4 2021 and comments received are being reviewed by the drafting group. A guideline is under development and is expected to be released for consultation in Q4 2022 and finalised by Q1 2023.
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**	In addition to the work of the NTWP, the list of EMA/CVMP stakeholders has been revised and interaction between CVMP (and its working parties) and stakeholders were discussed. A CVMP stakeholders meeting will take place in Q4 2022.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
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 28 January 2022
UPD - Union Product Database	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 28 January 2022 New versions released every 3-4 weeks Improvements to all UPD components
ASU - IT system for the Collection of Antimicrobials Sales and Use Data	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.	Completed integration with one external party (Eurostat) The development of the transactional and analytical part is ongoing, including the integration with other systems. The drafting of the protocols and templates for reporting the data is also on going.
MWD (formerly 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.	Go-live 28 January 2022

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
New scientific, regulatory and telematics curricula developed	0	0	3	1	0	2	1	-1	-50%
Number of training events advertised to the EU Network	36	36	20	27	25	40	60	+20	+50%
Number of reimbursed training events to the EU Network	1	0	1	7	19	12	5	-6	-50%
Number of NCAs that have opened their training for inclusion in EU NTC learning management system	7	10	6	6	4	10	14	+4	+40%

Performance indicators

Performance indicators related to core business	Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
Number of users registered to the EU NTC Learning Management System	n/a[1]	6,272	5,213	4,842	4,020	2,850
Number of NCA experts[4] registered to the EU NTC Learning Management System	n/a[2]	5,203	4,236	3,888	3,060	1,950

[1] Indicator to be reformulated during the 2022 planning cycle.
[2] Indicator to be reformulated during the 2022 planning cycle.

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**	In the first 6 months of 2022 DigiLab collected more than fifty ideas for digitalisation and automation across the Agency. Following an evaluation of the ideas and considering available resources DigiLab started five new DigiLab projects in the first half of 2022. These ideas aim to realise efficiency gains in the management of the EURD List, the Early Notification System, the assessment of invented names of medicinal products under evaluation, the accounts receivable mailbox, and the generation of a list with clinical breakpoints for anti-microbial medicines. In the first half of 2022 the Digital Innovation Lab (DigiLab) worked with the Analytics Centre of Excellence (ACE) to pilot five potential solutions to business challenges. The pilot to adopt the use of QR codes is being finalised, and the following four solutions are being implemented: the Discoverer tool which helps to find specific scientific information in certain documents faster, two validation tools to compare documents and the tool to automate registration of applications submitted to EMA. DigiLab also experimented with virtual reality (VR) as a novel technology to deliver immersive training experiences in the field of cybersecurity. Business

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				requirements have been collected and desirability and feasibility have been evaluated, and DigiLab successfully completed a small proof of concept. The next step is to pilot the technology and the process of purchasing the first few VR glasses is ongoing. Furthermore, DigiLab experimented and developed capabilities to design solutions using Microsoft Power Automate and applied this in the Early Notification System project. In 2022 ACE has been working on different initiatives in parallel such as: Document Identification Validation System (DIVS), New Certificates tool (CPS), including new type of submission in the existing Assisted Validation System (AVS) to automate the registration of the submissions, Discoverer, Speech to Text, the implementation of Chatbots at EMA deploying the first chatbot at EMA for Talent Acquisition, a document comparison tool for Parallel Distribution service, Improvements in the ASK-EMA automatic triage system, the implementation of a Product Name validation for the new vet regulation, PEDAR to identify personal data, etc. ACE has also provided support during the solve phase in the DigiLab process with its knowledge and capacity to design the best solution to solve the business requirements.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Besides these activities, DigiLab and ACE engaged with other medicines agencies in the network to exchange knowledge and experiences on experimenting with new technologies and the acceleration of the adoption of novel technologies across the Agency.
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 AI community has been meeting during the first semester to show different use cases among the agency in the network. The Leading Agencies are working on a conference together at the end of the year to present AI projects in each agency and how AI has been implemented across the network
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**	Surveys to HMA and LMS users on Training needs and Priorities in the Network. A new domain for international regulators has been set up in the EU NTC LMS and access provided to Product Information modules provided to a small number of African regulators. Efforts are ongoing to offer access to certain EU NTC courses to a wider number of international regulators. A contract has been signed with an external consultant for development of a learning design and development toolkit for curriculum steering groups and course developers. Work is ongoing with SAP to improve the reporting analytics of the LMS. Interactions initiated with EU-IN (training in new areas of innovation), and PIC/S (training in GMP).

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Discussions also initiated on Future of Learning topics – implementation of MAWP topics, interactions with external organisations, new areas, interactions with Academia. Discussions initiated on stand-alone EU NTC home page, as well as visibility on EMA corporate web page.
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**	The MDR/IVDR implementation and the Extended mandate (e.g., expert panel operation) are still ongoing and take priority. Priority was given to the setup and operation of the expert panels before the development of an integrated pathway. Expected start of this activity in Q4.
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**	See integrated regulatory pathway (3.4). In the context of the establishment and operation of the expert panels, a list of experts has been created along with a mapping of their expertise in the area of medical devices.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
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 information electronically between applicants and Regulatory Authorities.	*[to restart in 2023]*
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.	GCP Inspections in IRIS from April 2022 Variations process started in Q1 2022

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Data Analytics and Real World Interrogation Network (DARWIN EU) Deliver a sustainable platform to access and analyse healthcare data from across the EU. 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 (ECP 2)	Data Analytics and Real World Interrogation Network (DARWIN EU) established and operational.	**On track**	- Contract signed with Erasmus University Medical Centre (EMC) in Feb 2022, following tender procedure - Package of communication activities surrounding the launch, incl. a multi-stakeholder information webinar with ~700 attendees - Milestone 1 completed successfully - Milestone 2 delivery and review underway - Shortlist of 10-15 Data partners for onboarding agreed - Studies shortlist for phase I developed - DPIA in progress for expected July 2022 finalisation - Onboarding of data partners and first studies to follow in H2 2022, realising the first benefits for the network and stakeholders - Engagement with EMA committees, and via the DARWIN EU Advisory board, HTA and payers' bodies, plus the NCAs and ECDC for use cases and pilot studies to be conducted

