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Mid-year report 2024

Prepared by the Executive Director of the European Medicines Agency (EMA) and presented to the Agency's Management Board on 3 October 2024.

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Key developments

In the first half of 2024, the European Medicines Agency (EMA) made substantial progress in the three main focus areas identified in the Single Programming Document (SPD) 2024-2026, while continuing to deliver on its overall strategic priorities. This section highlights the achievements in these areas as well as other key developments that occurred during the first half of the year.

Main focus areas

Work on improving approaches to assessing key medicines continued in 2024, with the Agency building on the progress made in 2023. As envisaged in the SPD, the Agency has been using haematology and oncology products as pathfinders to enhance the assessment of key medicines, strengthen collaboration with stakeholders and improve communication on benefits and risks.

The Agency also continued its efforts to enhance the translation of innovation into medicines that reach patients, using initiatives such as the Data Analysis and Real-World Interrogation Network (DARWIN EU) and the Accelerating Clinical Trials in the EU (ACT EU) to improve evidence generation. DARWIN EU is a coordination centre, established by EMA and the European Medicines Regulatory Network, that enhances the capability to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the EU. ACT EU is a multi-annual programme aiming to create a favourable environment for research and development in life sciences, through harmonisation, innovation and collaboration with stakeholders.

The establishment of DARWIN EU is now complete, and the network currently operates with 20 public and private institutions from 13 European countries. In the first half of 2024, 12 new studies were initiated via DARWIN EU. The onboarding of new data partners is on track, and the network aims to onboard a total of 10 data partners in 2024. These data partners generate real-world evidence (RWE) from sources such as hospitals, primary care providers, health insurers, registries and biobanks to support the regulatory activities of EMA's scientific committees and national regulators in the EU.

In the context of the ACT EU initiative, the Agency established a multi-stakeholder platform (MSP) in March. The platform fosters collaboration and promotes open dialogue around the challenges and opportunities represented by advances in clinical trial regulation, methodologies and technology for the benefit of EU citizens. Topics for discussion include clinical trial design and conduct, statistical analysis, proposals for regulation optimisation, transparency of data and patient engagement. The MSP advisory group provides strategic and operational advice and comprises representatives from key stakeholder groups directly impacted by clinical trial-related activities in the EU.

With respect to the third main focus area — preparing for the revision of the general pharmaceutical legislation — the Agency has been conducting a series of preparatory activities, exploring innovative ways to design more efficient and data-driven approaches and providing regular internal updates on the proposed legislation.

One Health and antimicrobial resistance

One Health is an integrated approach that recognises that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely linked. In the area of

One Health, EMA joined forces with four other EU agencies - the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA) and the European Food Safety Authority (EFSA) — to launch a joint framework for action to strengthen cooperation on the implementation of the One Health agenda in the EU. A cross-agency task force will work on implementing the joint framework over the next three years (2024-2026), with the aim of ensuring that the scientific advice provided by the agencies is increasingly integrated, that the evidence base for One Health is strengthened and that the agencies are able to contribute with a common voice to the One Health agenda in the EU.

EMA also joined forces with the ECDC and EFSA in the area of antimicrobial resistance (AMR), publishing the fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals (JIACRA IV). Taking a One Health approach, the report presents data primarily collected between 2019 and 2021 on antibiotic consumption and AMR in Europe.

To support Member States in the crucial work of collecting data on the sale and use of antimicrobials in animals, EMA launched the new Antimicrobial Sales and Use (ASU) platform in the month of January. The new platform addresses the obligation for annual data submission which is one of the measures to fight antimicrobial resistance set out in the Veterinary Medicinal Products Regulation (Regulation (EU)2019/6). The platform streamlines the submission of data by Member States, strengthens the analysis and identification of trends in antimicrobial consumption in the EU and the wider European Economic Area (EEA), and provides insights for participating countries on the impact of their measures relating to the prudent use of antimicrobials in animals.

Managing medicines shortages

In the month of April, the Medicines Shortages Steering Group (MSSG) published recommendations to address vulnerabilities in the production and supply of medicines in the Union list of critical medicines and to strengthen their supply chains. The Agency continued the management of requests for the Solidarity Mechanism under auspices of the MSSG to support Member States experiencing critical shortages of important medicines when all other options have been exhausted.

On 1 July, the MSSG organised a multi-stakeholder workshop on shortages of glucagon-like peptide-1 (GLP-1) receptor agonists with the aim of clarifying the needs and challenges of the different stakeholder groups in the context of these shortages and sharing experiences with ongoing activities to mitigate and prevent shortages. The workshop also aimed at identifying novel solutions to mitigate and prevent shortages of these medicines and further strengthen cooperation and coordination amongst all stakeholders.

The Clinical Trials Information System

In June 2024, the revised transparency rules for the Clinical Trials Information System (CTIS) became applicable. The launch of the new version of CTIS allows for earlier and more efficient access to information about clinical trials in the European Union for patients, healthcare professionals and other stakeholders. As a result of the new rules, information on approximately 4,000 clinical trials with

issued decisions are now publicly accessible. The CTIS portal will add information on approximately 500 newly authorised clinical trials per month.

International cooperation and stakeholder engagement

In the area of international cooperation, the Agency started the year with the launch in January of a project to support regulatory systems at national and regional level in Africa and to assist in the setting up of the African Medicines Agency (AMA). The Agency is providing support to AMA and its technical committees and is assisting in the establishment of its governance, scientific and administrative processes. EMA is also sharing expertise on the assessment of medicines. The project is being implemented in collaboration with African, European and international stakeholders and is supported by a grant from the European Commission. A call for proposals was launched in April for a training programme for regulatory professionals working for national competent authorities in sub-Saharan African countries. In June, EMA hosted two visits of assessors and inspectors to receive dedicated training.

In the area of stakeholder engagement, the Agency published the biennial report on stakeholder engagement activities, covering activities involving the Agency's key stakeholder groups: patient and consumer organisations, healthcare professional organisations, academia and EU industry trade organisations. The report highlighted key topics, such as the EU clinical trial initiative ACT-EU, as well as targeted engagement activities with each stakeholder group.

Legal developments

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law or procedural irregularities continues to remain significant. EMA is currently involved in 10 court cases, without the assistance of outside counsel. During the first half of 2024, two significant judgments were delivered by the Court of Justice of the European Union.

In Case C-291/22 P (Hopveus), the Court of Justice set aside the first instance judgment in Case T-556/20 and annulled a Commission decision refusing the granting of a marketing authorisation for a medicinal product. In its judgment, the Court of Justice provided important guidance in relation to the organisation and impartiality of EMA's scientific advisory groups and ad hoc expert groups.

In Case T-416/22 (HES), the General Court sided with the Commission and EMA by confirming the lawfulness of the recommendation from the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) to suspend several marketing authorisations due to the risks of off-label use.

In the Inter-Agency Legal Network, EMA continued to lead the working group on transparency and ethics and the anti-fraud workstream, building on its previous experience and cooperation with the European Anti-Fraud Office (OLAF).

Information technology

During the first half of 2024, progress on automation of regulatory procedures and enhancement of the delivery of new products was delivered. All centrally authorised products (CAPs) and nationally authorised products (NAPs) are now covered by the central Product Management Service (PMS) and

can be viewed through a new product user interface (PUI). A new CAPs variation electronic application form has been introduced, and several EMA regulatory procedures are transitioning from legacy systems to the modern platform, using central products from PMS. Additionally, the electronic product information initiative has been successfully piloted, and the adoption of the eCTD4 standard is currently in the proof-of-concept stage. Systems already deployed such as the Union Product Database (UPD), the ASU platform and CTIS are being continuously simplified and modernised wad delivered.

A significant step towards operational excellence was marked when the Paediatrics, Variations, PMS (for CAPs) and PUI read pages on the IRIS platform went live. In SPOR, a major upgrade was the initial load of all authorised products in XEVMPD to PMS together with the near-real time sync from XEVMPD to PMS for updates. The go-live of the PMS Read application programming interface for industry which provides an automated way for stakeholders to access medicinal product data in PMS.

In line with EMA's Cloud Strategy, the decommissioning of the physical data centres hosted in Hamburg was completed as of March 2024. This milestone makes EMA the first EU agency to become fully operational from cloud-based, software-defined data centres (SDDCs). SDDCs enhance EMA's cybersecurity and facilitate the adoption of state-of-the-art technology (e.g. artificial intelligence (AI) and quantum computing) to support its mission of protecting human and animal health.

In April 2024, the first inter-agency technology innovation workshop was hosted at EMA in collaboration with other EU health agencies (ECHA, EFSA and ECDC) and the European Commission. The workshop provided a platform for participants to share experiences and best practices and to discuss upcoming opportunities and potential areas for collaboration in the fields of artificial intelligence, interoperability and innovation.

Finally, the Agency has been exploring, developing and piloting solutions that leverage AI capabilities to support regulatory decision-making. Scientific Explorer, an AI enabled knowledge-mining solution for EU regulators, was launched to enable staff and the EU Network to extract scientific information from regulatory documents, simplifying their daily work by enabling easy, focused and precise searching, improving efficiency in regulatory procedures and increasing the quality and consistency of scientific outputs. Other AI solutions that simplify day-to-day work of EMA staff and increase productivity are also being evaluated.

Key figures

This report describes the results and achievements of the Agency, working closely with the NCAs, during the first six months of 2024, and thus reflects the situation as of 30 June 2024. Here below we highlight the most relevant deviations from the annual work programme, registered in the first half of 2024. 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** increased by 16% compared to the first half of 2023, with 402 requests received in Q1/Q2 2024 (348 in Q1/Q2 2023). The annual forecast is revised downwards from 770 to 733.

The number of **novel technologies qualification advice/opinions** saw a significant decrease compared to the first half of 2023 with 8 opinions, compared to 13 in the first half of 2023 and a revised forecast of 14 for full the year 2024.

The applications for **orphan medicinal product designation** decreased by 10%, with 104 applications received (compared to 116 in the first half of 2023), and with a downwards revised annual forecast of 210 (initially 280).

Initial evaluation activities

New non-orphan medicinal products applications have for the second time seen an increase of 12% in the first half of the year (19 vs 17 applications in Q1-Q2 2023), and the forecast has been revised from 43 initially to 51 for the full year 2024.

Similar biological products have more than tripled (25 in Q1-Q2 2024 vs 8 in Q1-Q2 2023). New **orphan medicinal products also** increased in comparison to the first half of 2023 (11 in Q1-Q2 2024 vs 8 in Q1-Q2 2023).

The number of **companion diagnostics opinions** was significantly lower than the forecast, with 6 opinions and a forecast of 30 opinions for the whole year 2024.

Post-authorisation activities

The number of **type IA** variation applications remained stable compared to Q1-Q2 2023 (1,797 received), whereas **type IB** variation applications saw a 15% decrease compared to the same period (1,739 vs 1,470 applications). **Type II** variation applications increased by 14% (499 vs 571).

Transfer of marketing authorisation applications were significantly higher (29 applications in the first half of 2024, by contrast 15 were received in the same period in 2023). The initial forecast is corrected downwards for the full year 2024 from 64 to 53.

Article 61(3) applications remained high for the fourth consecutive year (142 applications) and the annual forecast remains unchanged (200 applications).

In Q1/Q2 2024, **Plasma** Master File annual update and variation applications remained stable in comparison to first half 2023 levels, with 7 applications received and the annual forecast of 25 is maintained for the full year 2024.

Pharmacovigilance

The number **Individual Case Safety Reports (ICSR) for CAPs** (reports received) was 18% lower than in the first half of 2024, with 648,116 reports received (2023 Q1-Q2: 787,783). The annual forecast is 1.3 million reports.

Assessment activities for veterinary medicines

The number of **Scientific advice requests received** was higher in the first half of 2024, with 14 received in Q1/Q2 2024, in comparison to 3 in the first half of 2023.

Requests for classification as limited market under Article 4(29) and eligibility under Article 23 dropped (4 requests in the first half of 2024, 9 in the first half of 2023). The initial forecast of 20 requests was revised to 10.

Initial evaluation applications decreased compared to Q1-Q2 2023 (11 vs 15 applications). The forecast for the full year 2024 however has been revised upwards from 18 to 33 applications, based on the number of intents to submit received.

The number of **variation applications** requiring assessment overall was 5% lower than in the first half of 2023, however, the forecast of the variation applications has been revised upwards from 267 to 304.

The number of **Signals** forecasts for the full year 2024 have been revised: for **Signals classified for close monitoring by MAH** (40 vs 80 initially forecast), and **Signals submitted by Regulatory authorities following risk-based review** (40 vs 80 initial forecast).

The number of **adverse event reports** (**AER**), 80,563 reports in total, increased in comparison to the first half of 2023 (14% overall increase, CAPs 29% increase, NAPs 5% decrease).

Inspections and compliance

The number **good manufacturing practice (GMP)** inspections saw a decrease of -10% with 189 inspections in comparison to the first half of 2023 (210 inspections). The forecast is revised upwards from initial 300 to 327 for the entire year.

Good clinical practice (**GCP**) inspections were 13% higher (53 inspections) in comparison to the first half of 2023 (47 GCP inspections in Q1-Q2 2023).

Plasma Master File (**PMF**) inspections showed for the second consecutive year a notable growth (107 inspections compared to 88 in the first half of 2023). The annual forecast is lowered from 158 to 134 initially estimated.

Standard certificate requests remained stable first half of 2024 (2,387 vs 2,486) while **urgent certificate requests** were 20% lower, with 487 requests received versus 612 in the first half of 2023.

1,365 **parallel distribution initial notifications** were received in the first half of 2024, the initial forecast was revised upwards from 2,125 to 2,200 for the full year; **parallel distribution annual updates** remained stable (2,804 received), and the forecast is revised downwards from 5,640 to 5,430.

Committees and working parties

The number of **plenary meetings and MB** remained stable in the first half of 2024 overall. Face-to-face Working parties have slightly decreased in the first half of 2024. The other meetings including workshops and seminars increased by 15% in comparison to the first half of 2023. This results from the AMA activities and the increase of collaborating experts visiting the Agency. The number of **virtual meetings** has decreased in comparison to the first half of 2023 (1,800 vs 2,300). However, the total number of meetings in 2024 is expected be the same as in 2023.

Information and transparency

The number of **Clinical Data Publication procedures published** was significantly higher (40 publications in the first half of 2024, and 27 in the first half of 2023). This is mostly due to phase 1 of the relaunch of CDP activities, the first publication of which was in January 2024. The forecast has been revised to 80 publications from initially 45. The volume of documents published significantly increased, (3,271 documents in the first half of 2024 compared to 471 in the first half of 2023).