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				-
Submission of Raw Data in Regulatory Submissions Build capability and capacity to receive, store, manage and analyse raw data	2.1 (ECP 2)	Determine the regulatory and public health benefit of analysis of raw data.	**On track**	- Selection criteria for the procedures to be included in the proof-of-concept pilot were endorsed by CHMP during the PROM meeting in May 2022 (Q2 2022). - Project milestones were amended since the initiation of the 2022 plan. As of end of June 2022, 40% deliverables have been achieved including the proof-of-concept pilot's design and plan. By the end of 2022, it is expected that 56% of them will be achieved. - Engagement with EMA committees, and via the Advisory Group on Raw Data, NCAs, patients and healthcare professional representatives, plus international regulators (FDA & PMDA), Industry and standards developing organisations (CDISC).
Data standardisation in medicines regulation across the lifecycle of a medicine: Develop a data standardisation strategy, drive standardisation of regulatory submissions across the lifecycle of a medicine, search the unstructured data stored at the Agency, collaborate with worldwide standards data organisations	2.1 (ECP 2)	Enable effective interrogation of scientific information across the lifecycle of medicines and for multiple types of users within and across regulatory procedures. Drive up the quality of data submitted to EMA through the use of standards	**On track**	- Data Standardisation Strategy published in Q1 2022. - EMA data board expected to be established in Q3 2022. - BDSG work plan 2022-2025 adopted June 2022 - Mandate of the EU NDB and BDSG reviewed Q1 2023.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- Collaboration with ICH M11 on the development of a logical model for clinical study protocols started in Q4 2021. - Development of a logical model for clinical study protocols on-going, expected completion for consultation in Q4 2022. - Work on FHIR messaging initiated in Q2 2022. - Demonstration for the Advanced Analytics Scientific Advice pilot made in Q2 2022.
Metadata, Data Quality Framework and Catalogues Project: 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). Upgrade the current EU PAS database to support the registration and transparency for observational studies	2.1	Data discoverability enabled for the Network	**On track**	- Performed a comprehensive review of existing data quality frameworks available in literature and/or developed by other regulators and organisations, with the view of using it as an input for the drafting of a Data Quality Framework intended for regulatory purposes - Conducted an in-depth stakeholder consultation with the view of drafting and improving the Data Quality Framework - Metadata list adopted and published on Big Data website - Developed a methodology to identify databases to include in the EMA Database Catalogue, to engage with database holders and collect the metadata required - Identified an initial set of 24 real-world data sources to be included in the EMA Database Catalogue

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Strengthen EU Network on methodology and RWE in committee advice and assessment Develop Big Data learning initiative where submissions on complex methodology and RWE are forecast and tracked, work with international partners on RWE to develop roadmap and guidance, drive the creation of guidance documents in the methodological area, drive the creation of the Methodology Working Party	2.2 (ECP 2, ECP 4)	Improved preparedness of the EU Network for applications with RWE and complex methodology. Systematic learnings from submissions with RWE and complex methodology. Published roadmap for collaboration with international partners. The Methodology Working Party is operational and publish a workplan for methodology guidelines.	**On track**	- Establishment of Methodology Working Party (MWP) and appointment of its members. - First virtual meetings held twice monthly since April 2022. - Transition from former working parties to MWP planned and initiated. - As of June 2022, about 70% of the overarching 2022 work plan for the Methodology Working Party written. - Workshop with ICMRA international regulators on RWE held on 29-30 June 2022. Output: ICMRA statement on international collaboration to enable RWE for regulatory decision-making.
RWE process and analysis EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	2.1 (ECP 2)	Enable better regulatory decision making through the provision of the high-quality RWE	**On track**	All mentioned committees had at least one pilot study performed - CAT (1), PDCO (8), COMP (5), SAWP (5), except CHMP which started the pilot on 10 June 2022, however they already proposed a study. Training materials were prepared and all newcomers are onboarded using the TDA Booklet on analytics and a module on Databases descriptions.
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 (ECP 1)	Establish a framework, mandate and objectives for a multi-stakeholder platform for discussion of new approaches for Clinical Studies	**On track**	The ACT EU Steering Group has agreed to a 4-year multiannual programme which may have an impact on the timelines of the initially foreseen deliverables and performance indicators.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				- Concept paper for multi-stakeholder platform under development, detailing framework, mandate, objectives etc. - As per the agreed multi-annual workplan there will be standalone single topic multi-stakeholder workshop in 2022 with creation of platform in 2023
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 (ECP 1)	Using the multi-stakeholder framework from 3.2.1.11 develop action plan and workstreams on complex clinical trials	**On track**	ACT EU priority action on methodologies has been established and will specifically address guidance for complex clinical trials. This priority action will work closely with the priority action addressing coordination of scientific advice, and also the priority action working on GCP modernisation. - Question & Answer document on Complex Clinical Trials published in June 2022. - Workshop on complex clinical trials Q&A planned for Q4 2022 - Workshop on decentralised clinical trials planned for Oct 2022, and final recommendation paper on DCT planned for end of 2022
Promote increased information sharing on clinical trial design, conduct, results and best practices. Build on this information and the multi-stakeholder platforms to enable further education, training and sharing of best practice in order to accelerate innovative change	3.2 (ECP 1)	Using the multi-stakeholder framework from 3.2.1.11 develop action plan and workstreams on complex clinical trials	**On track**	The ACT EU Steering Group has agreed to a 4-year multiannual programme which may have an impact on the timelines of the initially foreseen deliverables and performance indicators. ACT EU webpage created, and initial communication plan adopted

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Go live of CTIS and CTR: Training and operations and IT project	2.2	Deliver CTIS to support the Clinical trial regulation, continue to provide training of users, change management and deliver IT project by providing new functionality	**Delayed**	Number of bitesize talks = 5 Number of walk-in clinics = 7 Number of events (master trainers, info days, training) = 12 Governance meetings (6 CTIS ExG meetings, 2 CTIS MS meetings and 2 CTIS stakeholders meeting) Backlog management (BM) sessions started in Feb (weekly) S38/39 release launched in May 2022. Several Data fixes/hotfixes releases over this period to address incidents reported Comments on the status: - Change management: on track - Business activities related to IT deliver (e.g. BM session) and increment planning: on track - IT delivery: delayed by the contractor with the delivery of technical items and problem releases - approximately 3 months risk - ability to deliver new functionality before end of 2022
Full Implementation of the EU-DPR and monitoring of compliance	6.2	In the initial implementation phase, assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, data protection notices, DPIA reports, joint controllership agreements; adopt instruments for	**On track**	Continuation of advice on data protection matters, with main focus on: Follow-up on EDPS recommendations on the Administrative Arrangements with Health Canada;

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		international data transfers; conclude appropriate contracts with data processors). Following the first implementation phase, 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.		Drafting of the EudraVigilance Human Joint Controllership (endorsed by EMA MB on 30 June 2022); Drafting of the DARWIN EU® Data Protection Impact Assessment (DPIA) (establishment phase); Update of EudraVigilance DPIA. Drafting of the Lifecycle Regulatory Submissions Raw Data DPIA. Initiation of DPIA on Management of personal data in documents subject to exchange by EMA with public authorities and international organisations in third countries. Review of new Records of Processing Activities and Data Protection Notices or update of existing documents, as applicable[1]; Personal data breach management. Participation at EDPS/DPOs Network meetings and follow-up on EDPS recommendations/actions. Organisation of EMA internal Data Protection Co-ordinators meetings. Drafting of Guidance document on how to approach the protection of personal data and commercially confidential information