The number of Requests for access to documents (ATD) (254 requests received) was significantly lower in the first six months of 2024 in comparison to the same period in 2023 (416 requests in Q1-Q2 2023). It should be noted that despite all efforts to forecast the number of ATD requests, we cannot predict the level and area of interest of our external stakeholders.

The number of **requests for information** has moderately increased by 6% (3,835 requests received in the first half of 2024 compared to 3,642 in the first half 2023).

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted Annual Work Programme 2024. The forecasts of the workload indicators are revised during the mid-year reporting exercise to take into account the latest operational developments.

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% (included) 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

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.

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

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

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 2024'. For performance indicators that are expressed as a percentage, the mid-year target is assumed to be equivalent to the annual target.

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

Human Medicines Division

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Total scientific-advice and protocol-assistance requests	402	348	470	427	392	770	733	-37	-5%
Parallel scientific advice with international regulators requests	0	2	4	3	4	4	2	-2	-50%
Joint scientific advice with HTA bodies requests	2	3	3	2	1	3	3	0	0%
Scientific advice for PRIME designated products	19	-	-	-	-	42	34	-8	-19%
Protocol assistance	80	59	75	80	65	136	130	-6	-4%
Novel technologies qualification advice/opinions	8	13	14	14	9	23	14	-9	-39%
PRIME eligibility requests received	30	25	25	29	28	60	60	0	0%
Applications for orphan medicinal product designation	104	116	157	134	123	280	210	-70	-25%
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	327	362	346	368	339	718	718	0	0%
Requests for classification of ATMPs	24	25	25	46	54	50	45	-5	-10%

1.2 Initial evaluation activities

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
New non-orphan medicinal products	19	17	14	23	28	43	51	8	19%
New orphan medicinal products	11	8	12	10	17	30	29	-1	-3%
Similar biological products	25	8	4	4	7	17	36	19	112%
Generic, hybrid and abridged products	9	8	9	12	12	22	17	-5	-23%
Scientific opinions for non-EU markets (Art 58)	1	0	0	0	0	1	1	0	0%
Paediatric-use marketing authorisations	2	1	0	0	1	0	3	3	-
Number of granted requests for accelerated assessment	3	5	0	7	10	12	12	0	0%
ATMP marketing application authorisation requests received[1]	4	2	1	3	6	11	11	0	0%
COVID-19 related product applications received[1]	-	2	5	14	6	4	n/a	-	-
Companion diagnostics opinions[2]	6	3	-	-	-	30	30	0	0%

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

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Average assessment time for new active substances and biosimilars – *reversal of traffic lights*	205	203.75	190.00	199	199	198
Average clock-stop for new active substances and biosimilars – *reversal of traffic lights*	180	239.00	185.00	229	168	175
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	50%	66.66%	50.00%	33%	33%	60%

1.3 Post-authorisation activities

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Type IA variations	1,797	1,772	1,778	1,961	1,978	3,985	3,624	-361	-9%
Type IB variations	1,470	1,739	1,606	1,393	1,301	3,632	3,305	-327	-9%
Type II variations[3]	571	499	617	606	630	1,216	1,261	45	4%
Line extensions of marketing authorisations	17	18	11	16	24	30	25	-5	-17%
Renewal applications	48	54	58	49	44	80	64	-16	-20%
Annual reassessment applications[4]	15	12	9	8	7	31	31	0	0%

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

Procedure						2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Transfer of marketing authorisation applications	29	15	25	30	27	64	53	-11	-17%
	Article 61(3) applications	142	149	104	124	66	200	200	0	0%
	Post-authorisation measure data submissions	531	571	680	519	403	925	925	0	0%
	Plasma Master File annual update and variation applications	7	6	8	7	18	25	25	0	0%

Performance indicators

Performance indicators related to core business		Target 2024	Outcome at the end of				
			Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Average assessment time for variations that include extension of indication – *reversal of traffic lights*	180	191.73	177.51	171	162	160

1.4 Referrals

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Pharmacovigilance referrals started	1	2	4	2	2	5	3	-2	-40%
Non-pharmacovigilance referrals started	2	2	0	7	5	8	6	-2	-25%

1.5 Pharmacovigilance

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of signals peer-reviewed by EMA	792	822	1,126	858	1,015	1,800	1,300	-500	-28%
Number of ICSRs for CAPs (reports received)[5]	648,116	787,783	1,348,258	1,458,522	-	1.5M-2.5M	1.3M	-	-
Number of signals assessed by PRAC (validated by EMA)	23	25	26	33	25	40	40	0	0%
PSUSAs (CAPs only) started[6]	300	253	-	-	-	643	622	-21	-3%

[5] New indicator introduced in 2021 Work Programme.
[6] New indicators introduced in 2022.

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
PSUSAs (mix CAP/NAP) started[6]	26	18	-	-	-	48	48	0	0%
PSUSAs (NAPs only) started[6]	118	107	-	-	-	288	285	-3	-1%
Number of imposed PASS protocol procedures started	3	2	6	4	0	4	4	0	0%
Number of imposed PASS result procedures started	2	4	2	6	3	4	4	0	0%

1.6 Inspections and compliance

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
GMP inspections	189	210	89	77	127[7]	300	327	27	9%
GLP inspections	1	2	1	0	0	0	1	1	-
GCP inspections	53	47	53	15	39	80	78	-2	-3%
Pharmacovigilance inspections	12	13	10	10	3	12	17	5	42%
PMF inspections	107	88	20	20	16[8]	158	134	-24	-15%

[7] 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.
[8] The result has been affected by travel restrictions due to the COVID-19 pandemic.

Procedure							2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Notifications of suspected quality defects	108	127	131	87	87	250	250	0	0%
	Medicinal products included in the sampling and testing programme	33	75	94	94	70	70	66	-4	-6%
	Standard certificate requests received	2,387	2,486	2,012	1,938	1,538	4,588	5,367	779	17%
	Urgent certificate requests received	487	612	591	987	729	1,186	1,125	-61	-5%
	Parallel distribution initial notifications received	1,365	1,038	1,012	1,537	1,141	2,125	2,200	75	4%
	Parallel distribution annual updates received	2,804	2,742	2,851	2,331	7,778[9]	5,640	5,430	-210	-4%

Performance indicators

Performance indicators related to core business		Target 2024	Outcome at the end of				
			Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Standard certificates issued within the established timelines (30 working days)	90%	100.00%	100%	100%	99%	97%
	Average days to issue standard certificate[10] – *reversal of traffic lights*	15	5.00	4.80	3	16	26
	Urgent certificates issued within established timelines (2 working days)	98%	99.00%	100.00%	100%	99%	98%
	Parallel distribution initial notifications checked for compliance within the established timeline	98%	99.00%	99.00%	98.80%	98.80%	98%

[9] 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.
[10] In 2022 and 2023, 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						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of reimbursed meetings	151	151	24	0	52[11]	323	323	0	0%
Committee meetings[12]	25	26	11	51	15	76	76	0	0%
Working Parties	29	28	-	-	-	44	44	0	0%
Workshops, Forum, Seminars, Infoday	27	31	-	-	-	38	38	0	0%
Other meetings	58	48	-	-	-	165	165	0	0%
Number of virtual meetings (audio-, video- and web conferences)	1,800	2,300	3,000	3,220	2,660	6,500	6,500	0	0%
Number of reimbursed delegates	1,942	1,680	309	0	1,003	6,800	6,800	0	0%
Number of non-reimbursed delegates	718	517	44	7,129	60	1,500	1,500	0	0%
Herbal monographs, new	0	0	2	2	0	3	1	-2	-67%
Herbal monographs, reviewed[13]	7	12	19	8	5	20	15	-5	-25%
Herbal monographs, revised	8	2	1	0	5	5	8	3	60%
EU herbal List entries	2	0	0	0	0	1	2	1	100%

[11] The significant variation in the figures is due to the COVID-19 outbreak.
[12] Including Management Board meetings. Committee meetings held physically and remotely.
[13] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100.00%	100.00%	100%	100%	100%

Pillar 2 – Public health activities

Achievements

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Support the STAMP scientific advice pilot for repurposing established medicines	1.1 (ECP 1, ECP4)	Several prioritised established medicines are enlisted in the pilot	**On track**	Last scientific advice for the selected projects was completed in April 2024. Now that all SA for the selected projects have been completed, gathering and analysis of data on the candidates projects and SA outcome for the selected projects is ongoing to form the basis for the drafting of the repurposing report.
Provide parallel/joint EMA/HTA body scientific advice, also in anticipation of and with the new HTA Regulation	1.2 (ECP 1)	Scientific evidence for marketing authorisation is serving different decision-makers	**On track**	Seven applications were received, of which four have been accepted as parallel HTA/EMA scientific advices.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Discussion Meetings have already been concluded for two of these. Of the successful applications, three were for oncology products. In terms of applicants, one was from an SME-company. For the accepted procedure there were between three and four active HTA-participants per procedure and between six and eight HTA observers.
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**	Integration of learnings from the EMA/EUnetHTA review of recommendation for the optimisation of the CHMP AR into the ongoing Revamp project. Regular contributions to meetings of MEDEV/ESIP, providing feedback on completed product evaluations.
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	3.1 & 5.5 (ECP 1)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	**On track**	QIG: fully operational, 3 LLFG meetings delivered, product support mechanism established, guidance development, knowledge building/sharing ongoing, FDA

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
manufacturing technologies and 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				collaboration initiated, action plan agreed and regular touchpoints set-up PQKMS: ICMRA pilots completed (3 inspection, 5 assessment) Risk-based approaches: Variation classification GL revision ongoing to incorporate risk-based/science driven principles (finalisation by November 24 expected), risk-based approach and toolkit in development for BWP/QWP (finalisation by End 2024)
Deliver tailored engagement with academics and the community of ATMP developers (pilot) Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant guidance, e.g. on the safety and efficacy follow-up of ATMPs (guidance)	3.1 (ECP 1)	Increased support to the integration of scientific and technological progress in the development of ATMPs	**On track**	Comments on draft guidance for ATMP IMP collated and currently under review following second public consultation. Guidance on long-term efficacy/safety under revision. 2 new candidates onboarded into the ATMP support pilot - however there has been little/no engagement with the developers due to status of their programs and resources constraint. In addition, very few applications were

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				received this time to fill the remaining slots. Application window remains open.
Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/convergence of practices and training with the Pharmaceutical 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	5.3	Reinforced responsibility for product quality by harmonising and reinforcing guidance	**On track**	The EMA and the GMDP Inspectors Working Group have been working with PIC/s have progressed with drafting on Annex 11 on computerised systems, with the next step being a consultation with interested parties. Revision of chapter 4 has progressed in parallel as well. A successful training for Annex 1 has been organised in April 2024 by EC and EMA for EU Inspectors, but also PIC/s, African and Accession Countries inspectors. The ICH Q9 process for revision of the Quality Risk Management guidance as well as supporting training has been finalised in June 2024. Following the US MRA extension to veterinary products in May 2023, further work has been undertaken for the finalisation of recognition of US

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				FDA of the remaining EU veterinary agencies and allow for the implementation of the batch testing waver clause. The EU MSs and EMA have provided the data on time. However, a delay is expected on the final deadline from July 2024. There has been further operational progress on the MRA expansion on vaccines and plasma derived products the extension (however this has been delayed due to the Covid-19 Pandemic) and on the recognition of third country inspections.
Promote dedicated cooperative and enhanced supervision with strategic international partners for manufacturing sites, such as tailored supervision of API manufacturers and/or large sites that supply a significant number of markets or products	5.2	The exchange of information among MRA and PIC/s partners is being actively promoted through international programmes, such as the API International Programme and PICs and ICMRA initiatives on hybrid inspections, in order to increase collaboration on reliance and hybrid inspections. As part of the implementation of the Sartans Lesson Learnt Exercise recommendations, Annex 15 of the GMP	**On track**	The API Programme on exchange of information on inspections of API manufacturers is ongoing. In addition the partners are discussing the revision and enhancement of the collaboration scheme for exchange of information on supervision of API manufacturing sites. Discussions on a pilot on international collaboration on finished product inspections has also been restarted in Q1 2024.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		guideline on Qualification and Validation has been agreed to be revised with PIC/s in a global effort to extend scope to API manufacturers. Furthermore, the PIC/s PICs aide memoire "Evaluating management of quality risks at GMP facilities" has been revised for inclusion of reference to development of APIs and identification of impurities.		The ICMRA Collaborative Pilot on hybrid inspections has progressed with published guidance on protocol for the hybrid inspection and the expectations for hybrid inspections. 3 hybrid inspections were carried out under the pilot, the most recent in May 2024. The hybrid inspections allowed for the authorities to align on areas of focus, streamline process and reduce undue additional burden for inspected facilities. The revision of the Annex 15 of the GMP guideline on Qualification and Validation for the potential extension of scope to APIs, as recommended in the Sartans with nitrosamines Lessons Learnt Report, is in the PIC/s and GMDP IWG work plan and pending to be kicked off. As a result of the Sartans Lessons Learnt, as well as taking into consideration the revision of ICH Q9 R1, PIC/s is working on a revision of the aide memoire "Evaluating

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				management of quality risks at GMP facilities" for reference to development of APIs and identification of impurities, which is expected to be finalised in 2024.
Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	6.2	Improved benefit/risk communication	**On track**	Design of informal study about usefulness of patient preferences in benefit-risk assessment to include structured interviews of assessors instead of focus group; planning of interviews Q4.
Management of Medical Devices Expert Panels: Conduct a pilot for providing scientific advice to medical device manufacturers and have lessons learnt to establish an effective scientific advice service	Legislation	Experience gained to establish scientific advice for medical devices	**On track**	The first phase of the pilot has been concluded and we are doing a lessons learned exercise to launch in 2025 the standard procedure for the advice to manufacturers. The second phase of the pilot in currently ongoing to gather more experience, with manufacturers and experts, that will feed into the design of the advice to manufacturers. In addition, the third phase was initiated with application for parallel advice with HTAs. A term of reference was agreed with the HTACG (HTA Coordination group) and we are currently discussing the applications

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				received for the parallel advice with HTAs. Ongoing process of launching a new pilot programme on orphan devices with the EC following the publication of the new MDCG guidance on the clinical evaluation of orphan devices.
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)	**On track**	For principles and Annex 1 (substantive part of the document), EWG discussed major trends from comments and proposed updates to the guideline. Guideline was also presented at the CHMP PROM to prepare to anticipated September 2024 endorsement.
Defining operational guidance for EMA responsibilities under the HTA Regulation, in cooperation with the HTA structures Contributing to stakeholder trainings on the implementation of the HTA Regulation Engaging in technical cooperation on evidence requirements for regulatory assessment and HTA, respectively	Legislation	Readiness for the application of the HTA Regulation Effective and efficient interplay between regulatory and HTA processes, respecting remits Support evidence generation plans that address needs for regulatory assessment and HTA Efficient management of resource	**On track**	Establishment of Implementing Acts under the HTA Regulation progressing by the EC. The first one on Joint Clinical Assessment of medicinal products adopted; reflection of the interface with EMA in a dedicated article (Article 3). Development of operations on the basis of this tertiary legislation. Agreement between EC, EMA and HTACG on the joint use of a modified Letter of Intent for applicants to notify upcoming MAA submission for

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		impact for EMA and the EU Regulatory Network		products in the scope of JCA. Publication of guidance for applicants on these new operations as the first concrete operational delivery in preparation for the application of the legislation. Also, there is significant progress on the Implementing Acts for CoI management and on the Exchange of information with EMA, respectively. Both were developed by the EC with technical support from EMA. Joint training session was held with regulators and HTAs on the evolving interface under the HTA Regulation. A study visit was also organised for SANTE C2 to get insights from EMA on the running of a secretariat for a European network. Development of a technical webinar series involving regulators and HTAs on the strength of evidence and management of uncertainties (lead HTA agency NCPE). Kick-off meeting for initial learning / mutual exchange

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				ahead of deep-dive discussions in the second half of 2024.
Anticipate the changes stemming from the new pharmaceutical legislation by exploring possible ways to implement the legislative proposal and use this opportunity to future proof the operations of EMA	Legislation	Identify process improvements/increase in efficiency and gain experience with piloting some proposals	**On track**	The new pharma legislation project is currently focused on understanding and analysing the legal texts of the upcoming new pharmaceutical legislation. Cross-agency brainstorming sessions have been organised to ensure alignment on legal interpretations and strategies. In addition, efforts have been made to raise legal awareness among all EMA colleagues through initiatives such as lunchtime legal talks and Development Day events.
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	Legislation	Finalise the consultation procedure for medical devices composed of systemically absorbed substances.	**On track**	Set up of an internal team and preparation of a call to CHMP to have CHMP sponsors nomination
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	Legislation	Finalise the process for handling serious incident reports received by Medical Devices National Competent Authorities for ancillary medicinal substances and companion diagnostics.	**On track**	Two partly overlapping implementation actions, one on handling of vigilance notifications received by medical device NCAs for medical devices with ancillary substances (pursuant relevant MDR articles) and the other on

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				handling of vigilance notifications received by medical device NCAs for companion diagnostics (pursuant relevant IVDR articles). Ongoing discussions, in which EMA is taking part, on both implementation actions at MDCG working group level on content and system of transmission of relevant vigilance notifications between medical device and medicines authorities. Issue introduced and discussed at CMDh by MDCG topic lead in June following consultation with EMA. Interest from NL and SE expressed. Involvement of CMDh in further discussions at MDCG working group level will ensure that stakeholders impacted by the implementation of these articles are taking part in relevant MDCG discussions. Internally at EMA, procedural work with relevant teams ongoing. For the medical devices with ancillary substances related implementation

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				action internal teams leading the implementation are confirmed and procedural documentation is being finalized. For the companion diagnostics related action internal teams leading the implementation are being confirmed.
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	Legislation	Application of Art 117: EMA/CMDh Q&A update	**Completed**	The update of the EMA/CMDh Q&A (rev.4) on MDR/IVDR has been completed and published in May 2024, to provide in particular more guidance of the application of the Art 117 to reflect on experience since MDR entry into force.

Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1 Pre-authorisation activities

Workload indicators

Procedure	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast			
						Initial	Revised	Change	
Innovation Task Force briefing requests (Vet)	2	7	0	4	2	5	5	0	0%
Scientific advice requests received	14	3	18	11	14	20	20	0	0%
Requests for classification as limited market under article 4(29) and eligibility under article 23	4	9	11	-	-	20	10	-10	-50%

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Scientific advice procedures completed within set timeframes	100%	100.00%	100.00%	100%	100%	100%

2.2 Initial evaluation activities

Workload indicators

Procedure		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast Initial	Revised	Change	
	Initial evaluation applications	11	15	9	4	7	18	33	15	83%
	New MRL applications	0	0	0	0	0	2	1	-1	-50%
	MRL extension and modification applications	2	0	0	1	1	2	5	3	150%
	MRL extrapolations	0	0	0	0	0	1	1	0	0%
	Art 10, Biocides	0	0	0	0	0	0	0	0	-
	Review of draft Codex MRLs[14]	3	0	0	0	3	5	5	0	0%

Performance indicators

Performance indicators related to core business		Target 2024	Outcome at the end of Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Initial procedures completed within legal timeframes	100%	100.00%	100.00%	100%	100%	100%

[14] From 2022 includes also Codex extrapolations.

2.3 Post-authorisation activities

Workload indicators

Procedure	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast Initial	Revised	Change	
Variations requiring assessment, of which[15]	139	147	-	-	-	267	304	37	14%
Variations level 1	2	1	-	-	-	2	4	2	100%
Variations level 2	25	53	-	-	-	90	80	-10	-11%
Variations level 3	52	27	-	-	-	55	100	45	82%
Variations level 4	60	66	-	-	-	120	120	0	0%
Transfers of marketing authorisations	1	1	0	8	5	5	3	-2	-40%

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Post-authorisation applications evaluated within the legal timeframes	100%	100.00%	100.00%	100%	100%	100%

[15] Variations requiring assessment: New indicators introduced following Regulation (EU) 2019/6. For an explanation of the different Variation Levels, please refer to the Explanatory note on general fees payable to the European Medicines Agency (https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency).

2.4 Arbitrations and referrals

Workload indicators

Procedure	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast Initial	Revised	Change	
Arbitrations and Community referral procedures initiated	1	0	3	0	1	2	2	0	0%

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Referral procedures managed within the legal timelines	100%	100.00%	100.00%	n/a	100%	100%

2.5 Pharmacovigilance activities

Workload indicators

Procedure	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast Initial	Revised	Change	
Annual recording of signal management results and outcomes (Annual statements)[16]	165	-	-	-	-	250	250	0	0%
Total signals submitted by MAHs of which:[16]	158	-	-	-	-	416	376	-40	-10%
Emerging safety issues assessed by MAH and leading to regulatory action	0	-	-	-	-	1	1	0	0%

[16] New indicators introduced in 2024 work programme.

Procedure							2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Signals assessed by MAH leading to regulatory action (variations or other)	15	-	-	-	-	35	35	0	0%
	Signals classified for close monitoring by MAH	10	-	-	-	-	80	40	-40	-50%
	Signals classified as refuted by MAH	133	-	-	-	-	300	300	0	0%
	Signals submitted by Regulatory authorities following risk-based review[16]	10	-	-	-	-	80	40	-40	-50%
	Targeted signal management processes initiated by regulators[16]	1	-	-	-	-	4	4	0	0%
	Total AERs, of which:	80,563	70,899	91,939[17]	31,000	31,944	100,000	120,000	20,000	20%
	Adverse-event reports (AERs) for CAPs	50,146	38,950	57,211	15,000	14,195	50,000	70,000	20,000	40%
	Adverse-event reports (AERs) for NAPs	30,417	31,949	34,728	16,000	17,749	50,000	50,000	0	0%

[17] A large backlog was received in 2022, hence the figures are higher than average for mid-year reporting.

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 (ECP 1)	Guidance for novel therapies and biologicals developed	**Completed**	Activity completed in 2023.
Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs, and initiate the necessary preparatory and follow-up work	3.1 (ECP 1)	Analysis of impact and plan for future work on guidance and processes	**Completed**	Activity completed in 2023.
Implement in the veterinary medicines field the recommendations of the "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"	3.1 (ECP 1)	Harmonised methodology in place: legislation, guidelines and templates revised; exposure assessment tool made available to CVMP experts	**On track**	In Q1-Q2 2024 EMA had further meetings (bilateral with EFSA and trilateral with EC and EFSA) to prepare the elements to be included in the mandate. The activity to develop the common calculation tool will take place in an EFSA working group. The CVMP and the SWP-V representative in the EFSA working group have been appointed. The EC mandate was received on 1 July 2024.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	3.1 (ECP 1)	Guidance for surveillance and signal detection developed Enhanced communication with the network	**On track**	The P-SMEG interim report 2022-2023, was presented to CVMP in January 2024. The Union PhV Database Best Practice Guide is being updated by P-SMEG to provide additional practical guidance and examples to facilitate the interpretation and implementation of the VGVP guidelines to MAHs. A final report with in-depth review and recommendation will be provided in Q4 2024.
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 (ECP 1)	Methodology established and guidance developed	**On track**	The development work on the data warehouse to allow publishing the available reporting incidences was completed in January 2024.
Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	**On track**	A pilot study is being performed at the request of the EC. EMA drafting of a work programme/approach is ongoing.

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 Harmonised approach on ERA assessment	**On track**	In the first half of 2024, EMA participated to the following events: EMA-EFSA meeting - Aquaculture & ERA (22 April 2024) EFSA - Pesticide use negatively affects bumble bees across European landscapes - Online KIC ERA meeting (12 January 2024) EMA-EFSA - KIC - Aquaculture & ERA (22 April 2024)
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)	Support to EC provided "One Health" approach for ERA implemented	**On track**	EMA provides input to EC/other Agencies when requested on ERA "One Health" topics. No specific request was received in the first half of 2024.
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1 (ECP 1)	Establish governance for JIACRA report under EMA and CVMP	**On track**	The proposed focus of the 5th JIACRA report has been developed by ECDC, EFSA and EMA, and was sent to EC for agreement on 28 June 2024. Automated analysis templates have been prepared in line with the JIACRA IV code repository as published on GIThub
Implement use data collection by animal species	4.1	Collection of data on the use of antimicrobials per animal species and animal categories	**On track**	The ASU Platform went live on 29 January 2024. A product data quality clean-up campaign took place between January and

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578		May, in which the number of products with UPD data quality issues in the ASU scope fell from an average 22% to 2%. The data call for Member States to submit animal population data was opened on 24 April and the one to submit sales data on 17 May. By the legal deadline on 30 June, 26 MSs have presented sales data and 24 MSs have presented animal population data.
Communicate effectively on consumption data	4.1	The outline of the ESVAC report reviewed to improve communication Group of experts to define the outline of the volumes of sales and use of antimicrobials (Article 17 of the Commission Delegated Regulation (EU) 2021/578)	**On track**	Within the ESUAvet WG, a subgroup was created (analysis & reporting) to draft the outline of the future Agency's reports for both sales and use data. The group met several times to discuss and the first draft layout/outline was shared with ESUAvet WG and observers from the Commission. The proposal is currently being revised based on the comments received and it is expected to be discussed at the CVMP meeting in September.
Foster development of POC diagnostics for veterinary use	4.2	Review availability and characteristics of diagnostic tests	**On track**	Public consultation on the draft concept paper on the development of the reflection paper on Diagnostic Tests ended on 31 October 2023. The comments have been analysed and taken into account. The work on the reflection paper is ongoing. CVMP agreed to a set of questions

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				to be sent to FVE and AnimalHealthEurope to gather more information.
Prioritise and trigger referral procedures and/ or support MS in activities to review available data on emerging AMR risks, clinical effect, PK/PD, dose regimens	4.2	Support CVMP on VMP referrals and act on the recommendations from the Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation	**On track**	Answers to the questionnaire circulated in Q4 2023 were received and are currently being analysed to propose a list of candidate products for the review of dosages.
Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	4.3	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	**On track**	No specific activities were initiated in the first half of 2024.
Participate in international initiatives to reduce the risk of AMR	4.1 (ECP 1)	Actively participating in international fora	**On track**	In the first half of 2024, EMA veterinary colleagues participated in the following events: AACTING 4th international conference, 1-2 February 2024, Vienna, Austria WOAH AMR WG meeting, 27-29 February 2024, Paris, France AMR Legislator Initiative-3rd Hearing, 29 February 2024 (virtual)

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Belgian Presidency High-level meeting on AMR, 6-8 May 2024, Brussels, Belgium 12th International Conference on Antimicrobial Agents in Veterinary Medicine (AAVM), 16-19 June 2024, Athens, Greece TATFAR Video conference 6 June 2024 5 virtual meetings of dedicated TATFAR action groups 1.1 (chaired by EMA) on 23 April, group 2.3 on 4 March and 13 June, and group 4.3 on 17 January and 13 May 2024 3 virtual meetings of the RAGNA network on 17 January, 13 March and 19 June 2024
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 3)	Develop and revise relevant guidance	**On track**	The "Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances" and the "Guideline on the conduct of efficacy studies for intramammary products for use in cattle" were adopted by CVMP at its June 2024 meeting, for release for consultation.
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments	4.3 (ECP 3)	Reflection paper finalised and published	**On track**	The reflection paper was finalised and published in February 2021.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
received Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper		Review of novel risk assessment methodologies for AMR in the environment		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 (ECP 3)	Reflection paper developed Communication with stakeholders	**On track**	The horizon scanning was launched on 9 April 2024 with deadline for 30 June 2024. The results are currently being evaluated.
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	4.3 (ECP 3)	Guidance development Communication with stakeholders	**On track**	Public consultation on the draft concept paper on the development of the reflection paper on Diagnostic Tests ended on 31 October 2023. The comments have been analysed and taken into account. The work on the reflection paper is ongoing. CVMP agreed to a set of questions to be sent to FVE and AnimalHealthEurope to gather more information.
Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health	4.3 (ECP 3)	Guidance development on ATAm	**On track**	No specific activities were initiated in the first half of 2024.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the	4.3 (ECP 3)	Cooperation at EU and International level for events	**On track**	EMA is collaborating with EFSA, ECHA, ECDC and EEA on a scientific opinion on the impact of the use of azole fungicides on resistance in

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
responsible use of antimicrobials and their alternatives		Common approach agreed		Aspergillus. The 5 EU agencies asked an extension of deadline on the azoles opinion until the end of 2024. Good progress is being made in 2023 on terms of reference 1, 2 and 3 and the work has been started on term of reference 7 as well, where EMA takes the lead. The document about term of reference 1 was discussed at CVMP and is planned to be adopted at its July meeting. The other term of reference, where EMA is involved (TOR 7) is planned to be discussed at CVMP in September.
Include AMR as a regular topic at meetings with HMA and veterinary stakeholders	4.5	Actively propose AMR topics for HMA and stakeholders' meetings	**On track**	The EMANS review and update to 2028 is on track with Theme 4, AMR and other health threats being developed. A meeting took place on 6 June with the HMA Veterinary Strategy Focus Group (VSFG) and the two co-chairs of the ESUAvet Working Group on Member States' AMR use reporting readiness.
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**	The consultation period for: "Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets" and "Guideline on safety and efficacy data requirements for applications for immunological veterinary