[1] Please see Data protection and privacy | European Medicines Agency (europa.eu) and Central register of data processing records | European Medicines Agency (europa.eu)

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				in documents uploaded and published in the Clinical Trial Information System (CTIS) [1]; Review of international transfers of personal data and use of EC's Standard Contractual Clauses (SCCs) or other applicable transfer mechanisms by EMA vendors as applicable and preparation of Transfer Impact Assessment (TIA) template; Data protection advice on Zynteglo transfer of traceability data from MAH to Agency; Participation at internal audit on Business Continuity and Disaster Recovery; Planning of data protection training for Q4/2022 and Q1 2023; Support in Agency's procurement procedures.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
Lifecycle Regulatory Submission Raw Data	- Report on review of experience with IPD at EMA and other international regulatory agencies and develop protocol for IPD	- Initiated implementation and gathering of business requirements - Initiated communication and training

[1] Draft Guidance document on protection of personal data and commercially confidential information (CCI) in CTIS (europa.eu)

Project title	Long term objective	Achievements/results in Q1/Q2 2022
		- Business process ad operating model design completed
Lifecycle Regulatory Submission Metadata	- Identify relevant data sources; by defining and standardising the structure of the information (i.e. defining the 'metadata' and supported through relevant standards), the scientific information will become more accessible	- Development of a logical model for clinical study protocols in collaboration with ICH M11 working group started. - Advanced analytics pilot successfully finalised. - Development of user interface for Scientific Explorer started. - Screening of potential technology vendors for off-shelf solution for Scientific Explorer started.
Observational Studies DARWIN EU ** Real-world Metadata and Rapid Analytics merged with DARWIN into one project in Nov 2021*	- 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	- DARWIN EU coordination centre established and operational - CHMP pilot initiated
*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.	- Performed a comprehensive review of existing data quality frameworks available in literature and/or developed by other regulators and organisations, with the view of using it as an input for the drafting of a Data Quality Framework intended for regulatory purposes - Conducted an in-depth stakeholder consultation with the view of drafting and improving the Data Quality Framework - Metadata list adopted and published on Big data website - Developed a methodology to identify databases to include in the EMA Database Catalogue, to engage with database holders and collect the metadata required - Identified an initial set of 24 real-world data sources to be included in the EMA Database Catalogue

Project title	Long term objective	Achievements/results in Q1/Q2 2022
*Observational Studies Rapid Analytics**	- Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	Presentations made to EMA scientific committees for their participation into the rapid data analytics project Volunteers identified for PRAC, CAT, PDCO, CHMP, SAWP and CMDh (scientific officers and committee members) to advise on processes, identify research needs and serve as liaison between the Committee and the rapid analytics team. Proactive screening of confirmed signals to be discussed by the PRAC through the review of PRAC agenda and assessment reports. IHD rapid data analytics software tested and available for feasibility analyses and rapid studies, including development of user's guide From January to June 2022, a total of 36 feasibility analyses and 17 complete studies performed based on the PRAC list of signals and requests from different committees and scientific officers.
Signal and Safety Analytics	- Increase saleability and efficiency in processing of signals & safety data	- Collection of IT and business requirements for the design of the new EVDAS platform/eRMR solution/ADR website - Prepared communication plan for 2022 and held awareness sessions with EMA and MSs colleagues
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.	- Go-live 31 January 2022 - Post-go-live releases - Communication and training ongoing - Hypercare period until July 2022
Safety Implementation Regulation cooperation in safety assessment (CTIS scope extension)	- Implementation of IT systems to support cooperation in safety assessment in the context of the clinical trials	- Go-live 31 January 2022 - Continued communications, training programme and related documentation - First Annual Safety Report submitted in CTIS in June

Project title	Long term objective	Achievements/results in Q1/Q2 2022
Big Data curriculum	The initiative aims to develop 3 curricula to support knowledge development in the European Medicines Regulatory Network in the fields of Epidemiology, Biostatistics, clinical trial and data science	- Procurement for outsourcing the developing the curricula content launched.

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Innovation Task Force briefing meetings	16	21	15	11	10	35	35	0	0%
	Innovation Task Force Art 57 CHMP opinion requests	1	0	0	0	0	4	2	-2	-50%
	Business Pipeline briefing meetings[1]	8	6	-	-	-	18	21	+3	+17%
	Regulatory assistance, including SME briefing meetings[2]	97	105	-	-	-	183	183	0	0%
	Requests for SME qualification	240	312	303	328	254	516	516	0	0%
	Requests for SME status renewal	210	131	178	134	163	1,260	1,260	0	0%

Performance indicators

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Satisfaction level of SMEs	80%[3]	n/a	89%	88%	n/a	98%

[1] New indicator introduced in Work Programme 2021
[2] New indicator introduced in Work Programme 2021
[3] Satisfaction level is usually evaluated following events Q3/Q4.

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Improve further the collaboration with international partners on shortages at the level of ICMRA and the Global Regulators Working Group, including in the area of supply disruptions due to manufacturing quality issues	1.1 (ECP 1, ECP 4)	Established framework for collaboration with international regulators	**On track**	Collaboration with international partners on shortages at the level of the Global Regulators Working Group is now formally established with the group's Terms of Reference adopted in June 2022. Bilateral collaboration is also being established for the first time in the area of shortages with the US-FDA.
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	- Adding new experts to EMA DB that participated ITF BM, eg DCT, Ethic Cttees, national experts supporting IWG. - Dissemination of ITF BM within the Agency and EU-network by presenting each individual ITF BM and summary of trends in last 2 years - Support MWP, and NmWP re-establishment by providing relevant developments and experts - Conducting and presenting BLCG and innovation office surveys during EU-IN meetings
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1 (ECP 1)	New technologies identified and integrated within EU-NTC	**On track**	- Delivered HS ad hoc report on Big Data technologies to BDSG for revision of workplan 2022-2023 which will leads to EU-NTC implementation.
Identify, in consultation with research institutions, academia and other relevant stakeholders,	3.3	Topics for network training identified and communicated to EU-NTC	**On track**	- Reach out with EIT on genome editing

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients				- Supporting STARS conference and enabling FU measures by discussing and progressing developments withi EU-IN - Reach out with EPO. Planned EMA presentation to EPO on 27/09/2022 and planned EPO lunch talk at EMA on 25/10/2022 tbc
Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	6.1	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	**On track**	- Monthly circulation of upcoming early stakeholder interactions to CHMP, SAWP, CAT, COMP and other relevnt Cttee / WP - F2F presentation of relevant upcoming meetings to selected Cttee / WPs / Communities - Trend analysis and review of stakeholder interactions of the last 2 years - The pilot of the TRIP system was refactored and a version 2 has been prepared. - The gating process for TRIP portfolio board discussions is being prepared
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	**On track**	- HS deep dive report on Antimicrobial resistance to first layer internal consultation - HS ad hoc report on Big Data technologies to BDSG - HS ad hoc analysis to inform SCG discussion of China-only developments - Contributed to EU IN HS report on FMT