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6" ended on 31 January 2024. Due to an additional round of reviews, the guidelines are now expected to be discussed by CVMP at its September meeting and adopted in October 2024.
Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best practices on the use of veterinary antiparasitic medicines	4 (additional RSS recommendation)	Improve interaction with International organisations Best practices embedded in guidance	**On track**	EMA continues to attend webinars on acaricide resistance organised by FAO (2 webinars organised in Q1-Q2 2024). There was also an interaction with Royal GD (Dutch CRO) on anthelmintic stewardship and prudent use.
Promote responsible use of antiparasitics in the EU	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	Guideline for the demonstration of efficacy of ectoparasiticides: the revision of the guideline started in January 2024. The revised draft guideline is foreseen to be published for public consultation in Q4 2024. Revised VICH guidelines on efficacy of anthelmintics: the final comments on the revised guidelines and the overview of comments received during consultation and related responses were endorsed by CVMP at its June 2024 meeting. Final versions of the guidelines are expected to be adopted and

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				published in Q3-Q4 2024. Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations: the antiparasitic resistance section was further revised; the final reflection paper is foreseen to be adopted and published in Q3-Q4 2024. An infographic on lack of expected efficacy for antiparasitic veterinary medicinal products is under development by EWP-V and PhVWP-V and is expected to be finalised in Q4 2024.
Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision-making	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance	**On track**	A draft guideline on benefit-risk was adopted for release for a 6 months consultation at CVMP December 2023 meeting. Comments have been reviewed and the guideline is expected to be finalised in Q4 2024.
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	6.2 (ECP 2)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	**On track**	The EMA Veterinary Medicines Info Day was held in March 2024, and the CVMP Interested Parties Meeting was held in May 2024.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 2)	Compilation of a Veterinary data sources catalogue and metadata analysis	**On track**	A research study to develop a data sources catalogue was initiated in Q1 2023 and is expected to be completed in Q3 2024. The final version of the report was submitted on 5th July. The next step is a detailed internal EMA review of the report to be completed by 31 August. A plan for the next phase will be delivered in September. In parallel, agreement has been made with the RWE Catalogue team to include appropriate data sources identified in this analysis in the RWE Catalogue.
Contribution to Chemical Strategy for Sustainability, particularly on the 'One substance one assessment' (1S1A) initiative, including the establishment of the EU Common Data Platform for Chemicals (EU-CDPC) Consequently, implement the initiative as/if required	ECP 3	EMA data and legal requirements to be provided in the frame of the EU policy-making process Implementation of the initiative as/if required	**On track**	EMA contributed as necessary to the on-going legislative process, as well as provided input in the framework of experts/working groups meetings.

Task forces

Digital Business Transformation (TDT)

Pillar 2 – Public health activities

Workload indicators

Procedure							2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	New scientific, regulatory and network portfolio curricula developed	1	0	0	0	3	2	2	0	0%
	Number of training events advertised to the EU Network	86	49	36	36	20	60	60	0	0%
	Number of reimbursed training events to the EU Network	3	0	1	0	1	8	8	0	0%
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	7	0	7	10	6	10	10	0	0%
	Number of epics completed or ongoing[18]	25	-	-	-	-	29	29	0	0%

Achievements

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Develop a digital skills framework for EMA and		Validated Digital Skills framework for EMA	**On track**	In the first half of the year, the Agency continued opening up Digital Academy modules to the EU Medicines Regulatory

[18] New indicator introduced in 2024 work programme.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
lead on digital capability building		Creation of introductory training on topics in the digital skills framework with links to further learning on each topic to enable deeper skill development Creation of a platform to act as entry point to the introductory training content Deliver agency-wide awareness campaign to engage staff and create engagement through gamification and events		Network. This included: Digital Wellbeing, Agile, Design Thinking, Lean. In addition, the Agency developed and published a completely new Digital Academy module that was not part of the original Digital Skills framework on 'Process Mining'. This was a joint endeavour with the Audit team (AF-AUD). Furthermore, work around the modules on Data started with a view to publishing the following 3 new modules in the second half of the year: Data literacy, Data security, Data protection.
Establish an EU collaboration on AI with other Agencies in the EU Network	2.2. (ECP 2)	Develop and promote the AI community Increase synergies, re-use, and efficiency Share knowledge and increase maturity	**On track**	During the first half of the year the following activities where completed: Kick-off of the new collaboration method as EUAN Working Group; Endorsement of the Work plan 2024 by EUAN Troika;

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		Collaborate for the implementation of common AI initiatives and projects		Kick-off of a consultancy support to work on the 2024 working plan; Call for interest to new members in the network; Onboarding sessions to new agencies; 1 Community Meeting to introduce 2024 activities and to discuss AI topics of interest; 1 EUAN AI Talk about AI Act and the AI office; Launch of a survey to gather needs and expectations of the WK members. This will help to build the working plan for 2025 onwards; 5 SteerCo meeting to steer the WG.
Support future-proofing of EMA and the Network by developing regulatory capacity through the EU NTC		Training delivered to the EU Network F2F training delivered to the EU Network Extend access to EU NTC training to external audiences including analysis of the existing EU NTC training content	**On track**	In the first half of the year, we continued supporting the development and delivery of training courses for the EU Network. This included around 30 webinars and 3 face-to-face courses: Pre-clinical Assessors Meeting (PAM), February 2024; BWP-CAT training on AAV based gene therapy, May 2024; Environmental Risk Assessment, May 2024.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		Development of processes for providing access to subset of external audiences Investigate whether current platform is suitable or whether a new platform should be considered Investigate the setting up of an engagement portal/entry point to the LMS for external audiences		We also continued piloting the new remuneration scheme, from which 2 new courses have benefited: EMA-coordinated GCP and BE Inspections Online Training Course, available since June 2024, Annex 1 to the EU GMP guide (Manufacture of Sterile Medicinal Products), delivered in April 2024. In addition, the agency modernised the EU NTC newsletter by publishing it in Newsroom. 3 issues have been published so far (April, May and June 2024). Furthermore, the Agency took further steps to open up the EU NTC to: Patient/Consumer and Healthcare Professional representatives; A subset of non-EU regulators (i.e. IPA countries) drawing on the lessons learnt from the non-EU regulators pilot ran in 2023 in collaboration with International Affairs. We also launched the EU NTC portal, providing public access to our full training catalogue: https://euntc.ema.europa.eu/. Last but not least, we hosted a global face-to-face event to

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				mark the 10th anniversary of the EU NTC. The fruitful exchange of views and ideas has led to a number of concrete action points to take forward as part of the (soon-to-be revised) EU NTC strategy.

Data Analytics and Methods (TDA)

Pillar 2 – Public health activities

Workload indicators[19]

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	476	-	-	-	-	1,100	1,100	0	0%
Number of EudraVigilance Quality Assurance Test (QAT) requests received	75	-	-	-	-	130	130	0	0%
Number of non-interventional studies performed	15	-	-	-	-	70	70	0	0%
Number of methodological advice provided on product procedures	92	-	-	-	-	80	80	0	0%
Number of active methodology guideline drafting groups led by MWP	11	-	-	-	-	15	15	0	0%
Number of methodological contributions to guidelines led by other committees and working parties	12	-	-	-	-	10	10	0	0%
Number of business validation for CTIS releases	11	-	-	-	-	18	18	0	0%
Number of KPIs reports published	5	-	-	-	-	12	12	0	0%
Number of EudraCT reports and number of CTIS data analyses and reporting[20]	36	-	-	-	-	110	110	0	0%
Number of ACT EU multi-stakeholder workshops[21]	9	-	-	-	-	12	12	0	0%
Number of regular CTIS/CTR events[22]	42	-	-	-	-	86	86	0	0%

[19] New indicators introduced in 2024 work programme.
[20] Including ad-hoc and regular reporting (weekly dashboards for bi-weekly newsflash, MB monthly reports, ACT EU KPI reports, CTCG).
[21] Led and co-organised events; including multi-stakeholder platform (MSP) advisory group.
[22] CTIS Walk-in Clinics, Bitesize talks, Quarterly CTIS Forum with Stakeholders, CTIS Info event, CTCG Plenary, Assessors Roundtables, CTIS Sponsor End-user trainings, CTIS POEG.

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of CTIS newsflashes and CT highlights newsletters	16	-	-	-	-	26	26	0	0%

Performance indicators[23]

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
ATD/RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	90%	89.00%	-	-	-	-
Percentage of monthly updates of the ADR report website performed according to the timelines	90%	100.00%	-	-	-	-
Studies performed within less than 24 weeks[24]	70%	44.40%	-	-	-	-
Non-Interventional Study (NIS) protocols and summary results registered in EMA NIS registry within a month after finalisation	90%	92.00%	-	-	-	-
Product procedure requests for methodological support completed as per timelines	90%	100.00%	-	-	-	-
Planned MWP contribution to guidelines led by other committees and working parties	75%	100.00%	-	-	-	-
AtD/RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	90%	54.75%	-	-	-	-
WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	90%	100.00%	-	-	-	-
ACT EU multi-stakeholder workshops organised according to workplan	80%	90.00%	-	-	-	-

[23] New indicators introduced in 2024 work programme.
[24] Excluding framework contract studies.

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
News flash to CTIS users	90%	100.00%	-	-	-	-
Support to the secretariat for CTCG and physical hosting 4 times per year	100%	100.00%	-	-	-	-
Provide secretariat for CTCG weekly assessors round table	100%	100.00%	-	-	-	-

Achievements

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Build capacity and capability to receive, store, manage and analyse raw data	2.1 (ECP 2)	CHMP proof-of-concept pilot for individual patient level data from clinical trials and non-clinical data launched and carried out Proof-of-concept pilot protocol developed Interim and final pilot reports developed Guidance for applicants developed	**On track**	80% of target procedures included in the pilot are on track to reach the target of 10 by end of 2024. Interim pilot findings report developed following consultation with Network Advisory Group on Raw Data in Q2 2024. Presentation to CHMP of interim pilot findings delivered in Q2 2024. Publication of interim pilot report is foreseen in Q3 2024, this is due to the extended Network consultation period.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Implement the Clinical Trials Safety Monitoring Implementing regulation		Assure the functional specs of the safety implementation regulation are up to date Provide regular support to the Member States for the safety assessments	**On track**	IT functionalities (CTIS and EVDAS) for Safety with members of ACT EU Priority Action 09 (PA09) reviewed. Annual Safety Information (ASR) functionality of the CTIS and the process for selecting the safety assessing Member State (saMS) as part of the Simplification Task Force (STF) agreed to be reevaluated. Technical challenges faced by MSs and sponsors identified along with proposed solutions to further facilitate the implementation of the Commission Implementing Regulation (EU) 2022/20 of January 2022.
Support an initiative with the EC and HMA to transform CT in Europe. This includes: modernisation of CT design and good clinical practice; strengthening EU level governance of CT; improved coordination between NCAs and ethics committees through the 'CTR Collaborate' project, including		Strengthen EMA support to ACT EU Project manage the "CTR Collaborate" project which will deliver enhanced collaboration between NCAs and Ethics Committees to support sponsors/CROs, develop effective procedures and training/information sharing and support the development of an EU forum for ethics committees to come together	**On track**	ACT EU priority actions reinforced with contributions from the paediatric office, SME office and TRS academia office, supporting EMA efforts already in place. CTR Collaborate delivery supported including the report on the project analysis phase and planned stakeholder meeting in September 2024. Paid ads campaign to promote the CTR

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
during public health emergencies; leveraging data on CT to support regulatory decision making; supporting non-commercial sponsors to conduct more multi-national clinical trials; enhanced dialogue between clinical trial stakeholders.		Support communication and change management including training on operation of CTR and CTIS Launch scheme to support large multinational CTs, including a one stop-shop for academic sponsors Engage external stakeholders and establish a multi-stakeholder platform and advisory group Adopt a plan for GCP modernisation Further develop and manage a stand-alone ACT EU website Develop a CT research agenda Develop a pilot for consolidated pre-clinical trial application (CTA) advice (CHMP SA linked with SNSA/CTCG advice) Develop RACI matrix for network governance groups		transition delivered. As part of the action plan to support academic sponsors, a mapping of initiatives at national level, created with the CTCG, published on the ACT EU website. A mapping of the different EMRN groups and stakeholder fora, with detailed information on each group, also published, to clarify the CT landscape for sponsors. The ACT EU multi-stakeholder advisory group established, its composition adopted by the ACT EU Steering Group, regulatory and stakeholder co-chairs appointed, kick-off meetings held. Consolidated advice pilots (pre-CTA and SAWP/CTCG) launched in June.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		Strengthened process and regulatory approval of large, multinational clinical trials in the EU during public health emergencies		
Business support to operations to Clinical Trials regulation including business support to CTIS		Provide hands on support to the numerous sponsors and MS users of CTIS through the business service desk Assure the business testing of the candidate releases	**On track**	Continuous support to sponsors and Member States delivered. Important code fix in CTIS for substantial modifications for large trials delivered.
Change management activities related to CTR/CTIS		Regular communications in the form of newsletters and news flashes, maintenance of the CTIS training catalogue, and running of regular CTIS events e.g. walk-in clinics, bite size talks, CTIS forum	**On track**	13 issues of the CTIS newsflash and 3 issues of the CT highlights newsletter published. 3 Walk-in clinics held. 3 Bitesize Talks held. 1 Info Event and 1 CTIS Forum delivered.
Deliver a data science curriculum for the EU Regulatory Network	2.2	Lead the work of the contractor to which the Data science curriculum has been outsourced	**On track**	5 modules developed: Introduction to Data Science, Big Data, AI, Data Management, Data Visualisation.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				These modules will become available to the Network by end of October 2024.
Development of the EU Data Quality Framework for big data used in the regulatory context and of the DQ considerations for Real World Data (RWD) and for Adverse Drug Reactions (ADRs)	2.1	EU Data Quality Framework for big data used in the regulatory context and of the DQ considerations for Real World Data (RWD) and for Adverse Drug Reactions (ADRs)	**On track**	EU Data Quality (EU DQ) Framework adopted by CHMP and published in 2023 and a draft of RWD considerations produced and on target for publication in 2024. Multi-stakeholder workshop on Adverse Drug Reactions (ADR) considerations held. Creation of a first draft of ADR considerations, and subsequently, publication in 2025, in progress.
Ensure compliance with the European Union Data Protection Regulation (Reg (EU 2018/1725) and guidance of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB) and provide advice on data protection related matters at EMA		Yearly report on data protection activities to EMA Management Board	**On track**	Training: Bitesize data protection training, consisting of 6 modules. Additional training sessions planned for: AI and data protection, data protection and technology selection process, conduct of transfer impact assessments. EDPS notifications:

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Signal and Safety Analytics (SSA) Data Protection Impact Assessment: in accordance with Article 40 Regulation (EU) 2018/1725, a prior consultation of the EDPS initiated on 5 June 2024. SSA: In accordance with Article 48(3)(a) of Regulation (EU) 2018/1725 contractual clauses for international transfers were submitted for EDPS authorisation on 5 June 2024. EMA and Council of Europe/EDQM Collaboration Agreement Sampling and Testing Programme: In accordance with Article 48(3)(a) of Regulation (EU) 2018/1725, contractual clauses for transfers to an international organisation submitted for EDPS authorisation on 20 June 2024.
Enable clinical trial data standards in EMA and Network systems and processes	2.2.	Coordination of European contribution to ICH M11 activities Roadmap on clinical trial standardisation	**On track**	Progress on ICH M11 as planned: Network expert onboarded. A draft roadmap on clinical trial

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		Identification of use cases for clinical trial analytics Network experts' contribution in clinical trial standards Updated version of the FHIR standards		standardisation and related epics presented to business owner. Dedicated session on clinical trial standardisation held to raise awareness.
Provide methodological expertise to support EMA scientific committees in alignment with external stakeholders' needs Strengthen the EU Network on methodology in committee advice and assessment Harmonisation of international methodological standards	2.2	Revised Methodology Work Plan. Draft Methodology stakeholder interaction plan Draft methodology research needs Deliver guidance documents on emerging methodological topics Systematic lessons-learnt process for procedures with complex methodology, deliver first modules of the training curriculum in biostatistics, embed identification of committee requests with complex methodological aspects into EMA forecast and tracking processes Drafting groups and operational expert	**On track**	Draft workplan 2025-2027 created. First MWP's Interested Parties meeting held; significant interest and engaging participation from regulators and industry noted. Milestones for 60% of the priority guidelines achieved. Drafting groups and operational expert groups established and managed. Clear roles and responsibilities in the Methodology domain defined.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		groups established and managed Clear roles and responsibilities in the Methodology domain to maximise resource efficiency Drafting of ICH E6(R3) Annex 2, E11A and E20 guidelines Organisation of cluster meetings		
Improving development and implementation of clinical trial methodology guidance in the EMRN. Contributing to the delivery of CT curriculum		Methodology workshops with external stakeholders to scope and prioritise clinical trial methodology guidance topics Methodology guidance roadmap Process for aligning guideline development on multidisciplinary methodology topics involving a large variety of relevant Network expert groups Training plan for new guidance documents and associated process Completion of training needs	**On track**	Methodology workshop report finalised in March 2024 and published on ACT EU website. A process for coordinating guidance development strategically between the CTCG, MWP and HTACG Methodology subgroup successfully established in April 2024, with quarterly meetings between the chairs of the respective groups. Following input from the 2024 ACT EU methodology workshop, development of a methodology guidance roadmap was superseded by a best practice for guidance which is in preparation.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		assessments for regulators and defined stakeholder groups Training curriculum elaboration		
Further develop and maintain a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network - DARWIN EU®). To support better decision-making on medicines by informing those decisions with robust evidence based on appropriate real-world data	2.1	DARWIN EU® Coordination Centre maintained Access to various real-world data sources in terms of data type and geographical coverage DARWIN EU® pilot with EHDS conducted Processes for EMA oversight of DARWIN EU® activities operated, incl. review of all deliverables and DARWIN EU® outputs	**Delayed**	The period covers the end of the DARWIN EU establishment phase as well as additional pilot use cases with extended discussions to make decisions. Process improvements, and increased knowledge in DARWIN EU for RWE generation from various stakeholders, are expected to increase the number of studies completed in the second half of 2024. 12 studies initiated via DARWIN EU 2 new data partners are under onboarding phase; 8 more are under exploration. On track to onboard 10 additional data partners by end of 2024.
Build appropriate EMA business processes to identify the need for RWE and to generate and deliver that evidence in order to support the regulatory decision making process	2.4	Processes for prioritising analytical requests established Development of a phenotypes library Users' training on utilisation of IHD and analytical templates	**Delayed**	In depth discussion on research questions and study designs with various stakeholders is necessary to ensure that we generate and deliver relevant and impactful real-world evidence. This work imposes significant complexity and need for stakeholder engagement.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				15 studies initiated via 3 different pathways available for RWE generation. Regular IHD trainings delivered.
Pilot the use of AI/ML to increase efficiency to extract information in EMA documents and real-world data		Successful experimentation on the extraction of information using AI/NLP techniques Report on lessons learnt from test use cases shared within EMRN Planning of additional experimentation with AI/NLP at EMA considering the lessons learnt	**On track**	This project, called EurEKA, was tested on over 1000 documents. One application is currently being developed (an initial one changed due to new requirements and new website structure). The data from EurEKA is being processed in the context of the Signal and Safety Assessment (SSA) project. As such, EurEKA's database is provided for the new SSA system (RxLogic) to identify listed adverse drug reactions. It was used to improve the quality of wording for haemophagocytic lymphohistiocytosis and as a basis for veterinary product information extraction tool named "EurEKA for Vets".
Further development of a monitoring system for the post-authorisation safety		Core infrastructure for the prioritisation, launch and supervision of vaccine studies in place	**On track**	8 studies led by EMA conducted or ongoing under the Vaccine Monitoring Platform (VMP).

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
and effectiveness monitoring of vaccines (Vaccine Monitoring Platform)		Working arrangements with ECDC established and operational EU networks with capacity to perform representative and reliable studies identified Processes in place to identify need for studies Results of studies made available to EU decision-makers and the public		This includes 3 studies via EMA's framework contracts (1 completed, 2 on-going), and 5 studies via DARWIN EU (1 completed, 4 ongoing). An IVMAB meeting is scheduled for October 2024 as face-to-face in Amsterdam.
Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data		Establishment of the Health Data Lab as a stream following DigiLab's framework Pilot the experimentation framework with two pharmacovigilance-related projects	**On track**	4 pilots currently run by Health Data Lab: 2 new Pharmacovigilance pilots. 2 legacy pilots. Two of the pilots (one new and one legacy) were used to support the minimum viable product of the Signal and Safety Assessment project. One of the pilots, named ERATO, is under validation.
Perform the EMA data governance and support EMRN data governance through development and implementation of an		Plans and activities to implement EMA data strategy, EMRN data standardisation strategy and EMA data	**On track**	EMA: Data Board meetings organised monthly.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
EMA and EMRN data strategy and data standardisation strategy as well as relevant policies, procedures as part of implementing a federated data governance at EMA, ensuring gradual evolution.		governance including roles, responsibilities, processes, policies, structures and a data catalogue & glossary EMRN data strategy Communications, trainings and stakeholder engagement		Essential EMA Data roles agreed (MVP), nominations pending. Data catalogue template agreed. Data asset identification ongoing. Data roles cohort 1 roll out pending. Data community mandate pending. Data glossary not started. Data quality area lead appointed. Communication plan drafted; initial communications disseminated. Training approach agreed to enable Data roles roll out. Network: BDSG meeting organised monthly. BDSG workplan implementation coordination ongoing. Network data strategy in drafting. Network data governance streamlining (mandate) in drafting (additional activity).
Perform a capability and capacity assessment for big data use cases, as per BDSG work plan 2022-2025		A report including recommendations for actions	**On track**	Survey completed in May 2024. Results to be discussed with BDSG members at the 6 September 2024 meeting.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Support EMA operations and committees/working parties with advice and epidemiological expertise on: methods for RWE collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; portfolio of real-world data sources existing in Europe and elsewhere to answer research questions; identification of research questions appropriate for further investigation and their translation into study protocols; evidentiary standards and formats and contents of RWE submitted by MAAs/MAHs; lessons learnt from review of RWE submitted by MAAs/MAHs; literature review of published articles with RWE on utilisation, safety and effectiveness of medicinal products.		Draft guideline on methodological aspects, formats and contents of RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of real-world data sources used in regulatory decision-making (e.g. registries, electronic healthcare records) Process for identification of procedures from relevant committees/WPs that need methodological input, participation and contribution to SAWP, pre-submission, PRIME and other relevant meetings where RWE is addressed	**On track**	Mapping of activities and processes finalised and reviewed for optimisation. Implementation plan being developed.

Regulatory Science and Innovation (TRS)

Pillar 2 – Public health activities

Workload indicators

Procedure							2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Innovation Task Force briefing meetings	16	17	16	21	15	40	40	0	0%
	Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[25]	0	0	1	0	0	4	4	0	0%
	Business Pipeline briefing meetings[26]	8	10	8	6	-	20	20	0	0%
	Regulatory assistance, including SME briefing meetings[27]	104	83	97	105	-	192	192	0	0%
	Requests for SME qualification	198	268	240	312	303	541	541	0	0%
	Requests for SME status renewal	122	124	210	131	178	1,323	1,323	0	0%
	Management of shortages of CAPs	720	-	-	-	-	1,600	1,600	0	0%
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party	33	-	-	-	-	60	60	0	0%
	Number of requests for information received from the SPOC Working Party and international partners	15	-	-	-	-	70	70	0	0%
	Number of SPOC Working Party meetings (including subgroups)	12	-	-	-	-	40	40	0	0%
	Number of MSSG meetings	6	-	-	-	-	12	12	0	0%

[25] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[26] New indicator introduced in Work Programme 2021.
[27] New indicator introduced in Work Programme 2021.

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use meetings + TW1	6	-	-	-	-	12	12	0	0%

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Additional indicators:[28]									
Number of Solidarity Mechanism cases	4	-	-	-	-	6	6	0	0%
Academia briefing meetings conducted	6	-	-	-	-	12	12	0	0%
New involvements in externally-funded regulatory science projects managed	8	-	-	-	-	10	10	0	0%
Collaborating experts onboarded or deliverables managed	7	-	-	-	-	10	10	0	0%

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Satisfaction level of SMEs	80%	90.00%	88.00%	n/a[29]	89%	88%

[28] Indicators not included in the SPD.
[29] Satisfaction level evaluated following events Q3/Q4.

Achievements

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
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**	Annual 2023 TRS-INO intel presentations to Committees, relevant WPs and EMA communities. Monthly dissemination of information about upcoming stakeholder meetings. Summaries on specific areas of interest provided e.g. AI, 3Rs, platform.
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**	Organisation of EU-IN webinar in collaboration with EU-NTC and EC SoHO colleagues promoting the EU preparedness for the regulation of FMT products
Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	3.4	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	**On track**	TRS staff involved in TRIP items curation. Presentation to EU-IN and other EMA entities (H-EG management).
Integrate EMA's Regulatory Science Strategy into the EMAN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in	6.1	RSS integrated within EMAN Strategy Implementation tracked	**On track**	Support EMANS to 2028 drafting and collecting input including merging RSS items. Co-lead on DG Theme 3.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
expertise and provide continuous training through the EU Network Training Centre		systematically to ensure delivery		
Innovation relevant preparation for the implementation of new legislation (Sandbox, Borderline Classification)		Proposals for re-designed processes for the implementation of new pharma legislation	**Delayed**	Concrete process proposals are premature, hence delayed.
Preparation for ESMP database Extended mandate activities on shortages of MPs and MDs		Extended mandate activities on shortages of MPs and MDs	**On track**	The development of the ESMP is on track, with planned go-live of its first functionalities for MAHs in Q4 2024. The first UAT with SMEs was held in April 2024, change management activities completed milestones such as: the launch of the ESMP webpage on the corporate website in April 2024, the development of an extensive communications/stakeholder engagement plan, the first open ESMP Essentials webinar with wide attendance
Union list of critical medicines SPMPs organisations of SC meetings of the TFAAM (4 per year) Thematic working group 1 meetings (30 per year)		Human product availability, Veterinary product availability / MUMS	**On track**	The revision of the Union list of critical products is on track (3 batches shared with the MS according to set deadline). Furthermore, the stakeholder consultation has been concluded, and the processing of data received is currently ongoing.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				In June 2024 EMA issued templates for Shortage Prevention Plans (SPPs) and Shortage Mitigation Plans (SMPs). Marketing authorization holders (MAHs) in the European Union/European Economic Area are encouraged to create Shortage Prevention Plans to minimize the risk of medicinal shortages.

Advisory functions

(International Affairs, Internal Audit, Legal Department, Institutional and Policy Department, Information Security, Public Health Threats)

Workload indicators[30]

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of product-related interactions with international stakeholders – including requests for information and requests for documents	151	127	-	-	-	130	250	120	92%
Number of participations in external forums	14	15	-	-	-	60	40	-20	-33%
Number of external participants in training organised by International Affairs	580	441	-	-	-	150	700	550	367%
Number of visits to EMA / fellowships organised by International Affairs	9	8	-	-	-	10	15	5	50%

[30] New workload indicators starting in 2023.

Pillar 2 – Public health activities and Business Services

Achievements

Public Health Threats

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Define approaches for review of data with international regulators	4.2 (ECP 1)	Build on the experience acquired with COVID to establish the approach for future emergencies	**On track**	A workshop conducted by the ICMRA in February 2024 focused on the alignment of COVID-19 vaccine updates. Several discussions occurred with WHO and international regulatory bodies on vaccine development.
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**	The first meeting of the Vaccine Outreach Group took place in Q2; the plan was presented to the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party. EMA, in collaboration with the ECDC, issued a joint recommendation for avian flu vaccines.
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**	Active participation and contributions in meetings and webinars with NITAGs highlight ongoing collaboration.
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**	In May 2024, an alignment workshop on Vaccine Effectiveness (VE) studies in Europe was conducted, leading to the development of a VE report and the formulation of a roadmap for VE studies across the continent.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Operate the ETF during COVID-19 public health emergency and to ensure preparedness		Provide scientific advice to developers, engage in discussions with Academia and relevant EU bodies or International regulators, support sponsors of CT to conduct larger trials	**On track**	Engaged in multiple interactions with pharmaceutical developers and clinical trial networks to enhance drug development efforts for medical countermeasures.
Develop and implement the AMR EMA strategy		Have suitable vaccines and therapeutics for treatment of infection including those caused by multi-drug resistant organism	**On track**	International discussions on aligning requirements for AMR strategy took place in Q1-Q2, alongside engagements regarding phage products within the framework of TATFAR.
Operate the ETF during COVID-19 public health emergency. As a working assumption for this MAWP, it is assumed that the COVID pandemic PHE will end December 2024		Proper regulatory decisions in the context of an emergency	**Completed**	The EMA Emergency Task Force (ETF) played a critical role during the COVID-19 pandemic, delivering over 220 Scientific Advices, 145 Informal Advices, 350 Product Interactions, and conducting 250 ETF meetings. Following the World Health Organization's declaration of the pandemic's end on May 5, 2023, the ETF has shifted its focus to preparedness for future public health emergencies, incorporating lessons learned from the pandemic.