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Review of the mandate of EMA to include the activities of the EU Executive steering group, the I-SPOC, and the EU SPOC Network	1.1 (ECP 1, ECP4)	Fulfilment of the requirements established by EMA's extended mandate for availability of medicines	**On track**	- The MSSG and the medicine shortages SPOC Working Party have been established and are fully operational. - A list of critical medicines for COVID-19 was adopted by the MSSG as well as a list of main therapeutic groups. Both lists have been published in the EMA website. - The i-SPOC registration was launched on 28 June so that MAHs of all medicines authorised in the EU can register an i-SPOC by 2 September 2022. - MAHs in scope of the list of critical medicines for COVID-19 can submit actual or potential shortages of their products from 15 July 2022.
Improve monitoring of shortages and enhance communication of supply problems to EU citizens, their representatives and HCPs	1.1 (ECP 1, ECP4)	Enhanced communication of supply problems to stakeholders to facilitate mediating action	**On track**	- Publication of the guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use on 15 July 2022. - Workshop with HCPs organisations is planned for November 2023 and a multi-stakeholder workshop is planned for Q1 2023.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
EUMSD database	To support development of functional specifications for the EUMSD database, together with a plan for the implementation of national IT systems, and consultation with stakeholders.	• Regulation (EU) 2022/123 adopted 25 January 2022 • iSPOC registration tool go-live in June
Digital workspace (TRIP)	To use a Digital workspace for capturing, filtering and scientifically assessing HS signals by users from the Horizon Scanning team (TRS) and by Regulatory Observatory members (experts across the Agency, and eventually the EMRN).	*[possible start in 2022 depending on resource and budget availability]*
EMA's Regulatory Science Observatory	To support review of TRS operations with a view to optimise, create synergies and efficiencies leading to fulfilling our mandate as a EMA's Regulatory Science Observatory. Operations to review include the Business Pipeline, Horizon Scanning, Innovation Task Force as well as Academia and SME liaisons.	No action during Q1 and Q2 of 2022 Service request completed with procurement team in August 2022 Project expected to start in November 2022
Shortages (new mandate)	EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand.	- Regulation (EU) 2022/123 adopted 25 January 2022 - iSPOC registration tool go-live in June

Clinical Studies and Manufacturing (TCS)

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual.	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**Delayed**	Annex 1 close to finalisation, Step 2 expected by Nov 2022
Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level.	3.2 (ECP 1)	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	**Delayed**	Annex 1 close to finalisation, Step 2 expected by Nov 2022
Promote the inclusion of neglected populations, such as pregnant and lactating women, the elderly, and those of diverse ethnicity in clinical trials.	3.2 (ECP 1)	Use the revision of ICH E8 and E6 to remove barriers and to encourage the inclusion of neglected populations in clinical trials.	**Delayed**	Annex 1 close to finalisation, Step 2 expected by Nov 2022.
Foster development of POC diagnostics for human and veterinary use	4.2 (ECP 1)	Inclusion of diagnostics in the discussion on new business model on the antibacterial agent	**Suspended**	The activity has been suspended and will be reviewed on the basis of an agreed AMR strategy
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.	**Delayed**	The activity is delayed as capacity has been absorbed by the two ongoing public health emergencies.
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**	Several communications activities conducted in the context of COVID and MPX
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**	NITAGs meetings are attended regularly, and feedback provided.
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**	Advisory Board and platform established as pilot in 2021 for COVID (2 meetings

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				held); studies were conducted on COVID vaccines. The platform and the board are being revised in 2022 to improve efficiency and structure, and to enlarge scope to other vaccines including monkeypox. First meeting of the new Board scheduled for October 2022, on track.

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

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Interactions with FDA	382	377	368	-[1]	-	700	700	0	0%
Interactions with PMDA/MHLW	83	72	60[2]	-[1]	-	200	150	-50	-25%
Interactions with Health Canada	105	91	93	-[1]	-	200	200	0	0%
Interactions with any other stakeholders	372	384	390	-[1]	-	700	700	0	0%
Number of information and/or document exchanges	507	512	498	-[1]	-	900	900	0	0%
Number of teleconferences organised	107	112	97[3]	-[1]	-	150	150	0	0%

[1] Data not available as tracking of activities was not a priority for Q1/Q2 in 2019
[2] 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.
[3] Higher result and revised forecast are linked to the COVID-19 pandemic and the need to arrange online conferences.

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	ICMRA executive committee and full membership TC	19	48	21[1]	-[2]	-[6]	14	25	+11	+46%
	International stakeholders' visits (fellowships, experts, observers	2	0	1[3]	-[6]	-[6]	5	5	0	0%
	Organisation of International awareness sessions[4]	0	0	0[5]	-[6]	-[6]	2	2	0	0%

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 (ECP 1, ECP 4)	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication	**On track**	Three technical workshops organized: two WS on Omicron variant and vaccine/booster composition on 12 Jan and 30 June generated a lot of attention from regulatory agencies around the world, industry and the press. A third WS was organized at EMA (hybrid) on Real World Evidence on 29-30 June. Statements were released after the workshops. The vaccine confidence

[1] The high result and revised forecast reflect the increased ICMRA work related to COVID-19.
[2] New indicators introduced in 2020 work programme
[3] The very low result and revised forecast are mainly due to COVID-19 restrictions to travelling and accessing the EMA building.
[4] No international awareness sessions for non-EU regulators were organised in first half of 2022 due to COVID-19 priorities and restrictions.
[5] Veterinary awareness session has been postponed to 2021 and no other awareness session is planned to be organised in 2020.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				statement for health practitioners was updated to include latest developments. PQKMS pilots launched. Working on rationalisation of ICMRA working groups and ways of working and planning the ICMRA Plenary in July, including the elections of Chair and Vice-Chairs for the new term.
Nitrosamines	1.1 5.5 (ECP 1, ECP 4)	Participation in Nitrosamines International Steering Group (NISG)	**On track**	Ensuring information exchange and alignment between international authorities regarding new nitrosamines acceptable intakes.
Extension of US MRA	1.1 5.5 (ECP 1, ECP 4)	Extension to vaccines and vet medicines	**On track**	*Extension to Veterinary medicines* EU audit report of FDA CVM finalised and adopted by the GMDP IWG in June. Progress continued on NCAs audits and submission of assessment packages to FDA. Draft Commission Decision on the extension of the scope including schedule of assessments under discussion with FDA. *Extension to vaccines and plasma derived products* Preparatory work has started; Joint/observed inspections are being organised; Technical group (EU+FDA) was set up and first meeting took place.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				JSC agreed to postpone the decision on whether to include vaccines and plasma derived products in the MRA scope ; this should be done on the basis of the experience from joint/observed inspections and due to COVID-19 pandemic it was not possible to get such experience yet. *Improvement of MRA for human medicines* A number of topics have been discussed between EC/EMA and FDA to increase the efficiency of the MRA in place. This included progress on FDA proposal for a GMP inspection summary. Joint Sectoral Committee meeting took place on 30 June. In addition to the JSC meeting there were two technical meetings in March between EMA and EC and FDA to discuss amongst others MRA related topics. FDA conducted two inspections in India (Bio E DS and DP sites) on behalf of EU for Janssen vaccine, under the EU-US MRA. First third-country biological inspection recognised under MRA. - Internal discussions, with GMDP IWG and with FDA on (proposals for) improvement of

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				functioning of MRA Human regarding exchange of GMP documents; - 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 (ECP 1)	Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	Takeda Dengue vaccine parallel submission ongoing. One guidance TC organised with NRAs in June 2022 to facilitate their review. 2 new EU-M4all opinions ~~(Actrapid and Insulatard)~~ - 1 withdrawal ~~(Umbipro)~~ - 2 pre-submission interaction ~~(Arpraziquantel) and Lilly (polypill in diabetes)~~. 3 Scientific advice: ~~Bedaquiline (leprosy), FUSION PROTEIN DERIVED FROM MYCOBACTERIUM TUBERCULOSIS ANTIGENS MTB32A AND MTB39A (tuberculosis) , Ivermectin (malaria)~~ Technical discussions with 4 Opinion Holders to understand how the EMA could better support applicants in the post opinion phase. Pre-submission interactions with Medicines Patent pool on potential use of Art 58 for generics of covid therapeutics.
Reliance on scientific output of EMA committees	1.2 (ECP 1)	Promote reliance on scientific output of EMA committees by non-EU regulators, in particular through WHO facilitated pathways	**On track**	7 QIS validated for CRP since January 2022, for 4 new products and post-authorisation updates.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				'Presentations given in the following meetings: Monitoring the Safety of Marketed Medicines and Vaccines: Learning from International Good Practices - World Bank Group - February, 2022 Second Facilitation meeting for Janssen Ebola registration in Africa with 14 NRAs and WHO- May 2022 EU regulatory system Collaboration pathways and reliance - EU-Africa pharma and healthcare webinar May 2022 WHO-EMA Collaborative Registration Procedure – Advocacy workshops with national regulators in Africa, Asia and Latin America, June 2022. Preliminary discussions (with Quality Innovation Group) with industry on innovative technologies for local vaccine manufacturing in Africa.
Develop International collaboration and reliance including through Confidentiality Arrangements in accordance with defined priorities	6.5	Update existing and putting in place new confidentiality arrangements	**On track**	Priorities for work on new Confidentiality Arrangements discussed and agreed with Commission once the current on-going negotiations for a CA with PIC/S is completed. Draft CA with PIC/S text agreed with Commission and submitted to PIC/S for agreement before signature.
Capacity building	6.1	- Increased visibility of EMA	**On track**	As it is not possible to have face-to-face meetings in Amsterdam in 2022, request to

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
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.		- Training on acquis Communautaire of candidate and accessing countries		DG-NEAR including an extension of the deadline of the project to the end of 2023 submitted to DG NEAR. Consultation with contact points in IPA beneficiaries countries for training webinars in 2022 and face-to-face training in 2023 started. Agreement to include IPA beneficiaries countries plus Ukraine, Moldova and Georgia in the EU-NTC reached.
Supply chain	5.2	Work with project on shortages, on API with priority countries China project on API	**On track**	EMA participated regularly in the meetings and work of the Global Shortages and API clusters. In addition, contacts and a meeting took place with FDA to discuss specific shortages due to Ukrainian crisis. Preparatory work to establish a more systematic bilateral collaboration with FDA in the shortages area took place.
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	**On track**	Due to the pandemic and the crisis caused by the war in Ukraine, little activities on this aspect (on advice from European Commission). Discussion with India on future ICH and PIC/S membership will start in July 2022.
OPEN project	6.5	Active collaboration of selected regulatory authorities in CHMP and	**On track**	5 authorities included in the OPEN pilot (Australia, Canada, Japan, Switzerland,

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		European Task Force for COVID-19 MEDICINES		WHO). Continued participation in ETF and CHMP. One-year review completed and published in the March management board meeting documents. Stakeholders Meetings: Review meetings with Australia, Canada, Japan and Swizerland. OPEN presented at DIA Europe (March 2022), PCWP/HCPWP meeting (June 2022), and Industry stakeholder meeting (June 2022). Engagement with H-TA and others on operationalisation of OPEN as part of CHMP work plan for 2022.
Active participation in WHO activities, international fora and communication to stakeholders, including but not limited to ICDRA, DIA, ICH, IPRP.	1.1 (ECP 1, ECP 4)	Promote convergence of global standards and contribution to international fora	**On track**	Participation at Athens ICH and IPRP as part of EC, Europe delegation. Participation at DIA Euro and Annual Global meetings. WHO ICDRA preparations on hold pending WHO 'go/no go' decision for 2022 meeting. WHO awareness session for EMA staff (organised but postponed to July 2022.)
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	**Delayed**	Due to COVID-19 travel inspections, international inspections largely postponed.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
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**	Launch of 2 ICMRA pilot programmes with the duration of 1 year for Collaborative Assessment of COVID-19 Related CMC Post-approval Changes and Collaborative Hybrid Inspections. Development of a joint reflection paper on PQ KMS capability with ICH, PIC/S and IPRP aiming to support greater regulatory reliance, agility, and the timely and effective sharing of information concerning the state of manufacturers' pharmaceutical quality and risk management capabilities
Increase the number of opportunities for non-EU regulators, in particular those of candidate and potential candidate countries, to participate in scientific and regulatory training activities[1].	6.1	Support training and capacity building of non-EU regulators	**On track**	Pilot project to extend EU Network Training Centre access to non-EU Regulators has progressed. Decision was taken that first phase of the pilot will include extension to International Authorities with whom EMA has a Confidentiality Arrangement in place and Authorities from accession countries. Courses to be available in this phase were identified. Communication to concerned Authorities on this was agreed.
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	**On track**	No specific trainings were delivered during the first half of the year.

[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
				Pilot project to extend EU Network Training Centre access to non-EU Regulators has progressed and will allow International Authorities to access EU trainings. Decision was taken that first phase of the pilot will include extension to International Authorities with whom EMA has a Confidentiality Arrangement in place and Authorities from accession countries. Courses to be available in this phase were identified. Communication to concerned Authorities on this was agreed.
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	**Suspended**	No international awareness sessions for non-EU regulators were organised in first half of 2022 due to COVID-19 priorities and restrictions.
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**	Due to pandemic and relationships with China (in particular) and India, no progress on this aspect. (although note engagement with India on PIC/S membership - see above)..
ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA meetings.	1.1 (ECP 1, ECP 4)	Communication	**On track**	No Plenary meetings were held in first half of year. Preparations during May/June for July Plenary. Monthly Executive Committee meetings, monthly COVID-19 Policy TCs, monthly COVID-19 Working Group meetings (disbanded in first half of year), as well as

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				support/organisation of indidivual workstream meetings.
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 (ECP 1, ECP 4)	Support to the International Affairs Division and its specific activities	**On track**	-Update of 2 guidance, including the International guidance for sharing documents -Work programme report on the overall 2021 activities -organisation of 50+ cluster meetings, teleconferences -12 documents redacted -380+ interactions with FDA -100+ interactions with Health Canada -80+ interactions with PMDA/MHLW -370+ interactions with other stakeholders -Managing 19 ICMRA meetings
Support EU and EU/MRA team meetings	5.2	Reliance and supply chain integrity	**On track**	'For the EU / US FDA MRA support was provided to two technical meetings with FDA in March (one at EMA and other at EC) as well as to the JSC meeting in June. In addition support has been provided for several operational meetings (internal, EC, FDA). No International Affairs team activities relating to operation of other functioning MRAs (e.g. Australia, Canada, Japan, New Zealand, or equivalent with Israel).
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building through providing adequate guidance	**On track**	Development of the Action Document for Regional dimension and management of the

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa to support DG INTPA annual program and EMA funding Participation in different meetings with AMRH in support the operationalization of AMA and support to local vaccine manufacturing. EMA has representative on Advisory Committee for the creation of the AMA. Submission of an article for DIA Global Forum (publication on 09/07/2022). Presentations at various stakeholder conferences and platforms.

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
Number of cases of patient/consumer engagement[1] in EMA (medicines-related) activities	275	289	358	333	200	600	570	-30	-5%
Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	200	105	64	1102	102	200	350	+150	+75%
Number of messages circulated via 'Early Notification System'	329	635	373	215	217	440	500	+60	+13%
Number of EMA communications pro-actively sent to stakeholders	109	110	101	68	100	175	190	+15	+8%
Number of EPAR summaries and EPAR summaries updates published	97	118	164	144	149	300	200	-100	-33%
Number of summaries of orphan designation published	99	0	64	55	87	120	150	+30	+25%
Access to documents, requests received	375	342	316	362	462	750	750	0	0%
Access to documents, documents released	497	568	382	792	1,364	2,000	1,500	-500	-25%
Requests for information received	4,559	5,915	3,597	3,677	3,651	10,000	10,000	0	0%
Number of documents published on EMA website	3,787	4,071	3,628	3,533	3,871	7,500	7,500	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.

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Number of pages published and updated on EMA website	1,779	1,883	1,681	1,821	2,534	3,500	3,500	0	0%
	Number of press releases and news items published	87	122	86	63	99	170	170	0	0%
	Numbers of press briefings conducted	9	18	3	-	-	20	15	-5	-25%
	Numbers of social media posts published	488	975	484	-	-	1,200	900	-300	-25%
	Completed requests for interviews and comments by media representatives	996	4,057	598	564	732	3,000	1,800	-1,200	-40%
	Number of reports, brochures, leaflets laid out or printed, social media visuals	437	300	214	33	28	500	800	+300	+60%

Performance indicators

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Satisfaction level of patient and consumers' organisations	n/a	n/a	92%	n/a[1]	n/a[2]	n/a
	Satisfaction level of healthcare professionals' organisation	n/a	n/a	90%	n/a[2]	n/a[3]	
	Triage of incoming requests received via AskEMA within set timelines[3]	100%	99%	99%	-	-	-
	Responses to ATD within set timelines[4]	90%	89%	92%	86%	92%	97%
	Responses to RFI within set timelines	95%	89%	85%	92%	96%	97%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	80%	68%[5]	82%	82%	89%	90%

[1] Questionnaire to be sent at the end of the year
[2] No survey due to BCP
[3] New indicator introduced in 2021 Work Programme
[4] Calculated according to the legal timeline stated in Regulation (EC) No 1049/2001 and from the date on which the requester is informed of the start of the procedure.
[5] Low response rate (6.4%) doesn't allow a strong conclusion on this indicator.

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	80%	n/a	n/a	-[1]	n/a[2]	n/a
	Average rating of pages on corporate website during the year	3.5	3.1	3.5	3.7	3.2	3

Achievements

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
- Design communication campaigns in collaboration with relevant stakeholders to proactively approach to key public-health areas (e.g. vaccines) - Improve communication for patients, healthcare professionals and other stakeholders including HTAs and payers - Enhance professional outreach through scientific publications & conferences	1 (additional RSS recommendation)	Delivery of communication campaigns on key topics, with focus on COVID-19	**On track**	. CTIS launch campaign delivered, including new clinical trials website (January-February) . UPD launch campaign delivered, including new veterinary medicines information website (January-February) . European Immunization week campaign delivered (April) . Strategic plan for stakeholder engagement drafted . Consolidated EMA approach to scientific publications agreed and being implemented, in line with the Executive Director's updated decision on open access .Responses to requests for open access being processed in line with expected

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

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				timelines, with17 scientific publications published . Content on COVID-19 updated on corporate website at least once a week (January-June), including 'key facts' and related pages every month (January-June) . Lines to take on COVID-19 circulated to the Network regularly (frequency adapted to the pandemic situation) . Analysis of an evaluation of the utility of communication materials on Vaxzevria finalised

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2021
e-PI pilot	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.	- ePI set-up project closed in Q1 2022 - ePI pilot launched in Q2 2022
European Medicines web portal	Providing a unified and harmonised web-portal giving access to information on medicinal products	*[possible restart in 2023 depending on resource and budget availability]*

Information Management Division

Workload indicators

Procedure		2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2019 Q1–Q2	2018 Q1–Q2	2022 annual forecast Initial	Revised	Change	
	Number of Telematics information services provided by EMA	28	13	25[1]	25	23	28	28	0	0%
	Number of ongoing Telematics IT projects where EMA is the delivery organisation[2]	7	7	4[3]	3	7	7	9	+2	+29%
	Number of ongoing non-Telematics IT projects where EMA is the delivery organisation[4]	11	10	8	5	7	6	13	+7	+116%

Performance indicators

Performance indicators related to core business		Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Satisfaction of EMA internal and external users	80%	96%	96%	88.17	84%	-
	Availability of corporate/Telematics IT systems and corporate website	98%	98.2%	99.5%	99.06	98%	99%

[1] Annual forecast equivalent to midyear expectation, as the figure represents number of services continuously provided throughout the year
[2] Since the Agency is adopting the Agile framework, this indicator is no longer relevant.
[3] EudraCT is now integrated under CTIS.
[4] Since the Agency is adopting the Agile framework, this indicator is no longer relevant.

Pillar 3 – Programmes and projects

Project title	Long term objective	Achievements/results in Q1/Q2 2022
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	- Functional and technical design completed - Migration process planned - Staff training started

Administration Division

Performance indicators/Forecast activity

Performance indicators related to core business		Forecast/ Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Posts on the Agency establishment plan filled	100%	99.5%	97%[1]	98%	99%	99%
	Total TA staff recruited against vacant posts	50	30	40	13	23	-
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	7%	4%	3%	2%	4%	-
	Time to run selection procedures from vacancy notice to establishment of reserve list	100% <3 months	2.8 months	66%[2] < 3 months	<3 months	3 months	
	Revenue appropriations implemented	97%	45%	45%	50%	41%	40%
	Expenditure appropriations implemented	95%	70%	67%[4]	75%	67%	71%
	Payments against appropriations carried over from year N-1	95%	60%	70%	87%	71%[3]	68%
The maximum rate of carryover to year N+1, of total commitments within the title:							
	Title 1	10%	n/a%[6]	n/a[4]	n/a[4]	2.19 %	1.0%
	Title 2	20%	n/a%	n/a[4]	n/a[4]	10.79%	11.8%
	Title 3	30%	n/a%	n/a[4]	n/a[4]	29.16%	31.1%
	Payments made within 30 days' time	98%	97%	97%	94%	96.13%	97%

[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] Includes C8 and C2 - at acceptable level at the end of Q2.
[4] Annual target to be reached at year-end.

Performance indicators related to core business		Forecast/ Target 2022	Outcome at the end of Q2 2022	Q2 2021	Q2 2020	Q2 2019	Q2 2018
	Receivable overdue for more than 30 days (including provision for bad debts)	<10%	3.03%	2%	8.47%[1]	-[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**	Activities at level of service are being mapped in the 2022-23 planning cycle. The activity is on target to be completed by the end of the year.
Implement the revised human resource and talent management strategy (HR strategy)	6.2	The HR strategy will consolidate practices into coherent system and practices and will lead to continuously improving approaches in domains of staff wellbeing, leadership and management, talent management and culture Staff engagement survey carried out in Q4 2022	**On track**	Challenges to be addressed by the HR strategy identified Consultation with senior management completed Consultation with Staff Committee to be planned Consultation with management planned in Oct 2022 A set of wellbeing initiatives launched. Overview of wellbeing proposals concluded. Staff survey to prioritise initiatives launched, analysis of responses is taking place.
Implement the new competency management framework	6.2	Competency framework (behavioural and technical competencies); revised role descriptions with embedded competency profiles and proficiency	**On track**	Competency framework has been developed and implemented as of 2022 Role descriptions have been streamlined and revised and competencies with

[1] New indicator included in 2020 Work Programme

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
		levels of competencies leading to higher effectiveness, contributing to job satisfaction and development opportunities.		proficiency levels were embedded in each role Competencies are in use for the purpose of development throughout 2022 Significant change management effort took place. As of 2023 competencies will be assessed during the appraisal exercise
The potential replacement of the human resource management and the financial systems taking into account the discontinuation of the support for the current system by vendors	6.4	Gradual replacement of the financial and HR system in line with the future project plan.	**On track**	The replacement of the HR and Finance system have been included within the Managing the Agency Value Stream Roadmap, which have prioritised the start of both replacements in 2023. Confirmation of starting date by the end of Q4 2022, after budget commitment approved and contract in place. Cooperation with a sister agency and the commission is taking place.
Implement the Agency's new intranet and migrate or develop related content	6.4	The new intranet implemented. Content is gradually rolled out taking into account the business capacity	**On track**	Key features of the technical solution for new intranet configured Benchmarking satisfaction survey conducted with staff Business representatives from all areas onboarded Content audit of current intranet conducted Editorial support procured and onboarded The rollout of the minimum viable product moved to Autumn.

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
Further develop the procurement and contract management practices and implement the procurement tool	6.4	The procurement and contract management process are further improved with the further developed vendor management and market research capabilities A tool supporting procurement processes implemented	**On track**	On-boarding of the business units was done as planned. As of the end of June 2022, the Finance department provided a centralised procurement service to all divisions except the Administration that will be onboarded in July and September 2022. The documentation for procurement has been revised and new manuals were drafted: vendor management guidelines, market intelligence guidelines, IT sourcing strategy. An extensive market analysis to identify a suitable tool to support procurement activities completed. The EC's proposal for procurement and contract management activities (E procurement suite) has been selected and the module to support the procurement procedures, PPMT, is ready for use. The procurement team has been trained. During the second semester the tool will be used for 2 pilots procurement procedures and targeted business colleagues will be trained. The aim is to use PPMT tool for all procurement procedures as of the 1st January 2023.
Implement the revised risk management (RM) process	6.4	The new process adopted and implemented The tool facilitating risk management implemented	**On track**	RM IT development: configuration and testing completed. RM Training completed

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				Top down risk assessment Interview with HoDs completed Top down risk assessment report: drafting in progress. Communication plan: on track
Implement the project governance in line with Agile development approach	6.2	The Agile portfolio office implemented in line with the implementation of the Agile governance and taking into account lessons learned from the ongoing pilots	**On track**	The new Agile governance is being implemented with 10 (out of 22) number of projects transitioned to the new approach. All projects (20) will be transferred to agile by the end of 2022 and 2 will be closed.
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**	An Epic, "New Fee regulation" has been created within the "Managing the Agency" value stream. Work to optimise, redesign and further automated the revenue (billing) and expenditure (to NCAs) processes will start in the second semester. The Finance department is using the opportunity of the new Fee Regulation to also optimise the existing processes. The analysis will be done on the basis of the draft legislative proposal for New fees that will be available in September 2022. The targeted introduction of new fees is 2024.
Improve efficiency of certain administrative processes	6.3	The identified improvement in the accounts receivable (AR) and customer data management processes implemented	**On track**	Business analysis was carried out during Q42021-Q12022. The outcome of the analysis was categorised under three key streams: a) SAP FIN AR enhancements,

Action	MAWP Strategic Goal	Expected result	Status	Achievements/results
				currently being implemented via SAP Platform Contract; b) One-Stop-Shop solution for applicants, to be address via CRM business strategy; c) CMD, to be mastered within OMS (SPOR) in order to share the common information across systems. Implementation of the identified improvements is ongoing.
Implement the administrative aspects of the extended mandate	6.3	The processes to manage procurement and payment processes in relation to the medical device expert panels are implemented	**On track**	All updated contracts with Experts were issued (around 250). The financial circuit are set up, with the 1st payments to be done in September 2022. A-FI-PPS and -FSS supported the drafting of technical requirements for the new Expert database as well as the project itself.

Annex 2: Project progress and delivery

Project progress and delivery as of 30 June 2022 against what was planned in the work programme 2022 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 2022, in comparison to what was planned and approved at the end of 2021 (i.e. as noted in the work programme 2022). Notes explaining the changes are added.

In cases where the project starts or end dates foreseen in the work programme 2022 were revised during Q1 and Q2 2022, the current dates are added in the relevant cells, with the original date from the work programme 2022 shown as crossed out.

Programme / project	Legal basis	Start date	End date	Project delivery against Time Budget Scope	Results Q1-Q2 2022
Information Security Programme					
Security Awareness **Integration of Critical Systems** **Identity Management** **PKI Infrastructure** **Data Sharing**	n/a	~~Q1 2022~~ Q4 2022	~~2024~~ 2025		• Contracts/procurement process ongoing
External User Journey	n/a	Q1 2022	Q4 2022		• Go-live of enhanced Self-service Registration • Enhanced integration with OMS • Roll out of communication plan
Clinical Trials programme					
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR)	Regulation (EU) 536/2014, art.80-82	Q3 2014	2023		• Go-live 31 January 2022 • Post-go-live releases • Communication and training ongoing • Hypercare period until July 2022
Safety Implementation Regulation - cooperation in safety assessment (CTIS scope extension)	Art. 11(3) of Implementing Regulation C(2022)30 to Regulation (EU) 536/2014	Q3 2021	2023		• Go-live 31 January 2022 • Continued communications, training programme and related documentation • First Annual Safety Report submitted in CTIS in June
New Veterinary Medicine Regulation Programme - VMP-Reg					
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2022		• Go-live 28 January 2022
UPD - Union Product Database	Regulation (EU) 2019/6; associated implementing act	2020	Q3 2022		• Go-live 28 January 2022 • New version released every 3-4 weeks • Improvements to all UPD components

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2022
				Time	Budget	Scope	
ASU - Collection of Antimicrobials Sales and Use Data	Regulation (EU) 2019/6; associated implementing act and delegated act	2021	2023				• Completed integration with one external party (Eurostat) • The development of the transactional and analytical part is ongoing, including the integration with other systems. The drafting of the protocols and templates for reporting the data is also on going. •
MWD (formerly EudraGMDP) - Union Manufacturers and Wholesale Distributors Database	Regulation (EU) 2019/6; associated implementing act and delegated act	2021	~~Q2 2022~~ Q3 2022				• Go-live 28 January 2022
Regulatory Business Process Optimisation Programme - RBOP							
EMA extended mandate implementation Monitoring and mitigating shortages of critical medicinal products and management of major events Monitoring and mitigating shortages of critical medical devices Medicinal Products with the potential to address public health emergencies (PHE) Support of medical device expert panels	Regulation (EU) 2022/123	2022	2023				• Regulation (EU) 2022/123 adopted 25 January 2022 • iSPOC registration tool go-live in June
SPMS Substances and products management services (SPM&S) EU SRS	Art.4 of Guideline on e-prescriptions dataset for electronic exchange under	2017	2024				• Development of interface and data migration to support IRIS • EU SRS handover preparations ongoing for handover in Q4 2022

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2022
				Time	Budget	Scope	
	cross-border Directive 2011/24/EU Regulation (EC) No 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 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						
IRIS Platform to support regulatory business processes of the Agency	n/a	2019	2025				• GCP Inspections in IRIS from April 2022 • Variations process started in Q1 2022
ePI pilot	n/a	2022	2023				• ePI set-up project closed in Q1 2022 • ePI pilot launched in Q2 2022
European Medicines web portal [possible restart in 2022 depending on resource and budget availability]	Regulation (EC) No 726/2004 Regulation (EC) No 1235/2010, art.26	2022	2023				*[not started]*

Programme / project	Legal basis	Start date	End date	Project delivery against Time Budget Scope	Results Q1-Q2 2022
IT Infrastructure & Legacy; Admin Digitalisation					
Replacement of Document Management System (DREAM replacement)	n/a	2021	2023		• Functional and technical design completed • Migration process planned • Staff training started
Data Centre 2.0	n/a	2022	2023		• Impact assessment on how to move to a cloud-based data centre solution
SAP Finance	n/a	2021	2025		• Options are being assessed for replacing old SAP Finance
Optimisation of the Administration supporting tools	n/a	2019	2024		• Intranet: technical configuration completedRisk Management: technical configuration completed
Digital Workspace TRIP [possible start in 2022 depending on resource and budget availability]	*n/a*	*2022*	*2023*		*[not started]*
Digital Business Transformation					
eCTD4: Implementation and adoption of eCTD v4.0 standard	n/a	~~Q4 2021~~ Q1 2023	2023		*[restart in 2023]*
Other Digital Business Transformation initiatives		2021	2025		• Digital Innovation Lab started five new DigiLab projects and worked with Analytics Centre of Excellence (ACE) to pilot five solutions to business challenges • First Chatbot launched in May 2022 • Virtual Reality proof of concept completed • EMA Digital Academy pilot with three modules
Data Analytics Programme					

Programme / project	Legal basis	Start date	End date	Project delivery against			Results Q1-Q2 2022
				Time	Budget	Scope	
Lifecycle Regulatory Submissions Raw Data	n/a	2021	2024				• Initiated implementation and gathering of business requirements • Initiated communication and training • Business process ad operating model design completed
Lifecycle Regulatory Submissions Meta Data	n/a	2020	2022				• Scientific Advice advanced Analytics pilot: present report/demo UI
Observational Studies DARWIN EU ** Real-world Metadata and Rapid Analytics merged with DARWIN into one project in Nov 2021*	n/a	2021	2025				• DARWIN EU coordination centre established and operational • Metadata list adopted and published on Big data website • CHPM pilot initiated
*Real-world Metadata, Quality Framework and Catalogues **	n/a	2020	2025				*[Included above]*
*Observational Studies Rapid Analytics **	n/a	2020	2022				Scientific officers and EMA Committee members identified to identify research needs. Screening of confirmed PRAC signals IHD rapid data analytics software in place 36 feasibility analyses and 17 complete studies performed
Signal and Safety Analytics	n/a	2021	2023				• Collection of IT and business requirements for the design of the new EVDAS platform/eRMR solution/ADR website

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, since June 2022 WOAH	World Organisation for Animal Health
PASS	Post-authorisation safety study
PBT	Persistent bio accumulative 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
PSUSA	PSUR single assessment
Q (1, 2, 3, 4)	Quarter (1, 2, 3, 4)

Term/abbreviation	Definition
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