Chief Medical Officer

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**	Work has been undertaken in the HMA/EMA working group on biosimilars to develop at communication tool-kit. Moreover, and in collaboration with the S-division and a collaborating expert current information on biosimilars on the EMA corporate website is being revised and updated with the aim of making these accessible in or transferrable to all EU national languages. The work is expected to be finalised by the end of 2024 or early 2025.

International Affairs

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
ICMRA secretariat management, including operational and financial contribution to ICMRA summit and plenary meetings Participation in and coordination of ICMRA Regulatory Forum, and work streams	1.1	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, aligning COVID-19 global response and collaboration Regulatory communication	**On track**	EMA continues to chair the ICMRA and be responsible for the ICMRA secretariat. 3 executive committee and 1 plenary virtual meeting, 3 regulatory forums TCs organised in the first part of the year. 2 ICMRA-related sessions at DIA conference in San Diego sponsored by EMA organised and held successfully. COVID 19 workshop organised and chaired by EMA. EMA is present in all the 7 active ICMRA workstreams, chair or co-chair in 4 of them.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				EMA is meeting coordinator of the "RARE" symposium and workshop to be held in Lugano in September, 6 meetings of the event steering committee organised by EMA. 5 documents published on the ICMRA website (EMA chairs the ICMRA communication group), including reports from the COVID 19 workshops and the 2023 ICMRA summit. EMA coordinated two ICMRA-related sessions at the DIA Annual Global Meeting held in San Diego in June 2024.
Support and foster use of the EU-M4all pathway Support applications scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO This includes early engagement with product developers and related sponsors.	1.2	Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	Pre-submission interactions with developers to clarify questions around the following topics: eligibility, collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, active participation by WHO and non-EU experts during scientific advice or during the evaluation (in particular supporting the use of the product in the target population and local knowledge), reliance on the EU MA to streamline WHO prequalification or speed up national authorisations, parallel EU-M4all and Centralised applications, independence in national decision making. Interactions with WHO to optimise the information WHO needs for experts' appointment and update process for experts to engage in PRAC discussions.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Support WHO/NRA expert involvement for 2 scientific advices on possible EU-M4all opinions. Organisation of a webinar together with Medicines Patent Pool members on EU-M4all.
Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO-SRA collaborative registration procedure, facilitated approvals and other pathways	1.2	Capacity building in low and middle income countries	**On track**	Coordination of 6 Collaborative Registration Procedures (SRA-CRP) that aimed to facilitate registration of 6 products in 12 countries. Participation in workshops organised by WHO to promote awareness, engagement and capacity building with CRP: Kigali July 2024.
Support continued implementation of the EU-US FDA MRA Support extension of EU-US FDA MRA to include vaccines and veterinary medicines	5.2	Support for several operational meetings (internal, EC, FDA) related to discussions in preparation for the extension of the MRA to veterinary medicines, increase in the efficiency of the MRA for human medicines and preparations for the potential extension to vaccines and plasma derived medicines	**On track**	Continue to provide support to EC and Inspections colleagues. This included discussion during EC/EMA-FDA bilateral. Re-audit of FDA took place in April. FDA GMP Summary Document was finalised and operationalised.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Discussions on extension of MRA to vaccines and plasma derived products will only take place in July 2025 (as per FDA's position). Joint inspections have taken place.
Provide assistance to candidate countries and potential candidates (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process	6.1	Participating authorities are better prepared for future potential EU accession, and integration to the European medicines regulatory network	**On track**	Observership to inspections working parties (61 observers/alternates) and shortages (20 observers/alternates) working group started. Participation to three trainings facilitated. Reporting on IPA II Programme completed.
Opening our Procedures at EMA to Non-EU authorities: Implementation of new working model as agreed by Management Board March 2022	1.1	Collaborative assessment involving OPEN participating regulators Alignment or convergence in regulatory outcomes Accelerated assessment and products approval by OPEN partners WHO participation facilitates PQ approvals and availability in LMIC markets	**On track**	Number of new experts registered in first half of year: 6 Number of new OPEN procedures initiated: 1 MFDS Korea has now joined the framework, and meetings held to introduce them to the procedures. Responding to industry feedback, a major development in the procedure is companies are now responsible for asking for OPEN for their applications. The Q&A, OPEN process and playbook have been updated accordingly, and this has also been

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				announced at various stakeholder events (e.g. DIA Euromeeting).
Organisation of awareness sessions for international regulators	1.1	Increase Awareness of the EU system Agency public image	**Suspended**	The activity is linked to "Support and foster use of the EU-M4all pathway". Webinar with Medicines Patent Pool members on EU-M4all organised.
Data protection impact assessment and simplification of personal data redaction for exchange with international partners		Protection of personal data	**Delayed**	Work continued towards finalisation of the AA with Health Canada and on clarifying process and responsibilities for redaction of documents. Focus in the first part of the year in providing answers to the observation related to the EDPS audit on the eudravigilance database in March 2024.
Under the DG INTPA contract, support creation of AMA and regulatory system strengthening at African continental, regional and national levels	6.1	Establishment of the AMA	**On track**	DG INTPA contribution agreement signed Internal and external communication and engagement with stakeholders Participation and engagement with AUDA-NEPAD/AMRH technical committees EMP and GMP TC committees visited EMA

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				2 calls for proposals EMA/GRANT/2024/02/IA and EMA/GRANT/2024/01/IA launched Delivery of 2 Webinars to SADC region Facilitation of attendance of African inspectors at EC Workshop Delivery of 2 in-person trainings in Amsterdam of EMP and GMP Technical Committees In-person EU-EMP TC alignment platform
Communication of information, answer to queries, internal coordination Monitoring of the matrix of the tracking of interactions Preparations of visits, missions' preparation, support to international partners, fellowships and expert visits		Streamline and promote awareness of international activities within the Agency	**On track**	Update of 4 guidance, including the expert nomination. Organisation of 40+ face to face meetings and teleconferences Management of 151 product-related interactions with international stakeholders – including requests for information and requests for documents Management of 580 in person and remote participants in training organised by International Affairs

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Management of 9 visits organised by International Affairs Managing 12+ ICMRA meetings
Collaboration with WHO to support availability of child-friendly TB medicines in the EU	1.1	Approval and availability of paediatric anti-TB medicines for unmet medical needs in the EU	**Completed**	DG HERA call to speed-up the development, availability and access to anti-tuberculosis medicines for children (HADEA/2023/OP/0052) launched in April 2024.
Sustained development and operation of the International Cooperation Platform	1.1	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	**On track**	No meeting took place between January and June 2024. The next meeting will take place on 4 July 2024.
Implementation and support to engagement with US FDA	1.1	Maintain and develop relationship between EMA and FDA Identify and develop existing and new areas of cooperation	**On track**	Support to EC/EMA-FDA F2F bilateral meeting to discuss strategic areas for collaboration; moved forward on actions agreed Visit FDA Commissioner to EMA Meeting IA / FDA Europe Office to progress outcomes of bilateral and discuss priorities Liaison Program Support 4 visits from FDA colleagues to EMA

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Agreement on procedure for EMA participation in project Orbis as observer; first product for pilot agreed Meetings and other interactions with FDA Oncology Center of Excellence to review / progress interactions Agreement on collaboration on gene therapies for ultra-rare diseases (CoGenT) Support, as needed, collaboration in Advanced Manufacturing Established contacts and first discussions for collaboration in AI (in addition to AI in PhV) Preparatory discussions for collaboration on combination products Preparatory discussions for collaboration on scientific advice for high risk medical products Establish contacts for discussion on misinformation/disinformation EMA/FDA Training Pilot

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
				Support to development of 3Rs IWG Ensure regular activities: facilitate requests from EMA and FDA, cluster activities Preparation for and participation in EC-FDA Bilateral, April 2024; the first face-to-face bilateral in more than 4 years.
Active participation in international forums and communication to stakeholders, including but not limited to DIA, ICH, IPRP.	1.1	Greater visibility of the Agency and of its activities	**On track**	International team has placed active stakeholder engagement and communication as one its strategic objectives for 2024. In addition to internal communication efforts, external stakeholder engagement has included: 18 formal presentation opportunities at events with external partners, 14 missions/duty travel opportunities attended either in-person or remotely.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Maintenance, exchange of information and engagement with existing Confidentiality Arrangement partners; Establishment of new Confidentiality Arrangements; Establishment of new Ad Hoc Confidentiality Undertakings	1.1	Facilitate and foster International cooperation	**On track**	CA with MFDS signed in April 2024; No additional ad hoc CAs or working arrangements.

Stakeholders and Communication Division

Pillar 2 – Public health activities

Workload indicators

Procedure		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	2024 annual forecast Initial	Revised	Change	
	Number of EPAR summaries and EPAR summaries updates published	116	81	97	118	164	160	170	10	6%
	Number of documents published on EMA website	3,766	3,834	3,787	4,071	3,628	7,500	7,500	0	0%
	Number of pages published and updated on EMA website	1,779	2,076	1,779	1,883	1,681	3,500	3,500	0	0%
	Number of press releases and news items published	66	64	87	122	86	120	120	0	0%
	Numbers of press and other external briefings conducted[31]	3	-	-	-	-	5	6	1	20%
	Numbers of social media posts published	329	667	488	975	484	1,300	650	-650	-50%
	Number of completed interviews[31]	10	-	-	-	-	30	20	-10	-33%
	Number of media queries responded[31]	598	-	-	-	-	1,200	1,000	-200	-17%
	Number of reports, brochures, leaflets laid out or printed, social media visuals	651	360	437	300	214	800	1,000	200	25%
	Number of professional membership organisation events attended by participating Agency staff	12	12	-	-	-	25	25	0	0%
	Number of sessions with Agency representatives	138	116	-	-	-	120	150	30	25%
	Number of patients and consumers eligible organisations[31]	41	-	-	-	-	42	41	-1	-2%

[31] New indicators introduced in 2024 work programme.

Procedure							2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Number of healthcare professionals eligible organisations[31]	41	-	-	-	-	38	41	3	8%
	Active patients expert nominated by EMA[31]	180	-	-	-	-	145	180	35	24%
	Active healthcare professionals experts nominated by EMA[31]	81	-	-	-	-	80	81	1	1%
	Number of messages circulated via 'Early Notification System'	271	277	329	635	373	500	500	0	0%
	Number of EMA communications pro-actively sent to stakeholders	111	106	109	110	101	200	200	0	0%
	Access to documents, requests received	254	416	375	342	316	750	650	-100	-13%
	Access to documents, documents released	605	652	497	568	382	2,000	1,500	-500	-25%
	Requests for information received	3,835	3,624	4,559	5,915	3,597	10,000	7,500	-2,500	-25%
	Clinical Data Publication (CDP), Procedures published[32]	40	27	-	-	-	45	80	35	78%
	Clinical Data Publication (CDP), Documents published[32]	3,271	471	-	-	-	750	5,600	4,850	647%

Performance indicators

Performance indicators related to core business		Target 2024	Outcome at the end of				
			Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Average rating of pages on corporate website during the year	3.7	n/a[33]	3.8	3.1	3.5	3.7

[32] New indicators introduced in 2023 work programme.
[33] Data unavailable.

Performance indicators related to core business		Target 2024	Outcome at the end of				
			Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Satisfaction level of patient and consumer organisations[34]	n/a	n/a	100.00%	n/a	92%	n/a
	Satisfaction level of healthcare professionals organisations[34]	n/a	n/a	88.00%	n/a	90%	n/a
	Triage of incoming requests received via AskEMA within set timelines[35]	100%	99.60%	99.00%	99%	99%	-
	Responses to ATD within set timelines[36]	90%	98.60%	91.40%	89%	92%	86%
	Responses to RFI within set timelines (for EMA)	95%	84.00%	82.00%	89%	85%	92%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	75%	76%	73.00%	68%[37]	82%	82%
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"[38]	80%	70.3%	n/a	n/a	n/a	-

[34] Survey carried out every 2 years.
[35] New indicator introduced in 2021 Work Programme.
[36] 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.
[37] Low response rate (6.4%).
[38] Survey carried out every 2 years.

Achievements

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Contribute to the implementation of EMANS (European Medicines Agency Network Strategy) and RSS (Regulatory Science Strategy) ensuring that the views of stakeholders are brought into the process		Implementation of strategic plan for stakeholder engagement Support monitoring of implementation, reporting, and review and update of EMANS to 2028	**On track**	EMA's biennial report on stakeholder engagement activities: published in April 2024 (https://www.ema.europa.eu/en/documents/report/stakeholder-engagement-report-2022-2023_en.pdf). The strategic plan for stakeholder engagement update is ongoing. Mid-term reporting of EMANS 2025 was published in December 2023 Review and update of EMANS to 2028 is ongoing. Reflection paper has been finalised in July 2024. The strategy is being drafted.
Planning of communication activities and campaigns in key topic areas including clinical trials and ACT EU, data-driven legislation, cancer as a pathfinder to support development and approval of innovative medicines, work to address shortages, and preparing for implementation of the HTA regulation and for the review of the EU pharma legislation		Maximise public health impact of communication	**On track**	A paid social media campaign to support transition to CTIS has been launched and is still running. A communication plan for cancer as a pathfinder has been developed and agreed with the project team. A press- and social media campaign to support behaviour change with regards the use and prescription of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) in view of ongoing shortages was carried out. A communication group to advise on issues related to the ongoing legislative process to review the pharma legislation was established and is operational.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Implementation of scientific publication strategy		Maximise public health impact of communication	**On track**	Delivery of timely publications: 50 manuscripts internally reviewed and 42 published, including 22 with EMA staff as leading author. 78% of papers published in 2024 as open access. EMA covered the cost of 7 of them following internal evaluation. Key strategic priorities for scientific publications have been identified. Continued collaboration with high-impact journals, including the British Journal of Clinical Pharmacology (BJCP), the European Journal of Cancer (EJC), Clinical Pharmacology and Therapeutics and the European Heart Journal.
Manage and further develop EMA's social media activities		Expand outreach to broader targeted audience	**On track**	Paid campaigns have been successfully implemented. A number of videos have been launched. A social media campaign in support of the EU elections was put in place.
Collaboration with EC (DG SANTE & HERA) / ECDC and HCIN, to share information and update on communication plans		Aligned and streamlined approach to communication across EU	**On track**	Weekly meetings held, continuous discussion of upcoming communication activities and alignment of messaging; membership of European Vaccination Information Portal (EVIP) Steering Committee
Work with Working Group of Communication Professionals (WGCP) to agree communication plans and		Tailored communication at national level supported by strong	**On track**	Communication action plan to strengthen joint communication activities developed; A joint communication strategy has been developed; WGCP / EMA campaigns on rational use of medicines, antimicrobial resistance (AMR) and medicine shortages under development

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
appoint joint leads with EMA, as appropriate		co-ordination at EU level		
Coordination of International Coalition of Medicines Regulatory Authorities (ICMRA) communications		Increase the visibility of ICMRA	**On track**	Regular updates for ICMRA website provided and presentations for plenary meetings prepared; general slide deck and document summarising ICMRA achievements related to COVID-19 response under development
Continue work on automation of processes for requests for information and access to documents from third parties		Increased efficiency of ATD, RFI and clinical data publication (CDP)	**On track**	Some of the planned automated systems are now in place where planned (e.g. DIVs, automated triage, etc) and efficiency gains continue to be monitored.
Implementation of phase 2 of the strategy for CDP re-launch beyond COVID-19		Increased transparency by providing access to clinical documents supporting EMA decisions on centrally authorised products (CAPs)	**On track**	Phase 1 of the relaunch has been successfully implemented. Plans for the adoption of the strategy for phase 2 of the Clinical Data Publication relaunch are on track for the end of 2024 prior to planned implementation in 2025.
Develop a more proactive approach to countering misinformation		Better and earlier awareness of mis- and disinformation, enabling tailored counter-information / transparency	**On track**	A draft outline for a framework has been prepared; actions and deliverables are being agreed; collaboration with international partners, such as FDA, has initiated

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Ensure day-to-day coordination of the overall Agency's response to ongoing crises, including public health emergencies		Ensure that actions required in the context of ongoing crisis events are taken in an efficient and coordinated manner	**On track**	There have been no crises for the Agency in first half of 2024. Coordination of activities for crisis preparedness and monitoring of issues that may potentially evolve into crises has been ensured.
Review and improve crisis communication processes based on lessons learnt from COVID-19		EMA's ability to communicate effectively during a crisis is reinforced	**On track**	EMA crisis communication plan has been finalised.

Information Management Division

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Number of information services/IT systems provided by EMA[39]	28	28	-	-	-	28	28	0	0%

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Satisfaction of EMA internal and external users	80%	96.18%	95.00%	96%	96%	88.17%
Availability of IT systems and corporate website	98%	99.17%	98.00%	98.20%	99.50%	99.06%

[39] New indicator introduced in 2024 work programme.

Administration Division

Workload indicators

Procedure						2024 annual forecast			
	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
Total TA staff recruited against vacant posts	35	27	30	40	13	50	50	0	0%
Staff turnover rate (staff leaving against total no. of staff TA & CA)	2.20%	3.10%	4%	3%	2%	5%	3%	-2%	-40%
Total TA, CA, END at the Agency[40]	946	927	-	-	-	950	950	0	0%
Onboarding of staff (TAs, CAs, ENDs)[40]	51	77	-	-	-	75	75	0	0%
Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)	24	-	-	-	-	72	72	0	0%
Procurement procedures finalised[40]	28	11	-	-	-	46	46	0	0%
Financial commitments initiated[40]	495	641	-	-	-	1,500	1,500	0	0%
Payment transactions initiated[40]	10,094	16,066	-	-	-	27,000	27,000	0	0%
Number of sales orders[40]	16,000	13,104	-	-	-	50,000	50,000	0	0%
Number of registration activities[40]	6,566	6,319	-	-	-	14,000	14,000	0	0%
PRE financial queries and disputes[40]	175	160	-	-	-	250	250	0	0%

[40] New indicators introduced in 2023.

Procedure						2024 annual forecast			
		2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2020 Q1–Q2	Initial	Revised	Change	
	Receivable overdue for more than 30 days (including provision for bad debts)	3.38%	3.76%	3.03%	2%	8.47%	<10%	<10%	-	-

Performance indicators

Performance indicators related to core business	Target 2024	Outcome at the end of				
		Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
Posts on the Agency establishment plan filled	100%	98.00%	97.00%	99.50%	97%[41]	98%
Average time to run selection procedures from vacancy notice to establishment of reserve list	100% average < 3 months	2.99 months	3.0 months	2.8 months	66% < 3 months	<3 months
Revenue appropriations implemented[42]	97%	49.00%	42.00%	45%	45%	50%
Expenditure appropriations implemented	95%	75.00%	71.00%	70%	67%	75%
Payments against appropriations carried over from year N-1	95%	77.00%	61.00%	60%	70%	87%
The maximum rate of carryover to year N+1, of total commitments within the title:						
Title 1	10%	n/a	n/a	n/a	n/a	n/a
Title 2	20%	n/a	n/a	n/a	n/a	n/a
Title 3	30%	n/a	n/a	n/a	n/a	n/a

[41] The figure does not include the posts linked to the new mandate, which are subject to the development of the legislative process.
[42] Invoices issued.

Performance indicators related to core business		Target 2024	Outcome at the end of				
			Q2 2024	Q2 2023	Q2 2022	Q2 2021	Q2 2020
	Payments made within 30 days' time	98%	97.57%	97.53%	97%	97%	94%
	Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)[43]	405	n/a	n/a	n/a	n/a	n/a

Achievements

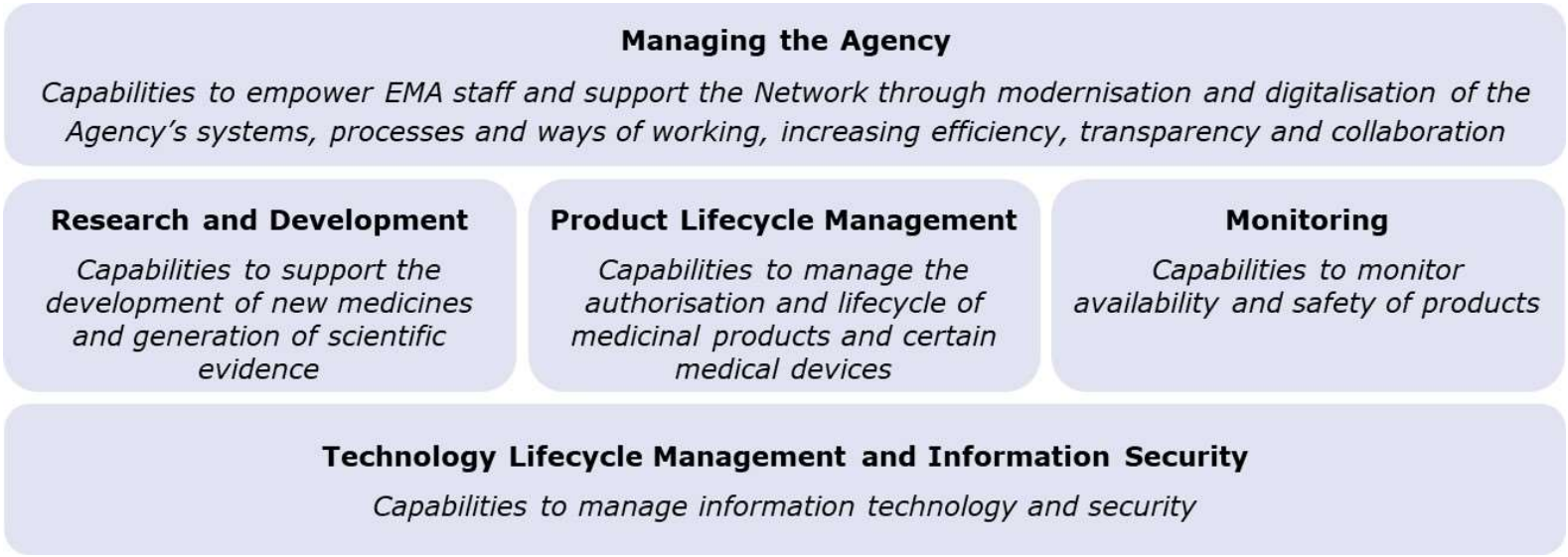
Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
Implementation of the HR strategy & priorities 2023-2025	6.2	The following improvements are expected by strategic ambition: Sustainable organisation will see improvement in resources and competencies needed versus actually available Talent management will see further improvements in career development tools provided by the Agency Optimised work environment will translate into an increased	**On track**	1. Sustainable organisation: Resource planning & allocation is progressing (ongoing - under development) 2. Talent management: Talent Reviews + Future Leaders is progressing (ongoing - under development), Exchange and Rotation programme - Job Shadowing programme is completed, Fellowship and Secondment are progressing (ongoing - under development), Development Day is successfully completed - to be decided whether it will go under Business As Usual (BAU) 3. Wellbeing: Wellbeing programme is successfully delivered and currently under BAU 4. Optimised work environment: Managers community is successfully delivered, Well-being room is delivered, Enhances

[43] New indicator introduced in 2023.

Action	MAWP Strategic Goal	Expected Result	Status	Achievements/results
		net promoter score Wellbeing activities will further improve staff wellbeing Staff and managers will show improved satisfaction with HR services		meeting rooms with modern audiovisual equipment is delivered, revision of Health & Safety policy and office etiquette guidance document are both completed, Smart technology on monitoring building capacity is currently on hold due to resources restriction 5. One Agile HR: Processes review, process review governance (guidelines, repository, baseline, roles, coaching) is delivered, HR Digitalisation: Fieldglass for interims' and 'Fieldglass Statement of work (contractors)' development are almost completed, ready for implementation in Q3 2024. Development/configuration of the Employee Central module is on track, still aiming at 75% of capabilities to be completed in Q4 2024.
Review of options for a replacement of the finance system Replacement of the human resource management system SAP and review of HR management processes	6.4	Gradual replacement of the financial and HR system in line with the future project plan.	**On track**	SAP Finance replacement - analysis ongoing SAP HR replacement - please refer to the Implementation of the HR Strategy and priorities 2023-2025 update on the One Agile HR (HR digitalisation).
Implementation of the new Fee Regulation Review of processes Implementation of the tools enabling of the new fee regulation (3 Epics)	6.3	Support provided to the EU institutions in the review of the new fee regulation to ensure sustainability of the Agency and the European Medicines Regulatory Network	**On track**	Implementation on-going in accordance to the plan for the 3 epics, currently analysis and development of modified systems solution as agreed in the Agile methodology. Regulatory documents adopted. See also New Fee Regulation updated in Annex 2: under Value Stream: Managing the Agency

Annex 2: Pillar III Network Portfolio

The Agency's Network Portfolio is organised under five Value Streams. These reflect the fundamental purpose of the organisation and align to the overall value it provides (e.g., safe and effective medicines for the public, discovery of innovative medicines that address unmet medical needs, etc.). Value streams help organise the portfolio into sub-portfolios that do not have to compete with each other, and that support long-term strategic goals of the Agency. Value streams are stable and long-lived, with fixed budget, leadership, resources and capacity:



To support the Agency's work and achievement of set objectives, several Agile initiatives are undertaken. The table below details the main products and deliverables (epics) that were planned for 2024; progress and delivery as of 30 of June 2024 against what was planned in the work programme 2024 is reported using the following status:

On Track,
Delayed,
Suspended,
Achieved.

Note 1: The budget figures for 2024 show the total estimated cost of the project, including internal and external costs for the Value Stream. Budget allocation to products within the Value Stream is reviewed regularly during the year.

Note 2: Necessary maintenance and improvements to newly developed systems are foreseen, even when not specifically listed as a deliverable.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
Product Lifecycle Management Value Stream (PLM VS) *Capabilities to authorise and manage lifecycle of medicines and medical devices*					**Budget 2024 (M€)13.6**	
Electronic Application Form *(part of the Product Lifecycle Management Portal)*		2021	2025	Human Variations Form go-live and support for centrally and non-centrally authorised products Progression of work on the Initial Marketing Authorisation form for Human and Veterinary products	Delayed	New homepage launched in May. The eAF form for variations has become strongly recommended for centrally authorised medicinal products for human use since May.
Product Data Management User Interface *(part of the Product Lifecycle Management Portal)*		2023	2025	Capabilities for viewing product data Initial introduction of functionalities for submission and correction of product data	On track	Read-only mode of the Product Management Service (PMS) is accessible through the Product User Interface (PUI) in the Product Lifecycle Management (PLM) Portal since May.
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2026	RPM capabilities for Variations, Transfers, Art 61.3 RPM capabilities for PSUR, PSUSA, PAMs Support for implementation of the New Fee Regulation	On track	First roll-out of capabilities for Variations, Transfers and Art. 61.3 in January. Development of capabilities for other post-authorisation regulatory processes (e.g., PSUSA, PAMs, line extensions, renewals) ongoing. Support for implementation of New Fee Regulation for variations and transfer of marketing authorisation ongoing.
Electronic Product Information (ePI)		2022	2024	ePI Pilot with volunteer National Competent Authorities and industry	On track	ePI pilot completed in June.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
(part of the Product Lifecycle Management Portal)				Preparations for further implementation of ePI		FHIR implementation guide for ePI published in June. Preparations for further implementation continue.
Medicinal Product Management System (PMS)	Regulation 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 Regulation (EC) 536/2014, art.81-93) (Clinical Trials regulation) Pharmacovig. fees reg. 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2024	IDMP Implementation (Data migration/transformation into ISO IDMP format) XEVMPD integration with PMS SIAMED data integration with PMS FHIR Adaptor (Capabilities to import IDMP compliant product data to PMS) XEVMPD replacement strategy: Analysis and roadmap towards a simplification and replacement of the existing Article 57 legacy submission systems	On track	Migration of data for centrally authorised products (CAPs) and nationally authorised products (NAPs) from SIAMED and XEVMPD to PMS completed in April.
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	Completion of eCTD v4.0 specification and implementation guide update for the Europe (EU) region Progression towards pilot and optional use support of eCTD v4.0 submissions for centrally authorised products	On track	Work ongoing for specification review and implementation guide update. EURSNext Proof of Concept (PoC) with NCAs is ongoing. Pilot plan drafting not started yet.
Veterinary Union Product Database (UPD)		2021	2025	UPD maintenance and improvements to meet legislative requirements, improve	On track	Version 1.7.2424 released in June, enabling the MAHs to save and resume draft VNRAs.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
				usability and support improved data quality		
European Medicines Web Portal (EMWP)	Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2026	Refresh of the strategy towards a European Medicines Web Portal for medicinal products for human use, in alignment with the existing portal for veterinary medicines	On track	Strategy refresh is ongoing and expected to conclude in Q4/2024.
Research and Development Management Value Stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*					**Budget 2024 (M€) 12.6**	
Regulatory Procedure Management (RPM) for R&D		2023	2024	Paediatrics procedure Support for implementation of the New Fee Regulation Maintenance and improvements	Achieved On track	Paediatrics procedure go-live on 4 June. Support for New Fee Regulation ongoing. Maintenance and improvements ongoing.
Clinical Trials Information System (CTIS)	Regulation (EC) 536/2014, art.80-82 Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	tbc	CTIS maintenance and improvements CTIS Business Intelligence (CTIS BI) maintenance and improvements	On track	CTIS maintenance and improvements ongoing. CTIS BI maintenance and improvements ongoing.
Clinical Trial Navigator (CTN)		2023	2025	Development of Clinical trial study protocol conceptual and logical data model (ICH M11)	On track	Business activities to develop the data model ongoing.
Real World Metadata Catalogues		2021	2024	Go-live of the Catalogue of real-world evidence data sources and studies in Q1/2024	Achieved	HMA-EMA catalogues of real-world data sources and studies launched on 15 February.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
				Maintenance and improvements		Maintenance and improvements ongoing.
Scientific Explorer		2020	2024	Completion of the Minimum Viable Product (MVP) for the interrogation of regulatory and scientific documents and Go-live in Q1/2024 Maintenance and improvements	Achieved	Scientific Explorer go-live on 4 March for use by staff of the European Medicines Regulatory Network. Maintenance and improvements ongoing.
T.R.I.P. (Horizon Scanning)		2023	2024	Completion of the Minimum Viable Product (MVP) for the horizon scanning capability (identify future innovations and trends earlier to support development) and Go-live in Q1/2024 Maintenance and improvements	Achieved	TRIP launched for EMA internal use on 15 January. TRIP launched for use by European Medicines Regulatory Network in June. Maintenance and improvements ongoing.
Data Analytics Platform		2024	2024	Support generation of scientific evidence	On track	Platform core set-up completed and initial capabilities for self-service analytics enabled.
Monitoring Value Stream (MON VS) *Capabilities to monitor availability and safety of products*					**Budget 2024 (M€) 9.3**	
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2025	Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) Monitoring of Critical Medicines during PHE/major events Interoperability of ESMP	On track	ESMP Interoperability approach agreed with MAHs and NCAs and endorsed by the MSSG. Dedicated ESMP webpage launched in April. User acceptance testing conducted in April. Reporting requirements communicated to industry. Webinar on MAH reporting requirements in June.
Inspections		2023	2025	Maintenance, improvements and support for implementation of the New Fee Regulation	On track	Maintenance, improvements and implementation of Minimum Viable Product

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
						(MVP) for pre-payment process in IRIS completed.
Parallel Distribution		2023	2025	Maintenance, improvements and support for implementation of the New Fee Regulation	On track	Maintenance, improvements and implementation of Minimum Viable Product (MVP) for pre-payment process in IRIS ongoing.
Union Pharmacovigilance Database (UPhD, formerly EVVet3)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2024	Maintenance and improvements	On track	Pharmacovigilance inspections dashboard implemented. Completed line listing for pre-calculations at active substance level for signaling dashboard. Maintenance and improvements ongoing.
Antimicrobial Sales & Use (ASU)	Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578 Commission Implementing act 2022/209	2021	2024	Minimum viable product completion Maintenance and improvements	On track	ASU Platform (MVP) launched in January. MS deadline to submit sales and animal population data by 30 June. Maintenance and improvements ongoing.
Signal and Safety Analytics (SSA)		2023	2024	Signal and Safety Analytics – minimum viable product	Delayed	Implementation of initial and incremental Extract Transform & Load (ETLs) completed. Initial configuration of electronic Reaction Monitoring Report (eRMR) in PV Signal completed. Data Protection package sent to EDPS in June.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
Managing the Agency Value Stream (MTA VS) *Capabilities to empower EMA staff and support the Network through modernisation and digitalization of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration*					**Budget 2024 (M€) 12.5**	
SAP Finance replacement		2023	2025	Finalise analysis and technology selection	On track	Analysis ongoing
SAP HR replacement		2023	2025	Kick off implementation of HR Data Organisation and processes	On track	SAP Core HR (Employee Central) replacement ongoing. Contingent workforce (interims) go-live planned for Q3. Statement of Work (contractors) go-live planned for Q3.
New Fee Regulation	Regulation (EU) 2024/568 of 7 February 2024 on fees and charges payable to the European Medicines Agency	2023	2025	Implementation of new fee process in existing EMA applications Pre-payment process implementation for some procedures Vet pharmacovigilance fees implementation	On track	Technical analysis and integration with IRIS for propagating fee details to financial and accounting application completed. Integration of case management for referrals completed.
EU Network Training Centre (EU NTC)		2022	2024	EU NTC engagement portal for public	Achieved	Engagement portal for public went live in January.
Document Management System replacement		2023	2024	Kick off implementation of DREAM replacement	On track	Vendor selection completed.
AskEMA		2023	2024	AskEMA replacement implementation	On track	Implementation ongoing.
Customer Relationship Management (CRM) tool		2024	2026	Kick off analysis for an Agency CRM tool	Suspended	Not started.
Audit workflow management tool *[new]*		2023	2024	Audit workflow management tool	Achieved	Audit workflow management tool went live in February.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2024	Status	Achievements/Results Q1/Q2 2024
Workplace Experience *[new]*		2024	2027	Finalise analysis and technology selection	On track	Business analysis ongoing
Technology Lifecycle Management and Information Security Value Stream (TLM VS) *Capabilities to manage information technology and security*					**Budget 2024 (M€) 4.2**	
Information Security and Cyber Security enhancements		2022	2024	Cyber & Information Security enhancements Operational Security enhancements Application Security enhancements	On track	Continuous improvements to information security and cyber security.
Remaining legacy application modernisation analysis		2023	2024	Analysis on the future-proof solutions the current legacy apps could be migrated to Prioritisation of the legacy apps Proof of Concept for one app	Achieved	Analysis and prioritisation completed. Proof of Concept for two applications completed.
Data Centre 2.0 (DC 2.0)		2023	2024	Migration of all workloads in the AWS cloud Migration/activation of the infrastructure components Decommissioning of the current physical equipment (physical DC)	Achieved	Migration to cloud completed. Decommissioning of physical data centre completed.

Annex 3: Terms and abbreviations

Term/abbreviation	Definition
AA	Administrative Agreement
AACTING	Network on quantification of veterinary Antimicrobial usage at herd level and Analysis, Communication and benchmarking to improve responsible usage
AAV	Adeno-associated viral vector
AAVM	Antimicrobial Agents in Veterinary Medicine
ACT EU	Accelerating Clinical Trials in the EU
ADR	Adverse drug reaction
AER	Adverse event report
Agency	European Medicines Agency
AI	Artificial intelligence
AM	Antimicrobial
AMA	African Medicines Agency
AMEG	Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization programme
API	Active pharmaceutical ingredient
AR	Assessment report
Art	Article
ASR	Annual Safety Information
ASU	Antimicrobial sales and use
ATAm	Alternative to Antimicrobials
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUD	Audit
AUDA-NEPAD/AMRH	African Union Development Agency/African Medicines Regulatory Harmonization
AV	audiovisual
BAU	Business as usual
BDSG	Big data steering group
BI	Business Intelligence
BJCP	British Journal of Clinical Pharmacology
BWP	Biologics Working Party
CA	Contract agent

Term/abbreviation	Definition
CAP	Centrally authorised product
CAT	Committee for Advanced Therapies
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CHMP	Committee for Medicinal Products for Human Use
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
COLT	Core Operational Leadership Team
Commission	European Commission
CR	Common Repository
CRM	Customer Relationship Management
CRO	Clinical research organisations
CRP	Collaborative Registration Procedure
CT	Clinical trial
CTA	Clinical Trial Application
CTCG	Clinical Trials Coordination Group
CTD	common technical document
CTIS	Clinical trial information system
CTN	Clinical Trial Navigator
CTR	Clinical Trials Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
DARWIN EU	Data Analytics and Real World Interrogation Network
DC	Data Centre
DG	Directorate-General of the European Commission
DG INTPA	European Commission Directorate-General for International Partnerships
DG SANTE	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DIVs	Document Identification Validation System
DQ	Data Quality
DREAM	Document Records Electronic Archive Management system
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission priority
EDPB	European Data Protection Board

Term/abbreviation	Definition
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EJC	European Journal of Cancer
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMP-TC	Evaluation of Medicinal Products Technical Committee
EMRN	European medicines regulatory network
EMWP	European Medicines Web Portal
END	Seconded national expert (Experts nationaux détachés)
EPAR	European public assessment report
ERA	Environmental risk assessment
ERATO	Enhanced Review of Abstracts with Transformer Models
eRMR	Electronic Reaction Monitoring Report
ESIP	European Social Insurance Platform
ESMP	European Shortages Monitoring Platform
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	Emergency Task Force
EU	European Union
EUAN	EU Agencies Network
EU-IN	EU-Innovation Network
EU-M4all	Medicines for use outside the EU
EUR	Euro
EURS	European Review System for eCTDs
EVDAS	EudraVigilance data analysis system
EVIP	European Vaccination Information Portal
EVV	Union Pharmacovigilance Database
EWG	Expert Working Group
EWP	Efficacy Working Party
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FMT	Faecal Microbiota Transplantation

Term/abbreviation	Definition
FTE	Full-time equivalent
FVE	Federation of Veterinarians of Europe
GCP	Good clinical practice
GLP	Good laboratory practice
GLP-1 RAs	Glucagon-like peptide-1 agonists
GMDP	Good manufacturing and distribution practice
GMP	Good manufacturing practice
HaDEA	European Health and Digital Executive Agency
HCIN	Heads of Communication and Information Network (EU agencies network)
H-EG	Human Medicines - Scientific Evidence Generation Department
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
HTACG	Member State Coordination Group on HTA
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
IHD	Instant Health Data
IMP	Investigational medicinal product
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme
IRIS	Platform facilitating the exchange of regulatory and scientific information between EMA and organisations developing medicinal research products for potential use in the European Union
ISO	International Organisation for Standardisation
IT	Information technology
IVDR	In vitro Diagnostics Regulation
IVMAB	Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JCA	Joint Controllership Agreement
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
KIC	Knowledge and innovation community

Term/abbreviation	Definition
KPI	Key performance indicator
LMIC	Low-and middle-income countries
LMS	EU Network Training Centre Learning Management System
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MAWP	EMA multiannual work programme
MD	Medical devices
MDR	Medical Devices Regulation
MEDEV	Medicine Evaluation Committee
Member State	Member State of the European Union
MFDS	Ministry of Drug and Food Safety (South Korea)
ML	Machine learning
MON VS	Monitoring Value Stream
MP	Medicinal Products
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MS	Member State of the European Union
MSP	Multi-Stakeholder Platform
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA VS	Managing the Agency Value Stream
MUMS	Minor use, minor species
MVP	Minimum viable product
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority
NCPE	National Centre for Pharmacoeconomics, Ireland
Network	European medicines regulatory network
NIS	Non-Interventional Study
NITAG	National immunization technical advisory groups of WHO
NLP	Natural language processing
NPL	New pharmaceutical legislation
NRA	National Regulatory Agencies
NTC	EU Network training centre
OLAF	European Anti-Fraud Office

Term/abbreviation	Definition
OPEN	Opening our Procedures at EMA to Non-EU authorities
PAM	Pre-clinical Assessors Meeting
PASS	Post-authorisation safety study
PHE	Public Health Emergency
PhVWP	Pharmacovigilance working party
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/Pharmacodynamic
PLM	Product Lifecycle Management Value Stream
PMS	Medicinal Product Management System
POC	Point of Contact
POEG	CTIS Member State Product Owners Experts Group
PQ	Pre-qualification
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROM	CHMP's preparatory and organisational matters meeting
P-SMEG	Pilot Signal Management Expert Group
PSUR	Periodic safety-update report
PSUSA	PSUR single assessment
PUI	Product User Interface
PV	Pharmacovigilance
Q (1, 2, 3, 4)	Quarter (1, 2, 3, 4)
Q&A	Questions and answers
QAT	Quality control, assurance and acceptance testing
R&D	Research and Development Management Value Stream
RACI	Responsible, Accountable, Consulted, Informed
RAGNA	Regulatory Agencies Global Network against AMR
RFI	Request for information
RPM	Regulatory Procedure Management
RSS	Regulatory Science Strategy
RWD	Real world data
RWE	Real-world evidence

Term/abbreviation	Definition
SA	Scientific advice
SAWP	Scientific Advice Working Party
SC	Scientific committee
SCORE	Strategic Communication Review Group
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SNSA	Simultaneous National Scientific Advice
SoHo	Substances of human origin
SPC	Summary of product characteristics
SPMP	Shortage prevention and mitigation plan
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
SRA (WHO)	Stringent Regulatory Authority
SSA	Signal and Safety Analytics
STAMP	Expert Group on Safe and Timely Access to Medicines for Patients
STF	Simplification Task Force
SWP-V	Committee for Veterinary Medicinal Products (CVMP) Safety Working Party
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TC	Technical Committee
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TFAAM	HMA-EMA Task Force on Availability of Medicines
TLM	Technology Lifecycle Management and Information Security Value Stream
TOR	Terms of reference
TRIP	Topics of innovation, Relationships between external and internal topics, Identification of challenges and opportunities, Proposals for action.
TRS	EMA Regulatory Science and Innovation Task Force
TRS-INO	Regulatory Science and Innovation Task Force - Innovation and Development Accelerator
TW1	Thematic working group 1
UAT	User Acceptance Test
UPD	Union product database
UPhD	Union Pharmacovigilance Database
US	United States of America

Term/abbreviation	Definition
VE	Vaccine Effectiveness
VGVP	Veterinary good pharmacovigilance practices
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform
VNRA	Variations not requiring assessment
VS	Value Stream
VSFG	HMA Veterinary Strategy Focus Group
WG	Working group
WGCP	Working Group of Communication Professionals
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary