EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mid-year report 2025

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Key developments

In the first half of 2025, the European Medicines Agency (EMA) made substantial progress in the main focus areas presented in the Single Programming Document (SPD) 2025-2027. This section highlights achievements in these areas as well as other key developments that occurred over this period.

Main focus areas

Accelerating and optimising the assessment of key medicines

Building on the Agency's experience using cancer medicines as a pathfinder, the Agency is applying the learnings to key medicines in other therapeutic areas. A number of activities are ongoing with the aim of accelerating and optimising assessment. The Revamp Project has updated a number of key templates for assessment, and introduced more streamlined collaboration through the implementation of co-authoring in SharePoint between assessment teams. An AI tool is being developed which will help greatly in the quality control of draft assessment reports, ensuring alignment with templates. The Group for Internal Rules on Extensions of Clock Stops (GIREX) project has introduced a systematic discussion of all clock-stop extension requests at CAT and CHMP, leading to better harmonised extensions and a return to the strict implementation of the 2009 guideline on clock-stop extensions. This in turn has seen an overall reduction of the time to approval for MAAs for the first half of 2025, compared to previous years. In addition, work is ongoing on ensuring a change of culture regarding the number of questions raised during evaluation, focussing on the key questions and not the "nice-to-haves". Workbooks for clinical and quality assessors have been created and dedicated workshops are planned for the second half of 2025. Finally, work is ongoing in the Pre-submission Interaction Group (Pre-SIG) project, looking to fundamentally reshaping the pre-submission interactions between the Agency, Rapporteur teams and applicants, with the aim of avoiding premature submissions and greatly enhancing submission predictability.

In addition, the Clinical Trials Regulation became fully applicable in January 2025, marking the end of a three-year transition period, during which more than 5,000 clinical trials were transitioned to the Clinical Trials Information System (CTIS), the single-entry point for sponsors and regulators for the submission and assessment of applications for clinical trials in the EU.

The Accelerating Clinical Trials in the EU (ACT EU) initiative supports activities related to the CTR. In January 2025, the Agency published the revised ACT EU workplan, setting out the programme's deliverables and timelines for 2025-2026. The work plan covers three main areas: the operation of the Clinical Trials Regulation, maximising the impact of clinical trials, and clinical trials in public health emergencies.

As part of the ACT EU workplan, a new clinical trial map was launched on the CTIS public website. The map is designed to provide patients and healthcare professionals with easy access to comprehensive, real-time information about clinical trials for different medical conditions in their geographic area. The map also allows users to search using lay language and includes an autocorrect system that provides suggestions in case of misspellings. Search results offer investigators' contact details, enabling members of the public to enquire directly about potential enrolment into a given trial. The first version of the map is provided in English. Additional EU languages will be added in future releases.

In the area of real-world data, the DARWIN EU® network now includes 30 data partners providing data from approximately 180 million people across 16 European countries. Five additional partners are at an advanced stage of onboarding and 5 more are being considered for onboarding by the end of 2025. Forty-five studies have been initiated or are ongoing, with 73 study requests currently being processed.

As artificial intelligence will be crucial for optimising the assessment of medicines, the Heads of Medicines Agencies (HMA) and EMA published the joint work plan Data and AI in medicines regulation to 2028. This sets out how the European medicines regulatory network plans to leverage large volumes of regulatory and health data as well as new tools to encourage research, innovation and to support regulatory decision-making. The workplan lays out a roadmap for managing, analysing and sharing data across the network, while adhering to high data security and ethical standards. It also provides a framework to address new legislation and initiatives in the European Union (EU), notably the new pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act.

Facilitating the path to accessibility and strengthening the availability of medicines

To improve the accessibility and availability of medicines in the EU, the Agency is supporting the implementation of the health technology assessment (HTA) Regulation and coordinating efforts to prevent and mitigate shortages, while strengthening the security of supply chains for critical medicines.

The new regulation, which became applicable in January 2025, creates an EU framework for the health technology assessment of medicines and medical devices, by fostering collaboration and coordination between EU Member States. The Agency is supporting the implementation of the regulation in 3 areas: joint clinical assessments (JCAs) by providing information from the regulatory review; collaboration in parallel joint scientific consultations (JSCs) to facilitate the generation of evidence necessary for both regulatory and HTA decision-making; and the exchange of information about upcoming applications and future health technologies, both for planning purposes but also for horizon scanning.

Working closely with Member States, the Agency has also continued to play a significant role in addressing challenges related to the availability of medicines and the security of supply for critical medicines. This includes work with the Critical Medicines Alliance on preventing and addressing shortages and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) which published recommendations to address vulnerabilities in the supply chain of radiopharmaceuticals.

A key milestone in managing shortages was reached in January 2025 when the European Shortages Monitoring Platform (ESMP) became fully functional. The platform facilitates monitoring and management of critical medicines during public health emergencies and major events and in the context of preparedness activities by enabling marketing authorisation holders (MAHs) and national competent authorities (NCAs) to directly report information on supply, demand and availability of nationally and centrally authorised medicines during crises and preparedness actions led by the MSSG. The use of the ESMP became mandatory for marketing authorisation holders and NCAs as of 2 February 2025.

Seizing the opportunities to futureproof medicines regulation in the EU

EMA and the Heads of Medicines Agencies (HMA) published their joint EU medicines agencies' network strategy to 2028 (EMANS) in March 2025, following its adoption by the HMA and the EMA Management Board.

The strategy, titled 'Seizing opportunities in a changing medicines landscape', is a comprehensive review and update of the five-year strategy which was developed to cover the period 2021 to 2025 (EMANS 2025). The updated document will guide the European medicines regulatory network over the

next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance.

Prepared in a post-pandemic setting, the strategy draws on the extensive experience gained from tackling COVID-19. It also takes into account the ongoing revision of the EU's pharmaceutical legislation, laying the groundwork for its implementation.

In this context, EMA has continued to provide technical support to the legislative process, working closely with the European Commission and network partners to assess the implications of the evolving text. Early engagement has started with scientific committees to explore future ways of working in line with the proposed committee reform, aiming to ensure continuity of expertise and a smooth transition. In parallel, the raw data pilot is now underway, paving the way for a more systematic evaluation of clinical trial data submitted at the time of marketing authorisation, with the goal of enhancing data quality and regulatory decision-making. Scenario planning is also progressing to anticipate different implementation paths and ensure the regulatory network remains effective and responsive in the years ahead.

Other key developments and activities

One Health and antimicrobial resistance

In March 2025, the Agency published the first European sales and use of antimicrobials for veterinary medicine (ESUAvet) annual surveillance report. For the first time, all 27 EU countries, together with Iceland and Norway, have collected and reported data on both sales and use of antimicrobials in animals in their countries. The data cover the year 2023, marking the beginning of a regular exercise that will result in yearly reports.

The data in the annual ESUAvet reports, collected via the ASU Platform, will help to identify trends in antimicrobial consumption in animals more accurately and with more granularity, enabling decision-makers to address the increasing complexity of antimicrobial resistance and to take appropriate measures to protect both animal and human health in Europe.

As part of the implementation of the cross agency One Health Task Force framework for action published in 2024, EMA continues to strengthen cooperation on the implementation of the One Health agenda in the EU, working with four other EU agencies (ECHA, ECDC, EFSA and EEA) on promoting strategic coordination, research alignment, capacity building, communication and stakeholders' engagement on One Health and supporting the development of partnerships through joint activities across these EU agencies.

This collaboration enhances the agency's ability to provide integrated scientific advice, particularly in areas such as antimicrobial resistance, zoonotic diseases, and environmental health risks and supports EMA's preparedness and response capabilities, ensuring that health policies are informed by comprehensive, cross-sectoral evidence.

International cooperation

EMA continued to support the journey towards the setup of the establishment of the African Medicines Agency and contributing to regulatory strengthening at national and regional levels. The African Medicines Regulatory Harmonisation (AMRH) Initiative of AUDA NEPAD completed the successful assessment and listing of the first five medicinal products at the continental level as part of a pilot to test regulatory processes and procedures.

In June, EMA and heads of European national agencies hosted the African Medicines Agency Governing Board, together with colleagues from African national regulatory agencies, African Union bodies, the European Commission, and the World Health Organization (WHO). This was the first meeting between the African and European regulatory networks. The meeting, held on 11-12 June 2025, focused on operationalisation of the AMA and reinforcing the African regulatory network.

Legal developments

EMA's opinions and decisions are occasionally challenged in the Union courts. At present, EMA is handling seven such legal challenges. The cases concern various matters, including the validity of scientific assessments performed by EMA committees, the handling of requests for public access to documents by EMA and a claim for damages related to EMA activities. In the first half of 2025, the General Court issued an order in favour of EMA in Case T-373/24, in which the Court rejected as inadmissible a pharmaceutical company's attempt to call into question a 2017 EMA scientific assessment. This ruling is particularly significant, as it clarifies whether companies may challenge EMA scientific assessments years after their adoption, that is to say, beyond the strict time-limit for appealing the related decision adopted by the European Commission. The company has since appealed the decision before the Court of Justice, which will now review whether the General Court was correct in dismissing the case.

Key figures

This report describes the results and achievements of the Agency, working closely with the NCAs, during the first six months of 2025, and thus reflects the situation as of 30 June 2025. Here below are highlighted the most relevant deviations from the annual work programme, registered in the first half of 2025. Further developments have taken place since, which have not been included in this document. The reference for comparison is the first half of the year.

Assessment activities for human medicines

Pre-authorisation activities

The total scientific advice and protocol assistance requests remained relatively stable, compared to the first half of 2024, with 384 requests received in Q1/Q2 2025 (402 in Q1/Q2 2024). The annual forecast is revised downwards from 770 to 720.

The number of **paediatric-procedure applications** received has increased by 29%, compared to the first half of 2024, from 327 to 421 applications, and the total number of applications expected is increased from 654 to 799 for the full year 2025. The number of applications for **orphan designation** also increased by 11%, with 115 applications received. PRIME eligibility requests received remained stable and the forecast is maintained at 60 for the full year.

The number of requests for **qualification of novel methodologies** decreased from 8 in the first half of 2024 to 6 in the first half of 2025.

Initial evaluation activities

Applications for **non-orphan medicinal products** remained relatively stable in the first half of the year (17 vs 19 applications received in the first half of 2024), and the forecast for the full year remains stable at 50 applications.

The **number of reviews on the maintenance of the orphan designation criteria at MAA stage** has increased by 30% (26 vs 20 in the first half of 2024). The forecast is increased from 30 to 40 for the full year.

Applications for **similar biological products** were significantly lower than in the first half of 2024 (13 received vs 25 in the first half of 2025). Similarly, **ATMP marketing authorisation applications** (2 received) and **companion diagnostics opinions** (3) decreased by 50% respectively.

Post-authorisation activities

The number of **extensions of marketing authorisation** applications have increased by 24% (21 vs 17 applications in the first half of 2024).

The number of **type IA** variation applications fell by 13% compared to Q1-Q2 2024 (1,561 vs 1,797 received). By contrast, **type IB** variation applications have increased by 23% compared to the same period (1,809 vs 1,739 applications).

Pharmacovigilance

The number of **PSURs overall decreased,** however **PSURs single assessment (NAPs only) started** increased by 14%.

Assessment activities for veterinary medicines

The number of **ITF briefing requests** received in the veterinary area was significantly higher than in the previous year, with 5 requests received, compared to 2 in Q1-Q2 2024.

Requests for **Scientific advice** regarding veterinary medicines were lower in the first half of 2025, with 7 requests received, in comparison to 14 in the first half of 2024. The forecast however remains stable with 20 requests expected for the year 2025 in total.

While the total number of **initial marketing authorisation applications** increased by 9% (12 in Q1-Q2 2025), no **MRL** applications or extension/modification applications and review of draft Codex MRL were received.

The **total number of variation applications** requiring assessment was overall relatively stable (5% lower than in the first half of 2024), with 132 applications received (in comparison to 139 in the first half of 2024). The forecast is 320 variations for the full year. Despite this development, there was significant growth of **level 2 variation** applications (35 applications), as well as an increase from 60 to 71 in **level 4** variation applications.

The total number of **Signals submitted by Marketing authorisation holders** in the veterinary area was 17% lower than in the first half of 2024 (131 vs 158 Signals in Q1-Q2 2024). Signals classified for **close monitoring by Marketing Authorisation Holders** increased (29 in Q1-Q2 2025, versus 10 in Q1-Q2 2024), while the number of **signals classified as refuted by Marketing Authorisation Holders** decreased from 133 in the first half of 2024 to 86 in the first half of 2025.

The total number of adverse event reports (AER) increased in comparison to the first half of 2024, in the category **of non-CAP ADRs**, it increased by 117% (66,020 compared to 30,417 in the first half of 2024).

Inspections and compliance

The number of **notifications of suspected quality defects** more than doubled in the first half of 2025 in comparison to Q1-Q2 2024. There were 248 notifications received, and the yearly forecast was revised to 450.

The number of **standard and urgent certificate requests** are rising. Standard certificate requests increased in comparison to the first half of 2024 by 118% (5,194 requests vs 2,387 in Q1-Q2 2024), whereas the number of urgent certificate requests increased by 183% (1,378 requests vs 487 requests in Q1-Q2 2024).

By contrast, the number of **GMP inspections** (114) as well as **Pharmacovigilance inspections** (5) have fallen, by 40% and 58% respectively, in comparison to the first half of 2024.

Plasma Master File (PMF) inspections showed for the first time in three years a sharp decrease (30 inspections versus 107 in the first half of 2024).

Committees and working parties

The number of **reimbursed meetings** fell by 8% in comparison to the first half of 2024 (139 meetings held in total). This includes Committee meetings, Management Board, Working Parties, Workshops, Forum, Seminars, Infodays and other meetings held.

Information and transparency

Clinical Data Publication procedures published remained stable in comparison to Q1-Q2 2024, and is expected to increase in the second half of the year as the agency implements step 2 of CDP relaunch. The target remains 120 procedures for the full year 2025.

The number of **Requests for access to documents** has increased significantly, with 401 requests received in the first half of 2025. In addition, more than 2000 Requests for access to documents (ATD) were collectively received as part of a campaign for the release of the applications for marketing authorisation for the COVID-19 mRNA vaccines. These requests are being handled as part of the exceptional transparency measures for COVID-19 with publication on EMA's website.

Annexes

Annex 1: Detailed mid-year report

This part of the report reflects the progress of implementing the adopted Annual Work Programme 2025. 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 2025'. 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.

1. Human Medicines Division

1.1. Pre-authorisation activities

Workload indicators

	Procedure	2025 annual forecast								
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Total scientific-advice and protocol-assistance requests	384	402	348	470	427	770	720	-50	-6%
	Requests for parallel scientific advice and protocol assistance with international regulators	0	0	2	4	3	4	4	0	0%
	Requests for joint scientific advice and protocol assistance with HTA	3	2	3	3	2	8	8	0	0%
	Scientific advice for PRIME products	16	19	-	-	-	40	40	0	0%
	Protocol-assistance and follow-up requests	69	80	59	75	80	137	128	-9	-7%
	Requests for qualification of novel methodologies	6	8	13	14	14	16	16	0	0%
	PRIME eligibility requests received	30	30	25	25	29	60	60	0	0%
	Applications for orphan designation received	115	104	116	157	134	210	210	0	0%
	Total paediatric-procedure applications received	421	327	362	346	368	654	799	145	22%
	Submitted requests for ATMP classification	19	24	25	25	46	45	40	-5	-11%

1.2. Initial evaluation activities

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Non-orphan medicinal products	17	19	17	14	23	49	50	1	2%
	Orphan medicinal products	12	11	8	12	10	25	28	3	12%
	Similar biological products	13	25	8	4	4	26	24	-2	-8%
	Generics, hybrid, informed-consent applications, etc.	7	9	8	9	12	17	17	0	0%
	Scientific opinions for non-EU markets (Art 58)	1	1	0	0	0	1	1	0	0%
	Paediatric-use marketing authorisations	1	2	1	0	0	1	3	2	200%
	Requests for accelerated assessment accepted	3	3	5	0	7	5	5	0	0%
	ATMP marketing application authorisation requests received	2	4	2	1	3	5	5	0	0%
	Companion diagnostics opinions[1]	3	6	3	-	-	15	15	0	0%
	Reviews on the maintenance of the orphan designation criteria at MAA stage	26	20	-	-	-	30	40	10	33%

[1] Finalised.

Performance indicators

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	% of initial marketing authorisation applications that had received centralised scientific advice	70%	68.90%	n/a	43.00%	60%	70%
	Average assessment time for new active substances and biosimilars – *reversal of traffic lights*	205	189.97	203.75	190.00	199	199
	Average clock-stop for new active substances and biosimilars – *reversal of traffic lights*	180	132.97	239.00	185.00	229	168
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	50%	33.33%	66.66%	50.00%	33%	33%

1.3. Post-authorisation activities

Workload indicators

Procedure							2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Type IA variations	1,561	1,797	1,772	1,778	1,961	4,000	4,000	0	0%
	Type IB variations	1,809	1,470	1,739	1,606	1,393	3,750	3,750	0	0%
	Type II variations	544	571	499	617	606	1,406	1,411	5	0%
	Extensions of marketing authorisations	21	17	18	11	16	33	35	2	6%

Performance indicators

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Average assessment time for variations that include extension of indication – *reversal of traffic lights*	180	178.48	191.73	177.51	171	162

1.4. Referrals

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Pharmacovigilance-related referrals	1	1	2	4	2	5	4	-1	-20%
	Other referral procedures	2	2	2	0	7	8	7	-1	-13%

1.5. Pharmacovigilance

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Signals peer-reviewed by EMA	716	792	822	1,126	858	1,200	1,200	0	0%
	Number of ICSRs for CAPs (reports received)	676,941	648,116	787,783	1,348,258	1,458,522	1,500,000	1,500,000	0	0%
	Signals assessed by PRAC (validated by EMA)	26	23	25	26	33	40	40	0	0%

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	PSURs (standalone CAPs only) started[2]	276	300	253	-	-	608	556	-52	-9%
	PSURs single assessment (CAPs with NAPs)[3] started	20	26	18	-	-	42	54	12	29%
	PSURs single assessment (NAPs only) started[4]	134	118	107	-	-	373	308	-65	-17%

1.6. Inspections and compliance

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	GMP (excluding PMF)	114	189	210	89	77	299	405	106	35%
	GLP	0	1	2	1	0	1	0	-1	-100%
	GCP	41	53	47	53	15	90	108	18	20%
	Pharmacovigilance	5	12	13	10	10	15	11	-4	-27%
	PMF	30	107	88	20	20	76	60	-16	-21%
	Notifications of suspected quality defects	248	108	127	131	87	216	450	234	108%
	Medicinal products included in the sampling and testing programme	35	33	75	94	94	59	70	11	19%

[2] New indicator introduced in 2022.
[3] New indicator introduced in 2022.
[4] New indicator introduced in 2022.

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	Standard certificate requests	5,194	2,387	2,486	2,012	1,938	11,165	9,850	-1,315 -12%
	Urgent certificate requests	1,378	487	612	591	987	1,525	2,488	963 63%
	Parallel distribution initial notifications	1,548	1,365	1,038	1,012	1,537	2,244	2,800	556 25%
	Parallel distribution annual updates	3,169	2,804	2,742	2,851	2,331	4,600	5,500	900 20%

Performance indicators

Performance indicators related to core business	Target 2025	Outcome at the end of				
		Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
Standard certificates issued within the established timelines (30 working days)	90%	100.00%	100.00%	100%	100%	99%
Average days to issue standard certificate – *reversal of traffic lights*	15	14.70	5.00	4.80	3	16
Urgent certificates issued within established timelines (2 working days)	98%	98.00%	99.00%	100.00%	100%	99%
Parallel distribution initial notifications checked for compliance within the established timeline	98%	99.00%	99.00%	99.00%	98.80%	98.80%

1.7. Committees and working parties

Workload indicators

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	Number of reimbursed meetings	139	151	151	24	0	334	334	0 0%
	Committee meetings[5]	26	25	26	11	51	76	76	0 0%
	Working Parties	31	29	28	-	-	29	29	0 0%
	Workshops, Forum, Seminars, Infoday[6]	24	27	31	-	-	39	39	0 0%
	Other meetings	58	58	48	-	-	190	190	0 0%
	Number of virtual meetings (audio-, video- and web conferences)	-	1,800	2,300	3,000	3,220	6,500	6,500	0 0%
	Number of reimbursed delegates	1,683	1,942	1,680	309	0	5,000	5,000	0 0%
	Number of non-reimbursed delegates	818	718	517	44	7,129	1,500	1,500	0 0%
	New herbal monographs	1	0	0	2	2	1	1	0 0%
	Reviewed herbal monographs[7]	11	7	12	19	8	20	20	0 0%
	Revised herbal monographs	3	8	2	1	0	5	5	0 0%
	List entries	0	2	0	0	0	1	1	0 0%

[5] Including Management Board meetings. Committee meetings held physically and remotely. Declarations of interests of all Management Board and committee members and alternates are evaluated prior to their participation in the meeting.
[6] Includes EU Network training centre meetings.
[7] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published.

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Operate the Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative manufacturing technologies and methods Deliver on International activities relating to Pharmaceutical Quality Knowledge Management System (PQKMS) and continue supporting Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	3.1/5.5 (ECP 1 A new plan for Europe)	The implementation of novel manufacturing technologies and capacity enablers is facilitated	**On track**	Operation of Quality innovation group: full operationalisation. 1 EMA Listen and Learn Focus Group (LLFG) on personalised medicines, 5 1-to-1 meetings, 3 plenary meetings, 2 FDA exchanges, 1 site visit. Pharmaceutical Quality Knowledge Management System (PQKMS): collaborative assessment pilot extension agreed, call opened: new application received/start in mid-September Risk-based approaches in manufacturing and control strategy/ Q12: variation classification Guideline revision - draft delivered to EC in February 2025. Implementing guidance development under way: Q&A on complex manufacturing, post approval change management protocols (PACMP), Product Lifecycle Management (PLCM), medical devices, other
Deliver tailored engagement with academics and the community of Advanced Therapy Medicinal Product (ATMP) developers (ATMP support pilot) Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant guidance,	3.1 (ECP 1 A new plan for Europe)	Increased support for ATMP development and better understanding of academic developers need to enhance the integration of scientific and technological progress in the development of ATMPs	**On track**	Guideline on quality, non-clinical and clinical requirements for investigational ATMP finalised and published on 6 February 2025. Fee waiver for scientific advice for non-profit developers integrated into the new fee regulation that came into force in January 2025.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
e.g. on the safety and efficacy follow-up of ATMPs (guidance)				Regulatory/procedural and/or administrative support provided to products participating to the ATMP support pilot for academics where relevant.
Engage actively with International Partners to help increase awareness and facilitate the use of internationally- agreed quality and GxP standards globally. Support Network capacity for 3rd country inspections through reliance, International Regulators collaborative inspection pilots, Mutual Recognition Agreement (MRAs) extension and stronger EU presence in third countries.	5.3	Maintain the effectiveness and efficiency of GMP oversight by leveraging on collective efforts from global Regulators and greater convergence on internationally agreed quality standards	**On track**	Draft of the Annex 11 on computerised systems, and a new Annex 22 on artificial intelligence together with a revised Chapter 4 on Documentation have been revised and published for consultation in June 2025. Following 3 months consultation, the revision will be finalised by the GMDP IWG (Good Manufacturing and Distribution Practice Inspectors Working Group) until the end of 2025. A revision of Chapter 1 - Pharmaceutical Quality System has been conducted by the GMDP IWG in collaboration with Pharmaceutical Inspection Co-operation Scheme (PIC/s), as a result of the revision of the ICH Q9 guideline on Quality Risk Management. The revision of the Annex 15, to reflect the revised ICH Q9 R1 and the sartan lessons learnt recommendation, was also progressed by the joint PICs - EU drafting group, however the IWG has decided that the complexity of the revision

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				will require a concept paper for public consultation. This is currently being drafted. Following the US MRA extension to veterinary products in May 2023, further work has been undertaken for the finalisation of recognition of US FDA of the remaining EU veterinary agencies and allow for the implementation of the batch testing waver clause. By March 2025, there were 24 EU veterinary authorities recognised by US FDA with only 2 pending, with the finalisation of the process expected by 31 January 2025. However, the findings raised by the US FDA concerning the veterinary inspectorates of the last 2 MSs (Croatia and Malta) require further time to be implemented at national level. This is currently being worked on, but a delay to the entry into force of the batch testing waiver is expected. There has been further operational progress on the MRA expansion on vaccines and plasma derived products the extension and on the recognition of third country inspections, however at the moment the expansions are currently pending.
Promote dedicated cooperative and enhanced supervision with strategic international partners for manufacturing	5.2	Reinforced supervision of API manufacturers	**On track**	The GMDP IWG (Good Manufacturing and Distribution Practice Inspectors Working Group) and EMA have agreed to establish a framework

Action	MAWP strategic goal	Expected result	Status	Achievements / results
sites, such as tailored supervision of API manufacturers and/or large sites that supply a significant number of markets or products				for sharing information and aligning GMP inspections conducted by the EEA Inspectorates for national products and centrally authorised products. The implementation of this collaboration is expected to be kicked off in Q4 2025. The Active Pharmaceutical Ingredient (API) Programme on exchange of information on inspections of API manufacturers is operational. Discussions on the pilot on international collaboration on finished product inspections are still pending. The ICMRA Collaborative Pilot on hybrid inspections has been finalised at the end of 2024 with and guidance and lessons learned about conducting hybrid inspections has been published.
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	3.2 (ECP 1 A new plan for Europe)	The ICH E6 (R3) guideline is updated to facilitate a more proportionate application of its principles and the use of alternative trial types/ technologies, and training is available for EU stakeholders	**On track**	For ICH E6 R3 Principles and Annex 1, Step 5 (including CHMP endorsement) reached in January 2025. For Annex 2 (focused on alternative trial types/technologies), step 4 scheduled for October 2025. Training material development on track for end of 2025/start of 2026.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Delivery of the action plan to strengthen the Qualification of Novel Methodologies (QoNM) framework		Explore involvement of additional decision-makers during QoNM: e.g. HTA, MD/IVD regulators Training for methodology developers less experienced in regulatory interactions, e.g. academics, HCPs and patient representatives Publishing specific unmet needs for novel methodologies as identified by Committees or Working Parties and linking to Regulatory Science Research Needs Establish active interaction with more professional societies and patient groups developing COAs Explore feasibility of (automated) monitoring and reporting of evidence generated by qualified methods that has informed regulatory decisions	**Delayed**	Regular meetings of QoNM core groups allowed to agree on important elements of the procedural guidance: methodologies in scope of QoNM, process for early-interaction support, lifecycle management of Qualification Opinions; these considerations have informed the first draft of the major update to the procedural guidance which will be discussed at SAWP in September. In parallel, drafting of briefing document templates (general and for registry qualification) is ongoing, with a consultation target in September 2025. Work on various Q&A documents has started but work will take into 2026; work on improving EMRN and external expert involvement is ongoing in collaboration with colleagues from S-Division and TDA-MET; work on improving QoNM webpage presentation has started with webteam. Industry trade organisations have agreed on process and format for publication of high-level information on Qualification Advice procedures.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
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 impact for EMA and the EU Regulatory Network	**On track**	In relation to support for HTA's Joint Clinical Assessments (JCA) for medicinal products: • Establishment of internal operational guidance for coordination across functions • Agreement with the HTA secretariat and Joint Clinical Assessment subgroup (JCASG) on information to be shared during the regulatory assessment (cf CHMP work plan item 1.2.9) • Establishment of notification process for MAA submission in scope of JCA production, with first notification submitted (March 2025) • Continuous refinement of Letter of Intent (LoI) Notification process together with the HTA secretariat In relation to parallel Joint Scientific Consultations (JSC) for medicinal products: • Establishment of operational touchpoints with the HTA secretariat • Contribution to finalisation and publication of guidance and templates for applicants • Initiation of procedural management of parallel JSC

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				In relation to information on forecasting: • Establishment of internal data collection and consolidated reporting for medicinal products and medical devices • First provision of such reporting (April 2025) Stakeholder training through Industry Standing Group and HTA Stakeholder Network, respectively, as well as external events such as DIA Europe, Cancer Drug Development Forum (CDDF) webinar and RAPS Publication of the Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions as outcome of a workshop series between HTA bodies and regulators.
Prepare for the new pharmaceutical legislation to future proof medicines regulation in the EU	Legislation	Engage Scientific Committees in the reform and explore ways to optimise regulatory activities	**On track**	With the Council text of the new pharmaceutical legislation now published, the dedicated team has been actively exploring potential impact areas across key processes. These early reflections aim to anticipate possible changes, although full clarity and formal implementation planning will only be possible once the final text is adopted. In the meantime, initial change management activities have started, including

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				lunchtime talks to raise staff awareness, and engagement has started with committees.
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 Finalise the process for handling serious incident reports received by Medical Devices National Competent Authorities for ancillary medicinal substances and companion diagnostics Application of Art 117: EMA/CMDh Q&A update	**Completed**	After holding few meetings with the drafting group to reflect on which substance-based medical devices fall within this procedure and to understand the scope and documentation for the assessment under this procedure and considering that since the entry into force of the MDR no such devices could be identified by various stakeholders, development of the procedural guidance is on hold and would be re-activated based on an actual case. (suspended) Process for handling serious incident received from MD NCAs is ongoing and progress is subject to EC/MDCG PMSV TF (EU Medical Device Coordination Group Post-market surveillance and vigilance Task Force) consultation. (suspended) Further EMA/CMDh Q&A update (rev.5) published in January 2025. (completed)

2. Veterinary Medicines Division

Pillar 1 – Product-related activities

2.1. Pre-authorisation activities

Workload indicators

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	ITF briefing meetings requests received	5	2	7	0	4	5	5	0	0%
	Scientific advice requests received and validated	7	14	3	18	11	20	20	0	0%
	Requests for classification as limited market under article 4(29) and eligibility under article 23	5	4	9	11	-	10	12	2	20%

Performance indicators

	Performance indicators related to core business	Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Scientific advice procedures completed within set timeframes	100%	100.00%	100.00%	100.00%	100%	100%

2.2. *Initial evaluation activities*

Workload indicators

	Procedure	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2025 annual forecast Initial	Revised	Change	
	Initial marketing authorisation applications	12	11	15	9	4	23	29	6	26%
	New MRL applications	0	0	0	0	0	1	0	-1	-100%
	MRL extension/modification applications	0	2	0	0	1	1	2	1	100%
	MRL extrapolations	0	0	0	0	0	1	1	0	0%
	Review of draft Codex MRLs[8]	0	3	0	0	0	5	5	0	0%

Performance indicators

	Performance indicators related to core business	Target 2025	Outcome at the end of Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Initial procedures completed within legal timeframes	100%	100.00%	100.00%	100.00%	100%	100%

[8] From 2022 includes also Codex extrapolations.

2.3. Post-authorisation activities

Workload indicators

	Procedure	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	2025 annual forecast Initial	Revised	Change	
	Total variations	132	139	147	-	-	318	320	2	1%
	Variations level 1	1	2	1	-	-	2	2	0	0%
	Variations level 2	35	25	53	-	-	91	91	0	0%
	Variations level 3	25	52	27	-	-	95	97	2	2%
	Variations level 4	71	60	66	-	-	130	110	-20	-15%
	Transfers of marketing authorisations	0	1	1	0	8	1	0	-1	-100%

Performance indicators

	Performance indicators related to core business	Target 2025	Outcome at the end of Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Post-authorisation applications evaluated within the legal timeframes	100%	100.00%	100.00%	100.00%	100%	100%

2.4. Arbitrations and referrals

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Total arbitrations and referrals	1	1	0	3	0	3	3	0	0%

Performance indicators

Performance indicators related to core business	Target 2025	Outcome at the end of				
		Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
Referral procedures managed within the legal timelines	100%	n/a	100.00%	100.00%	n/a	100%

2.5. Pharmacovigilance activities

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Annual recording of signal management results and outcomes (Annual statements)[9]	170	165	-	-	-	260	260	0	0%
	Total signals submitted by MAHs of which:[10]	131	158	-	-	-	381	381	0	0%
	Emerging safety issues assessed by MAH and leading to regulatory action	0	0	-	-	-	1	1	0	0%

[9] New indicator introduced in 2024 work programme.
[10] New indicators introduced in 2024 work programme.

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Signals assessed by MAH leading to regulatory action (variations or other)	16	15	-	-	-	40	40	0	0%
	Signals classified for close monitoring by MAH	29	10	-	-	-	40	40	0	0%
	Signals classified as refuted by MAH	86	133	-	-	-	300	300	0	0%
	Signals submitted by Regulatory authorities following risk-based review[11]	2	10	-	-	-	40	40	0	0%
	Targeted signal management processes initiated by regulators[12]	0	1	-	-	-	4	4	0	0%
	Total ADRs:	114,570	80,563	70,899	91,939[13]	31,000	150,000	150,000	0	0%
	Total CAP ADRs	48,550	50,146	38,950	57,211	15,000	75,000	75,000	0	0%
	Total non-CAP ADRs	66,020	30,417	31,949	34,728	16,000	75,000	75,000	0	0%

[11] New indicator introduced in 2024 work programme.
[12] New indicator introduced in 2024 work programme.
[13] A large backlog was received in 2022, hence the figures are higher than average for mid-year reporting.

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
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 A new plan for Europe)	Harmonised methodology in place: legislation, guidelines and templates revised Exposure assessment tool made available to CVMP experts	**On track**	The joint working group lead by EFSA met via teleconference on 4 February, 24 April and 19 June 2025. The user requirements for the calculation tool have been defined. CVMP Safety Working party (SWP-V) members were informed and consulted. EFSA contractor has developed the tool. The SWP-V experts who will contribute to test the tool have been identified.
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	3.1 (ECP 1 A new plan for Europe)	Guidance for surveillance and signal detection developed Enhanced communication with the network	**Completed**	The technical implementation in IRIS of the key aspects of the new process for signal detection and corresponding tutorials have been finalised in Q1 2025.
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 Pilot study to be performed for VMPs considering relevant provisions in the New Pharma Legislation for human medicines	**On track**	The pilot is currently on hold awaiting for further specifications.
Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish	3	Establish ERA framework with EU and international partners Harmonised	**On track**	In the first part of 2025, EMA participated to the following events:

Action	MAWP strategic goal	Expected result	Status	Achievements / results
cooperation with international institutions, academic organisations and relevant initiatives	(additional RSS recommendation)	approach on ERA assessment		• ERA ESEC (Environmental Risk Assessment EMA European Specialised Expert Community) Webinar – Antimicrobial Resistance in the Environment (6 May 2025) • Collaboration meeting with ECHA on environmental topics (8 May 2025) • ERA ESEC Workshop: Discussion on approaches proposed for use in the draft 'Guideline on the ERA for VMPs for use in aquaculture' (26 June 2025)
Provide scientific support to the European Commission and the EU network, upon request, 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 2025.
Establish contributions to Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1 (ECP 1 A new plan for Europe)	Establish governance for JIACRA report under EMA and CVMP	**On track**	The mandate for the report was received at end of 2024. So far three interagency meetings have been organised in 2025, and the initial analyses have already been completed. The report is expected to be finalised by the end of 2026.
Implement use data collection by animal species	4.1 (ECP 1 A new plan for Europe)	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in Article 15 of the	**Completed**	The first 'European Sales and Use of Antimicrobials for veterinary medicine report' (ESUAvet report) has been published on 31 March 2025.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		Commission Delegated Regulation (EU) 2021/578		
Communicate effectively on consumption data	4.1 (ECP 1 A new plan for Europe)	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)	**Completed**	The first 'European Sales and Use of Antimicrobials for veterinary medicine report' (ESUAvet report) has been published on 31 March 2025. An info session to veterinary practitioners to introduce the report has been held in June 2025, in cooperation with Federation of Veterinarians of Europe (FVE).
Providing a reflection on the use and availability of diagnostic tests to improve the responsible use of veterinary antimicrobial products	4.3 (ECP 1 A new plan for Europe)	Review availability and characteristics of diagnostic tests	**On track**	The development of the reflection paper is progressing, and the draft is expected to be ready for public consultation by the end of 2025.
Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	4.3 (ECP 1 A new plan for Europe)	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	**On track**	An adjustment of the AMEG categorisation is required to align it with the list of antimicrobials reserved for human use, including both the scientific advice and the infographic. This update will be carried out in the second half of 2025.
Participate in international initiatives to reduce the risk of AMR	4.1 (ECP 1 A new plan for Europe)	Actively participating in international fora	**On track**	In the first half of 2025, EMA veterinary colleagues participated in: • AMR One Health Network meeting in Brussels on 3-4 April 2025

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				• Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI) meeting in Bilbao (Spain) on 12-13 March 2025
Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	4.3 (ECP 1 A new plan for Europe)	Develop and revise relevant guidance	**On track**	The 'Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animal species' was published in January 2025. The revised '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 published in February 2025 on the Agency website. A concept paper on a future risk assessment guideline for AMs in companion animals is under development.
Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper	4.3 (ECP 1 A new plan for Europe)	Reflection paper finalised and published Review of novel risk assessment methodologies for AMR in the environment	**On track**	The reflection paper was finalised and published in February 2021. No action has been initiated for the 2nd deliverable yet.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Develop a regulatory approach/framework to promote products that can assist in the reduction of the use of antimicrobials and novel paradigms	4.3 (ECP 1 A new plan for Europe)	Reflection paper developed Communication with stakeholders	**On track**	The actions identified in the Reflection Paper have been reviewed and an update on progress for each of them has been prepared. An internal discussion is ongoing to decide if there is a need to update the Reflection Paper.
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	4.3 (ECP 1 A new plan for Europe)	Guidance development Communication with stakeholders	**On Track**	Following the publication of the 'Scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months' the 'Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions' will be revised in 2025 to align both documents. In 2024 the CVMP established the ADRA project (Project 'Dosage review and adjustment of selected veterinary antibiotics'). The scope of the project is to review the current dosage of old antibiotics with the intent to optimise the dosage, such

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				optimisation will maintain the efficacy of the antibiotic minimising the occurrence of resistance. A priority list of antimicrobial candidate substances was adopted by CVMP in February 2025. An info session to industry has been held on 22 May 2025.
Provide scientific and regulatory support to encourage development of veterinary products that can assist in the reduction of the use of antimicrobials, to fill therapeutic gaps, without adversely impacting public health	4.3 (ECP 1 A new plan for Europe)	Guidance development products that can assist in the reduction of the use of antimicrobials	**On track**	An analysis of the last 5 years advice on products that can assist in the reduction of the use of antimicrobials has been initiated to get an overview and to identify data gaps, to understand areas in need of further guidance. The data have been collected and analysed, the report is being drafted and will be finalised by Q4 2025.
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and products that can assist in the reduction of the use of antimicrobials	4.3 (ECP 1 A new plan for Europe)	Cooperation at EU and international level for events Common approach agreed	**On Track**	EMA attended the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI) meeting held in Spain on 12-13 March, contributing to a panel discussion on 'The case of access to benzylpenicillin for veterinary use'
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 to 2028 public consultation ended in November 2024. Comments received have been evaluated, the final document has been published in March 2025, theme 4 is entirely dedicated to antimicrobial resistance.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)		Identify different benefit-risk approaches per type of vaccines Guidance on benefit risk	**Completed**	Completed in 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 2025).
Promote responsible use of antiparasitics in the EU	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	**On track**	The revision of the 'Guideline for the demonstration of efficacy of ectoparasiticides' started in January 2024. The draft revised guideline is foreseen to be published for public consultation in Q4 2025. The antiparasitic resistance section of the Reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations was further revised; the final reflection paper was published in May 2025. An infographic on lack of expected efficacy for antiparasitic veterinary medicinal products is under development by EWP-V (EMA CVMP Efficacy Working Party) and PhVWP-V (EMA CVMP Pharmacovigilance Working Party) and is expected to be

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				finalised in 2025. Further communication and dissemination activities will follow in 2026. A concept paper for the revision of the 'Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees' was developed and published for consultation in 2024. The revision of the respective guideline started in Q1 2025. The draft revised guideline is foreseen to be published for public consultation in Q4 2025.
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 1 A new plan for Europe)	Analysis of current methodologies, development of harmonised approach and guidance	**Completed**	Completed in 2024.
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	6.2 (ECP 1 A new plan for Europe)	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	**On track**	The EMA Veterinary Innovation Day was held in March 2025, and the CVMP Interested Parties Meeting was held in May 2025. The CVMP highlights are being reconsidered to make them more accessible to all stakeholders.
Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	2 (ECP 1 A new plan for Europe)	Compilation of a Veterinary data sources catalogue and metadata analysis	**On track**	The next Data landscape study phase started in Q2 2025. The goal of this phase is to obtain all metadata for >100 prioritised sources to support an in-depth analysis and evaluate interoperability of data sources. It

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				is expected to upload selected veterinary data sources to the RWE catalogue in Q3 2025.
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 1 A new plan for Europe)	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. The regulation is expected to be finalised and published by end of 2025.

3. Task forces

3.1. Digital Business Transformation (TDT)

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	New scientific, regulatory and network portfolio curricula developed	1	1	0	0	0	2	2	0	0%
	Number of training events advertised to the EU Network	68	86	49	36	36	75	75	0	0%
	Number of reimbursed training events to the EU Network	4	3	0	1	0	8	8	0	0%
	Number of NCAs that have opened their training for inclusion in EU NTC learning management system	7	7	0	7	10	10	10	0	0%
	Number of epics completed or ongoing	19	25	-	-	-	33	33	-	-

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Develop a digital skills framework for EMA and lead on digital capability building		Validated Digital Skills framework for EMA Creation of introductory training on topics in the digital skills framework with links to further	**On track**	Under the framework of the Digital Academy, a proposal for an AI literacy curriculum has been endorsed by the Executive Board and is now in the process of being developed with the aim to

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		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		be launched in Q4 2025. A communication campaign is currently being prepared.
Support futureproofing 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 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	**On track**	In the first half of 2025, EMA advertised nearly 70 courses and 1 entirely new curriculum on Non-malignant haematology via the EU NTC newsletter. Furthermore, EMA has reimbursed 4 training events and granted remuneration to 5 NCAs for training development & delivery. In addition to HCPWP/PCWP representatives and candidate countries, EMA is in the process of opening access to the EU NTC LMS to African regulators, in the context of the African Medicines Agency (AMA) project. Under the MTA Value Stream, EMA has started preliminary work to add the replacement of the EU NTC Learning Management System to the MTA Value Stream's pipeline.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		Investigate the setting up of an engagement portal/entry point to the Learning Management System (LMS) for external audiences Develop a future state learning delivery model and landscape that serves new and existing audiences, in co-creation with the EU-NTC		
Lean Portfolio Management		1 - EMA portfolio processes related are in line with the lean-Agile SAFE framework 2- Standardisation of VS tools, templates and ways of working	**On track**	An updated Network Portfolio budget process has been designed and endorsed. Templates and guidance have been put in place to ensure standardisation across five value streams.
Team & technical agility		1- Agile roles and responsibilities are defined within the EMA role description framework 2- Define a process to onboard new team members into the agile roles	**On track**	5 Agile roles and responsibilities have been defined and are being reviewed by the HR core team.
Agile product delivery		1- Rest of portfolio teams and platform teams are transition to Agile way of working 2- Ensure EMA staff are coached based on their defined Agile role	**On track**	Portfolio teams have transitioned into the Agile ways of working.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Lead the Knowledge Mining and AI Use cases initiative including: 1. Collecting EMA and Networks needs to build the AI implementation roadmap of the Agency and the Network 2. Designing and delivering different Proof of Concepts (PoCs) under this initiative using design thinking principles		Better knowledge and information management at EMA	**On track**	A systematic exercise to collect needs and ideas has been put in place, resulted in the identification of 150 Use Cases, including 110 internal Use Cases and 40 from the EU Network. Review and prioritisation of KM and AI Use Cases resulted in the setup of 35 Proof of Concepts, of which 3 already show high potential for implementation and value delivery. 2 successful Planning Interval (PI) ceremonies were conducted in bridging experimentation to Network portfolio. AI target Architecture drafted and under review for finalisation in July. 3 workshops have been planned to be held with NCAs and are being prepared. The first one took place end of August to discuss with end users the use cases and the business requirements. Following this workshop and after assessment of the inputs, a second workshop will be held in October to discuss the AI Solutions needed to provide a solution for the use cases. A final workshop will be hosted to discuss the prioritisation and the final AI implementation roadmap.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Socialize the use of the power platform to business users and develop and maintain citizen developers framework, service and users community on the Microsoft Power Platform to boost digital acceleration		Operational power platform community Increased use of power platform Minimisation of the dependency on IT for the Automation of manual tasks/activity Efficiency gains due to automation	**On track**	Consultancy work on technical and governance aspects was delivered in Q1 2025, outlining a list of recommendations how to set up the community. Setting up a new Microsoft contract to support a power platform community 6 months pilot (targeting max 20 business users) in Q4 2025 - Q1 2026.
Develop a business architecture practice to support the alignment of EMA and EMRN strategy with organisational structures, processes, data and execution by introducing a structured approach to our Organisational Business Model design in support of: • Digital Business Transformation • Enterprise Architecture and • Portfolio Management aiming to close the Strategy to Execution Gap		Stronger alignment of digital transformation investments with organisational strategy Enhanced capabilities to leverage opportunities and support the implementation of changes brought about through new legislation and other external factors	**On track**	Procurement of Business consultancy services for business architecture and has a contract in place to deliver the services from June 2025. Work is ongoing with the aim to deliver a business architecture framework to support the alignment of EMA and EMRN strategy with organisational structures, processes and data, in support of: • Digital Business Transformation, • Enterprise Architecture and • Portfolio Management, aiming to close the Strategy to Execution Gap and to and to manage synergies and dependencies across the Network Portfolio deliverables. Deliverables include: Capability mapping (3 level), Value Stream mapping (max 2) and user journey mapping (max 2).

Action	MAWP strategic goal	Expected result	Status	Achievements / results
ROG reactivation ROG is a joint HMA/EMA group focused on activities for business/regulatory optimisation within the scope of the respective EMANS goals under key business priority "Optimisation of the regulatory operations' by leveraging digitalisation and innovation		Address prioritisation and challenges faced in the execution of the Network Portfolio building on the strategic needs and priorities	**On track**	Deliverables/outputs are defined in the ROG workplan as adopted and endorsed by HMA and EMA MB. ROG established the NCAs Business Representatives Community to support the Network Portfolio by strengthening the NCA business representation in the Network IT developments. The Community's goals are to align EMA and NCAs tactically, improve the governance model though empowering Network POs and SMEs, and support Agile operational delivery across the Network. ROG continued its work on Product Management Service (PMS) with a focus on addressing the quality gap concerning NCAs product legacy data and strengthening the trust in PMS among Network and industry stakeholders. A proposal of Feasibility Study towards EU-wide PMS Data Qualification has been developed and it is planned to be launch in the second half of 2025.
Chair the EUAN Working Group on AI		Collaboration within the European Agencies Network to share knowledge and experience on AI and Digital Solutions	**On track**	1. Put in place a new consultancy contract to support the WG on AI 2. Coordinate the EDPS requests across the Network 3. Plan activities to realise workplan 2025-2027

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				4. 2nd plenary meeting at EMA with all WG members
Virtual reality activity		Users are trained through a realistic training scenario allowing them to increase their decisions and actions	**Delayed** **On track**	The VR emergency scenario was delayed 2 months due to the decision to add additional scope and therefore new contractual agreement. VR Inspections is a new project that had not been planned for 2025. However, the current need to upskill EU inspectors resulted in a VR project led by TDT with the support of a multi-disciplinary team.

3.2. *Data Analytics and Methods (TDA)*

Workload indicators[14]

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	693	476	-	-	-	1,200	1,200	0	0%
	Number of EudraVigilance Quality Assurance Test (QAT) requests received	45	75	-	-	-	140	140	0	0%
	Number of non-interventional studies initiated	44	15	-	-	-	60	60	0	0%
	Number of methodological advice provided on product procedures	38	92	-	-	-	150	80	-70	-47%
	Number of active methodology guideline drafting groups led by MWP	14	11	-	-	-	15	15	0	0%
	Number of methodological contributions to guidelines led by other committees and working parties	7	12	-	-	-	15	15	0	0%
	Number of business validation for CTIS releases	5	11	-	-	-	18	18	0	0%
	Number of KPIs reports published	2	5	-	-	-	12	4	-8	-67%
	Number of EudraCT reports and number of CTIS data analyses and reporting	95	36	-	-	-	110	110	0	0%
	Number of ACT EU multi-stakeholder workshops[15]	5	9	-	-	-	12	12	0	0%
	Number of regular CTIS/CTR events[16]	39	42	-	-	-	86	86	0	0%
	Number of CTIS newsflashes and CT highlights newsletters	14	16	-	-	-	26	19	-7	-27%

[14] New indicators introduced in 2024.
[15] Led and co-organised events; including multi-stakeholder platform (MSP) advisory group.
[16] 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.

Performance indicators [17]

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	ATD/RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	90%	97.80%	89.00%	-	-	-
	Percentage of monthly updates of the ADR report website performed according to the timelines	90%	100.00%	100.00%	-	-	-
	Studies performed within less than 26 weeks[18]	60%	80.00%	44.40%	-	-	-
	Non-Interventional Study (NIS) protocols and summary results registered in EMA NIS registry within a month after finalisation	90%	100.00%	92.00%	-	-	-
	Product procedure requests for methodological support completed as per timelines	90%	100.00%	100.00%	-	-	-
	Planned MWP contribution to guidelines led by other committees and working parties	75%	100.00%	100.00%	-	-	-
	AtD/RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	90%	81.00%	54.75%	-	-	-
	WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	90%	100.00%	100.00%	-	-	-
	ACT EU multi-stakeholder workshops organised according to workplan	80%	80.00%	90.00%	-	-	-
	News flash to CTIS users	90%	100.00%	100.00%	-	-	-
	Support to the secretariat for CTCG and physical hosting 4 times per year	100%	100.00%	100.00%	-	-	-
	Provide secretariat for CTCG weekly assessors round table	100%	100.00%	100.00%	-	-	-

[17] New indicators introduced in 2024.
[18] Excluding framework contract studies.

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Build capacity and capability to receive, store, manage and analyse clinical study data		Proof-of-concept clinical study data pilot protocol developed CHMP proof-of-concept clinical study data pilot operated Updated pilot report on learnings and recommendations developed Guidance for applicants updated Workshop on the submission and analysis of clinical study data	**On track**	Guidance to Applicants updated in Q1. Epic hypothesis prepared and presented to Portfolio Board (collection of business requirements) in Q2. Change management activities intensified in Q1 and Q2: • several presentations to EMA and public fora delivered; • Industry Focus Group on Raw Data and Network Advisory Group on Raw Data meetings held. Technical specifications for reopening of competition (framework contract) to support IT development prepared.
Manage the EMA-HMA-EC co-led initiative Accelerating Clinical Trials (ACT EU) to transform CT in Europe. This includes strengthening EU level governance of CT and the CTR implementation; modernisation of CT design and good clinical practice; leveraging data on CT to support regulatory decision making; supporting non-commercial sponsors to conduct more multi-national clinical trials;		Strengthened EMA/EC/HMA collaboration within ACT EU via rationalised governance Launch of an action plan to support non-commercial sponsors External stakeholders engaged through the establishment of the	**On track**	Multistakeholder platform advisory group meetings held in Q1 and Q2. Survey on academic and SME training needs conducted in Q1. CTIS CT helpdesk operational, 509 tickets resolved.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
enhanced dialogue between clinical trial stakeholders.		multi-stakeholder platform and its advisory group Implementation of revised ICH E6(R3) GCP modernisation in the EU region supported Research priorities for better use of clinical trials data defined Stand-alone ACT EU website managed Consolidated scientific and regulatory advice pilots operated and results reviewed and made public Methodological aspects on CT design supported by a best practice on guidance Clinical trials safety aspects, trainings and clinical trials in emergency settings (PHE) delivered		Mature draft of CT analytics research priorities under review.
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	**On track**	Continuous support to sponsors and Member States delivered. Dedicated support for non-commercial sponsors provided.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		Assure the business testing of the candidate releases		List of CTIS functionalities for improvements, based on incidents reported by the end users, prioritised on a bi-weekly basis. Users informed regularly on CTIS deployed versions and improvements via: • newsflashes issued bi-weekly; • monthly newsletters; • quarterly CTIS Fora.
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**	CTIS stakeholders were supported through following change management activities: CM strategy and planning in Q1; • 2 CTIS Fora; • 3 newsletters; • 12 newsflashes; • 3 bitesize and walk-in clinics; • collaboration on the redesign of training material.
Lead the development of the Big Data	2.2	Training modules published on the EUNTC portal	**Delayed**	2 training modules - Data Quality and Omics Data - under development.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
curriculum on Data Science for the EU Regulatory Network	(ECP 1 A new plan for Europe)			These modules are expected to be completed by the end of 2025 and are planned for release to the EMRN in early 2026.
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 (ECP 1 A new plan for Europe)	Common framework for data quality available for EMRN and industry Specific and implementable guidelines for ADR and RWD data are available	**On track**	Public consultation on RWD chapter concluded, redrafting of the document in progress. ADR chapter consulted with the Network and enhanced with feedback from expert groups.
Ensure compliance with the European Union Data Protection Regulation (Regulation (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		Full compliance with Data Protection legislation Risks managed	**On track**	Data protection training: • data protection and AI - dedicated module as part of the AI literacy training developed; • further 5 training modules on AI and data protection under preparation; • dedicated training on data breach management in Learning Management System (LMS) prepared. Quarterly reports for Q1/Q2 prepared.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Data Protection Coordinator (DPC) meetings scheduled considering outputs of DPO Network meetings. Dedicated data protection intranet page prepared to facilitate access to guidance and training.
Strengthen the EU Network on methodology in committee advice and assessment through: • guideline development and implementation; • the provision of methodological expertise to support EMA scientific committees; • capacity building. Harmonisation of international methodological standards Programme management of the Methodology domain Understand and account for external stakeholders' needs	2.2 (ECP 1 A new plan for Europe)	Guidance documents on emerging methodological topics delivered Estimands from ICH E9(R1) implemented in newly written or updated clinical and methodological guidelines, where appropriate Draft methodology research needs listed Operational expert groups established and managed Systematic lessons-learnt process for procedures with complex methodology Training modules for EMRN developed and delivered ICH E6(R3) Annex 2 drafted. ICH E20 step 2 reached. EMA Q&A of ICH M12 drafted	**On track**	Methodology Domain governance meetings held in Q1 and Q2. Input related to Estimands provided for 100% of clinical guidelines were MWP was consulted (i.e. the beta-thalassemia and sickle cell disease, PsA). All guidelines and planned workshops progressing as planned with no major delays: workshop on Bayesian methods held in Q2. Guidance on RWE and several product-specific BE guidelines published. Comprehensive Estimands training delivered. ICH E20 step 2b reached in June; step 3 entered public consultation period.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		Yearly revised Methodology Work Plan Embed identification of committee requests with complex methodological aspects into EMA forecast and tracking processes Clear roles and responsibilities in the Methodology Domain to maximise resource efficiency established Draft Methodology stakeholder interaction plan Cluster meetings and Interested Parties meetings organised		Implementation of comments received during public consultation on ICH E6(R3) Annex 2 ongoing. Draft EMA CHMP Methodology Working Party (MWP) workplan update prepared and undergoing internal consultation process.
Improve development and implementation of clinical trial methodology guidance in the EMRN. Development of an inventory of training needs		Methodology workshops, or webinars, with external stakeholders to scope and prioritise clinical trial methodology guidance topics Process for aligning guideline development on multidisciplinary methodology topics involving a large variety of Network expert groups	**On track**	Guideline development coordination meeting held in Q1. Best practice finalised in Q2. SME and academia training needs survey finalised in Q1. 375 responses received. Survey results and findings summarised in a report. Report is currently under review.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
		Training plan for new guidance documents and associated process Completion of training needs assessments for regulators and defined stakeholder groups. Elaboration of training curriculum		
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 and reliable evidence based on appropriate real-world data	2.1 (ECP 1 A new plan for Europe)	DARWIN EU Coordination Centre maintained Access to various real-world data sources in terms of data type, population covered and geographical coverage increased DARWIN EU pilot with EHDS conducted and informed next steps Processes for EMA oversight of DARWIN EU activities operated and optimised, including review of DARWIN EU deliverables and outputs DARWIN EU studies delivered in line with contract	**On track**	DARWIN EU Coordination Centre continues to be fully operational; several actions taken to optimise its operations. 30 data partners onboarded (39 data sources) totalling approximately 180 million population across 16 European countries. 5 data partners are at an advanced stage of onboarding and additional 5 considered for onboarding by the end of 2025 as planned. 45 studies initiated and ongoing; in total 73 study requests are currently being processed, including new feasibility investigations.
Build appropriate EMA business processes to identify the need for RWE and to generate and	2.4	Processes to prioritise and triage study requests established	**Completed**	RWE report published on 30 June: Real-world evidence framework to support EU regulatory decision-

Action	MAWP strategic goal	Expected result	Status	Achievements / results
deliver that evidence in order to support the regulatory decision-making process		Development of a phenotype's library Users' training on utilisation of Instant Health Data (IHD) and analytical templates		making 3rd report on the experience gained with regulator-led studies from February 2024 to February 2025. Decision to end IHD taken in December 2024.
Coordinate implementation of HMA EMA AI multiannual workplan Contribute to implementation of actions led by TDA		Successful experimentation on the extraction of information using AI/ NLP techniques Reporting to HMA and MB on workplan progress	**On track**	Lessons learnt from AI/NLP pilots in the Health Data Lab concluded in Q1 and reported to Digital Acceleration Leadership Team (DALT) in Q2. Routine reports to HMA and MB on workplan progress provided. Annual AI workplan update concluded in Q1, additional deliverables identified.
Further development and use of a monitoring system for the post- authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform)		Processes for the prioritisation, launch and supervision of vaccine studies in place Working arrangements with ECDC operated Processes to identify a need for studies in place Results of studies made available to EU decision-makers and the public	**On track**	Studies on track with at least 4 vaccine studies at concept, feasibility assessment or protocol stage (flu VE, pneumo, meningo, varicella). ECDC agreement to participate in new Framework Contract Lot 5. 2 Steering Group (SG) meetings held. Communication plan endorsed by SG.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Workshop on vaccine effectiveness with Vaccines Europe held 20 June. As per SG decision, IVMAB will meet once a year.
Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data		Health Data Lab operates as a stream under the DigiLab's framework Pilot the experimentation framework with two pharmacovigilance-related use cases	**On track**	2 pharmacovigilance use cases in pilot deployment and under preparation for full deployment. Enhanced Review of Abstracts with Transformer models project – ERATO -in pilot deployment; preliminary data suggests it can save 50-60 hours per month with an increase in number of identified safety concerns. EU product information Entity Extraction and Knowledge Acquisition project (EurEKA), in pilot deployment as an application for users to explore.
Development and implementation of EMA and EMRN data strategies as part of data governance activities and evolution of EMA data governance including policies, procedures, procedures and responsibilities as well as management of the EMA Data Board and Network data governance		Finalised Network Data Strategy Established plans and activities to implement EMA data strategy EMA data governance structures and activities are in place Plan for EMRN and EMA communications, trainings and stakeholder engagement	**On track**	Network: • Network Data Steering Group (NDSG) established in January and meetings held monthly. • Network Data Strategy finalised and adopted. EMA:

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				• Data Board workplan approved. • Data Strategy area leads workplan developed and approved. • Data Owners and Data Stewards training material developed and onboarded. • Change Management Plan developed and approved. • Data Catalogue completion in progress (136 data assets identified, 77% mandatory fields completed). • Monthly Data Board meetings held. • Monthly Data Strategy area leads meetings held according to Data Strategy Area Mapping. • Data Community kick-off event held in January. • Data Community mandate developed and approved.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				• Metadata audit findings incorporated into workplan. • Onboarding of new core Data Governance team members completed.
Support EMA operations and committees/working parties with advice and epidemiological expertise on: • methods for RWD collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; • portfolio of RWD 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;		Reflection paper on methodological aspects, formats and contents of RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of RWD sources used in regulatory decision-making (e.g. registries, electronic healthcare records) Process of procedure identification, from relevant committees/WPs that require methodological input, participation and contribution to SAWP, pre-submission, PRIME and any other relevant meetings where RWE is addressed	**On track**	Process to screen marketing authorisation applications established and to be formalised in TDA business process documentation by end of 2025. Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes published in April. Outline of ICH concept paper on RWE/RWD terminology, metadata and general principles for assessment endorsed. Lessons learnt from review of RWE submitted by MAAs/MAHs close to completion.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
• literature review of published articles with RWE on utilisation, safety and effectiveness of medicinal products.				
Implement the Clinical Trials Safety Monitoring regulation		Assure the simplified functional specs of the safety implementation regulation are up to date Provide regular support to the Member States for the safety assessments	**On track**	Safety Monitoring through EudraVigilance and Annual Safety Reports (ASR) is in routine operation. All newly authorised trials assessed for collaboration on safety monitoring and tracked. saMS selection procedure triggered by EMA and concluded by the Member States for 288 newly tracked substances in 2025. Annual safety training event hosted. Use Cases for the Safety Module prototype reviewed. Active participation in the technical proof of concept of the Safety module prototype completed. High-level user stories for the Minimum Viable Product of the Safety Prototype reviewed and to be further developed and implemented during Q3 and Q4.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Deliver simpler CTIS business rules, which will support future modernisation of CTIS to improve user experience and streamline the operation of the system		Identified areas of the CTIS business rules are covered by Simplification Task Force	**On track**	The Simplification Taskforce endorsed 4 topics for simplification: • approval of the simplified user management; • approval of the status of the Investigational Medicinal Product Dossier Quality (IMPDQ) only submission type; • approval of the status on the ad hoc assessment; • approval of simplified notices and alerts.
Enable the use of clinical trials data to support medicinal product development, leveraging data standards and the Data Analytics Platform (DAP)		KPIs for regular measurement via DAP Yearly measurement of ACT EU performance indicators Make available interactive maps for patients	**On track**	KPI's for ACT EU published quarterly. Interactive trial map went live in March. HMA MB adoption of new KPIs for the EU CT environment planned go live in Q3.
Enable clinical trial data standards in EMA and Network systems and processes		Lead the European contribution to ICH M11 activities Change management strategy developed	**On track**	Review of the ICH M11 technical specification successfully completed before the EU public consultation of the document in April.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Agreement between Health Level 7 (HL7) & International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) M2/M11 for the Technical Implementation Guide (TIG) to be drafted by the Standard Development Organisation (SDO) in June. Roadmap of clinical trial standardisation epics agreed to be integrated to the CTIS modernisation work EPIC.

3.3. Regulatory Science and Innovation (TRS)

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Innovation Task Force briefing meetings conducted	15	16	17	16	21	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[19]	0	0	0	1	0	4	4	0	0%
	Portfolio and Technology meetings conducted[20]	9	-	-	-	-	20	20	0	0%
	Academia briefing meetings conducted[21]	14	-	-	-	-	16	16	0	0%
	New involvements in externally-funded regulatory science projects managed[22]	12	-	-	-	-	10	10	0	0%
	Collaborating experts onboarded or deliverables managed[23]	4	-	-	-	-	16	16	0	0%
	Number of MSSG meetings[24]	3	6	-	-	-	12	8	-4	-33%
	Management of shortages of CAPs[25]	345	720	-	-	-	2,000	750	-1,250	-63%
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party[26]	36	33	-	-	-	120	75	-45	-38%

[19] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[20] New indicators introduced in Work Programme 2025.
[21] New indicators introduced in Work Programme 2025.
[22] New indicators introduced in Work Programme 2025.
[23] New indicators introduced in Work Programme 2025.
[24] New indicators introduced in Work Programme 2024.
[25] New indicators introduced in Work Programme 2024.
[26] New indicators introduced in Work Programme 2024.

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of requests for information received from the SPOC Working Party and international partners[27]	10	15	-	-	-	80	30	-50	-63%
	Number of SPOC Working Party meetings (including subgroups)[28]	20	12	-	-	-	50	50	0	0%
	Number of Solidarity Mechanism cases[29]	4	-	-	-	-	10	10	0	0%
	Regulatory assistance, including SME briefing meetings	106	104	83	97	105	205	205	0	0%
	Requests for SME qualification	201	198	268	240	312	410	410	0	0%
	Requests for SME status renewal	106	122	124	210	131	1,389	1,389	0	0%

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Improve expertise to accommodate rapid evolution of the regulatory system	3.1 (ECP 1 A new plan for Europe)	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	**On track**	Organisation of EMA webinar on Engineered Living Materials in the context of Horizon Scanning in February 2025

[27] New indicators introduced in Work Programme 2024.
[28] New indicators introduced in Work Programme 2024.
[29] New indicators introduced in Work Programme 2025.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1 (ECP 1 A new plan for Europe)	New technologies identified and integrated within EU-NTC	**On track**	Bi-monthly meetings to analyse signals and identify new trends Publication of horizon scanning reports on Alzheimer, New Approach Methodologies and Nanomedicines
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	**On track**	Adoption of the EU Innovation Network workplan at HMA and EMA and completion of the mid-year delivery table
Innovation relevant preparation for the implementation of new legislation (Sandbox, Borderline Classification)		Proposals for re-designed processes to prepare for the implementation of new pharmaceutical legislation	**On track**	Internal meetings organised and preparation for the New Pharmaceutical Legislation
Preparation for ESMP database Extended mandate activities on shortages of Medicinal Products (MPs) and Medical Devices (MDs)		Extended mandate activities on shortages of MPs and MDs	**Completed**	The ESMP database became fully operational on 29 January 2025 with a full range of functionalities for MAHs and NCAs, ahead of the legal deadline
Union list of critical medicines Shortage prevention and mitigation plan (SPMPs)		Human product availability, veterinary product availability / MUMS	**Completed**	Completed in 2024, work is continuing under MSSG mandate

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Organisations of SC meetings of the HMA-EMA Task Force on Availability of Medicines (TFAAM) (4 per year) Thematic Working Group (TWG1) meetings (30 per year)				
Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients	3.3	Topics for network training identified and communicated to EU-NTC	**On track**	Perceived learning needs identified through collaboration in the EC-HMA-EMA Initiative Accelerating Clinical Trials in the EU, Priority Action 10; topics being identified through European platform for Regulatory science research

4. Advisory functions

Workload indicators[30]

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	126	151	127	-	-	250	250	0	0%
	Number of participations in external forums	16	14	15	-	-	40	40	0	0%
	Number of external participants in training organised by International Affairs	561	580	441	-	-	500	750	250	50%
	Number of visits to EMA / fellowships organised by International Affairs	6	9	8	-	-	15	12	-3	-20%

Pillar 2 – Public health activities and Business Services

Action	MAWP strategic goal	Expected result	Status	Achievements / results
International Coalition of Medicines Regulatory Authorities (ICMRA) secretariat management, including operational and financial contribution to ICMRA summit and plenary meetings	1.1 (ECP 1 A new plan for Europe)	Continue demonstrating leadership of ICMRA: Regulatory convergence and in particular, aligning COVID-19 global response and collaboration Regulatory communication	**On track**	EMA continued its mandate as chair of ICMRA and provided the ICMRA secretariat. 2 virtual and 1 face-to-face executive committee meetings, 1 virtual plenary meeting, 2 regulatory forums TCs (focusing on artificial intelligence), 1 ICMRA-related session at DIA global (focus on regulators as communicators).

[30] New workload indicators starting in 2023.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Participation in and coordination of ICMRA Regulatory Forum, and work streams				EMA participated in all 6 active ICMRA workstreams, including as chair or co-chair in 3 of them. New ICMRA Working Group formed aimed, as first deliverable, at developing a compendium of terms for development of medicines for small population diseases (further activities might be agreed once the first deliverable is completed). Work started on development of an 'ICMRA statement' on 3Rs (replacement, reduction and refinement of animal testing).
Support and foster use of the EU-M4all pathway Support applications and 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 (ECP 1 A new plan for Europe)	Support to developers and promotion of parallel art 58 and centralised submissions	**On track**	Six pre-submission interactions with developers to clarify questions related to eligibility, collaboration with WHO and non-EU authorities, active participation by WHO and non-EU experts during scientific advice or evaluation, reliance on EU marketing authorisations to streamline WHO prequalification or support timely national authorisations, parallel EU-M4all and centralised applications, and independence in national decision-making. Support for WHO and national regulatory authority expert involvement for scientific advice on possible EUM4all opinions. Participation in various workshops and public forums to introduce EU-M4all as facilitated tool to promote access to quality-assured medicines. These include EMA-Medicines Patent Pool Workshop, Bill & Melinda Gates Foundation Grand Challenge Annual Meeting,

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				WHO-EMA-Swissmedic-IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) workshop on facilitated pathways, and EMA-African Pharma Network on understanding EU-M4all and its role in health product security in Africa.
Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO collaborative registration procedure, facilitated approvals, prequalification and other pathways	1.2 (ECP 1 A new plan for Europe)	Capacity building in low and middle income countries	**On track**	Coordination of 4 collaborative registration procedures (SRA-CRP) with WHO, aimed at facilitating registration of 4 products in 7 countries. Participation in workshops or conferences to promote awareness, engagement and capacity building with CRP including a WHO workshop in El Salvador or other regulatory conferences.
Support continued implementation of the EU- US FDA MRA	5.2	Support for several operational meetings (internal, EC, FDA and NCAs) related to the finalisation of the MRA implementation for veterinary medicines, increase in the efficiency of the MRA for human medicines and preparations for the potential extension to vaccines and plasma derived medicines	**Delayed**	Discussions to support recognition of remaining EU veterinary national authorities. During first half of 2025, one EU veterinary medicines authority was recognised by US FDA (Romania). The deadline to recognise all EU veterinary authorities (and consequently waive batch testing) was 31.01.2025. Currently there are still two remaining veterinary authorities to be recognised.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
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**	2 contact points meetings held (April and June 2025). 19 trainings offered. Organisation of yearly f2f training ongoing.
Opening our Procedures at EMA to Non-EU authorities: Implementation of new working model as agreed by Management Board March 2022	1.1 (ECP 1 A new plan for Europe)	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 low- and middle-income countries markets	**On track**	Number of experts registered: 0 Number of new OPEN procedures initiated: 1 Discussions with industry associations took place Q1 2025 to gather feedback on the limited use of the OPEN framework. The OPEN framework requirements and processes are being reviewed to address the industry comments and improving the benefits of the framework for EMA and OPEN partners.
Maintenance, exchange of information and engagement with existing Confidentiality Arrangement partners	1.1 (ECP 1 A new plan for Europe)	Facilitate and foster international cooperation	**On track**	Limited disclosure notice has been implemented in May 2025 when sharing CMC information with non-EU regulators.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Establishment of new Ad Hoc Confidentiality Undertakings				
Active participation in international forums and communication to stakeholders, including but not limited to DIA, ICH, IPRP	1.1 (ECP 1 A new plan for Europe)	Greater visibility of the Agency and of its activities	**On track**	International team carried on its stakeholder engagement and communication in 2025. In addition to internal communication efforts, external stakeholder engagement has included: 14 presentations opportunities at events with external partners 16 missions/duty travel opportunities attended either in-person or remotely
Organisation of awareness sessions and engagement workshops for international regulators	1.1 (ECP 1 A new plan for Europe)	Increase Awareness of the EU system Agency public image	**Suspended**	Activity suspended due to change of priorities.
Data protection impact assessment and simplification of personal data redaction for exchange with international partners		Protection of personal data	**Completed**	Activity stopped due to change of priorities of partners involved.
Under the DG INTPA contract, support creation of AMA and regulatory system strengthening at	6.1	Establishment of the AMA	**On track**	16 African regulators attended PIC/s f2f training on Quality Risk Management at EMA in January. Online workshop in ICH E6 (R3) and Introduction to Estimand Framework was attended by AMA clinical and statistical assessors in February.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
African continental, regional and national levels				A webinar on ICH M7 guideline and control strategy and risk assessment for nitrosamines was given by EMA to two of the Regional Economic Communities (RECs) (East African Community (EAC) and Intergovernmental Authority on Development (IGAD)) in March. Grants were awarded in 2025 for the next five projects prepared by EU NCAs in response to the call for proposals for regulatory systems strengthening (EMA/GRANT/2024/02/IA), bringing the total number of awarded grants under the call to 11. A procurement tender for e-learning curriculum for junior assessors was launched in April. EMA hosted the historic first visit of the AMA Governing Board, AMA DG designate, African Maturity Level 3 Heads of Agency (ML3 HoA), WHO, DG INTPA, EMA Management Board (EMA MB) and Heads of Medicines Agencies Management Group (HMA MG) from 11-12 June. A call for proposals for laboratory systems strengthening was launched in Q2 2025 (EMA/GRANT/2025/03/IA).
Communication of information, answer to queries, internal coordination Monitoring and tracking of interactions		Streamline and promote awareness of international activities within the Agency	**On track**	Creation of 1 guidance and update of 3 guidance Organisation of 30+ face to face meetings and teleconferences

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Preparations of visits, missions' preparation, support to international partners, fellowships and expert visits				Management of 126 product-related interactions with international stakeholders including requests for information and requests for documents Management of 3 visits organised by International Affairs Management of 17 ICMRA meetings or ICMRA preparation meetings
Collaboration with WHO to support availability of child-friendly TB medicines in the EU	1.1 (ECP 1 A new plan for Europe)	Approval and availability of paediatric anti-TB medicines for unmet medical needs in the EU	**Completed**	Completed in 2024.
Sustained development and operation of the International Cooperation Platform	1.1 (ECP 1 A new plan for Europe)	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	**On track**	One in-person meeting, Warsaw, 4 June
Implementation and support to engagement with US FDA	1.1 (ECP 1 A new plan for Europe)	Maintain and develop relationship between EMA and FDA Identify and develop existing and new areas of cooperation	**On track**	Two technical meetings with FDA Europe Office to follow-up on agreed actions including discussion on Liaison Program priorities. • Supported 2 visits from EMA colleagues to FDA. • Support to Parallel Scientific Advice (4 requests received). • Support collaboration on gene therapies for ultra-rare diseases (CoGenT); first pilot procedure

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				ongoing. Several interactions, with EMA participating in FDA internal meetings and meetings with applicant and FDA participating in EMA Committees and Working Parties meetings. • Support to EMA participation in Project Orbis as observer. • Meetings and other interactions with FDA Oncology Center of Excellence to review / progress interactions. Regular interactions include Scientific Advice monthly meetings. • Support to meetings/discussions regarding collaboration in the area of artificial intelligence. • Finalisation of cluster framework, including Cluster Principles and Cluster Good Practice Guide. • Discussions with FDA on third country engagement. • Continued core engagement and support, including facilitating requests between EMA and FDA, and cluster activities • Outreaching activities of EMA/FDA Liaison Program and EMA/FDA collaborations, including presentations to FDA Offices/Divisions, to EMA scientific committees, and public conferences.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Organisation of the 2025 ICMRA Summit		Reaffirm importance of global regulatory convergence and collaboration Articulate achievements and impact of 6-years of leadership of ICMRA Promote regulatory communication	**On track**	Logistic preparation for the 2025 ICMRA summit (in Amsterdam, EMA premises, October 2025) under way. Scientific content of the Summit was agreed and discussed with ICMRA participants. Work on detailed preparation of sessions started.
Promoting reliance on EMA scientific outputs	1.2 (ECP 1 A new plan for Europe)	Position and promote EMA role as a leading reliance partner for non- EU regulators and pharmaceutical industry, in line with its responsibilities as a WLA designed authority	**On track**	Participation in the Joint EMA-Industry Focus Group on Regulatory Reliance aimed at promoting the use by Industry of EMA scientific output for the registration of medicinal products. Participation in a number of workshops and conferences to promote international collaboration and reliance. Supported the launch of 12 pilot procedures promoting reliance by international regulators of post-approval changes to demonstrate feasibility and public health benefit of regulatory reliance.
Define approaches for review of data with international regulator 1. Explore options for innovative regulatory science to support regulatory decisions before epidemics		Improved public health preparedness and protection	**On track**	In June, the EMA held a workshop centred on discussing primary efficacy endpoints for antivirals and monoclonal antibodies intended for the treatment of COVID-19 and influenza. The event aimed to strengthen regulatory guidance for clinical trials in these therapeutic areas. Additionally, ongoing discussions with the World Health Organization (WHO)

Action	MAWP strategic goal	Expected result	Status	Achievements / results
2. Define approaches for review of data with international regulator				were held, focusing on advancements in vaccines for influenza and flaviviruses.
Communicate proactively with key stakeholders on benefit-risk using evidence- based tools to tackle vaccine hesitancy		Better public understanding and confidence in the safety and efficacy of vaccines	**On track**	EMA is engaged in ongoing discussions with the Vaccine Outreach Group (VOG) to strengthen vaccine communication efforts, considering the current geopolitical situation in the US. There is ongoing work on vaccine communication efforts through collaboration with the European Centre for Disease Prevention and Control (ECDC).
Engage with public health authorities and NITAGs to better inform vaccine decisions		More consistent recommendations on vaccinations strategy	**On track**	EMA efforts together with the European Centre for Disease Prevention and Control (ECDC) are centred on re-launching collaboration with National Immunization Technical Advisory Groups (NITAGs).
Establish a platform for EU benefit-risk monitoring of vaccines post-approval		Evidence to drive benefit risk evaluation and vaccination policy	**On track**	In June 2025, Emergency Task Force and Vaccines Europe convened to discuss the generation of vaccine effectiveness data for influenza vaccines by brand in the EU, with key discussions focusing on Vaccines Monitoring Platform initiatives, industry perspectives, and other components for sustainability and applicability to other respiratory viruses.
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**	On AMR work, collaboration with WHO on the TB vaccine was enhanced. The ETF managed scientific advice procedures on AMR pathogens and conducted informal teleconferences with academia on diagnostics and new treatments.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Operate the ETF during a declared 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**	Under the ETF remit, the ETF SA-CTA scientific advice process was established to address clinical trial aspects through collaboration with the Clinical Trials Coordination Group (CTCG) and the newly formed Public Health Emergencies Ethics Advisory Group (PHE EAG). The ETF's scope was extended to include a selection of antimicrobial resistance (AMR) pathogens, and it also oversees SAs related to CBRN.
Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	1.1 (ECP 1 A new plan for Europe)	Increased awareness to facilitate the uptake of biosimilars	**Delayed**	This work has been stalled by the dismantling of the HMA-EMA working group of biosimilars. EMA (communication and stakeholders) are working on finalising the output from the working group.
30 years anniversary conference of EMA		Create awareness of the Agency and its scientific work including the developments over the past 30 years	**Completed**	30-year anniversary scientific conference was held on 25 June 2025 with around 300 in-person attendees and a wide scientific program, showcasing the agency’s activities.

5. Stakeholders and Communication Division

Workload indicators

	Procedure						2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of EPAR summaries and EPAR summaries updates published	110	116	81	97	118	170	170	0	0%
	Number of documents published on EMA website	4,695	3,766	3,834	3,787	4,071	7,500	7,500	0	0%
	Number of pages published and updated on EMA website	2,125	1,779	2,076	1,779	1,883	3,500	3,500	0	0%
	Number of press releases and news items published	69	66	64	87	122	120	120	0	0%
	Numbers of press and other external briefings conducted[31]	2	3	-	-	-	5	2	-4	-80%
	Numbers of social media posts published	232	329	667	488	975	650	450	-200	-31%
	Number of completed interviews[32]	15	10	-	-	-	20	20	0	0%
	Number of media queries responded[33]	439	598	-	-	-	1,200	900	-300	-25%
	Number of reports, brochures, leaflets laid out or printed, social media visuals	439	651	360	437	300	1,200	900	-300	-25%
	Number of professional membership organisation events attended by participating Agency staff[34]	13	12	12	-	-	25	25	0	0%
	Number of sessions with Agency representatives[35]	132	138	116	-	-	150	150	0	0%
	Number of patients and consumers eligible organisations[36]	41	41	-	-	-	41	42	0	0%

[31] New indicator introduced in 2024 work programme.
[32] New indicator introduced in 2024 work programme.
[33] New indicator introduced in 2024 work programme.
[34] New indicator introduced in 2023 work programme.
[35] New indicator introduced in 2023 work programme.
[36] New indicator introduced in 2024 work programme.

Procedure		2025 annual forecast								
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of healthcare professionals eligible organisations[37]	42	41	-	-	-	41	44	0	0%
	Active patients expert nominated by EMA[38]	139	180	-	-	-	180	180	0	0%
	Active healthcare professionals experts nominated by EMA[39]	73	81	-	-	-	80	80	0	0%
	Number of messages circulated via 'Early Notification System'	290	271	277	329	635	500	500	0	0%
	Number of EMA communications pro-actively sent to stakeholders	116	111	106	109	110	200	200	0	0%
	Access to documents, requests received	401	254	416	375	342	750	750	0	0%
	Access to documents, documents released	641	605	652	497	568	2,000	2,000	0	0%
	Requests for information received	3,671	3,835	3,624	4,559	5,915	8,000	8,000	0	0%
	Clinical Data Publication (CDP), Procedures published	38	40	27	-	-	120	120	0	0%
	Clinical Data Publication (CDP), Documents published	2,354	3,271	471	-	-	10,000	8,000	-2,000	-20%

Performance indicators

Performance indicators related to core business	Target 2025	Outcome at the end of				
		Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
Average rating of pages on corporate website during the year	3.8	3.0	n/a[40]	3.8	3.1	3.5

[37] New indicator introduced in 2024 work programme.
[38] New indicator introduced in 2024 work programme.
[39] New indicator introduced in 2024 work programme.
[40] Data unavailable.

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Satisfaction level of patient and consumer organisations[41]	80%	n/a	n/a	100.00%	n/a	92%
	Satisfaction level of Healthcare Professionals organisations[42]	80%	n/a	n/a	88.00%	n/a	90%
	Triage of incoming requests received via AskEMA within set timelines	100%	99.80%	99.60%	99.00%	99%	99%
	Responses to ATD within set timelines[43]	90%	97.14%	98.60%	91.40%	89%	92%
	Responses to RFI within set timelines (for EMA)	95%	84.75%	84.00%	82.00%	89%	85%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	75%	76.5%	76%	73.00%	68%[44]	82%
	Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'[45]	n/a	n/a	70.3%	n/a	n/a	n/a

[41] Survey carried out every 2 years.
[42] Survey carried out every 2 years.
[43] 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.
[44] Low response rate (6.4%).
[45] Survey carried out every 2 years.

Achievements

Pillar 2 – Public health activities

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Manage and further develop EMA's social media activities		Expand outreach to broader targeted audience	**On track**	Switch from X to Bluesky in January 2025, following a critical review of engagement results on X; audience growth from 0 to 23,000 followers in the first 6 months. Launch of social media ambassadors project; selection of ambassadors from across the Agency finalised by Q2. Launch of EMA thought leader programme; recruitment of an initial 7 thought leaders is concluded. Launch of a pilot to work with social media influencers on GLP-1 RA medicines: a contract with a service provider is in place; 40 influencers have been identified and verified by end of Q2. Contract for paid social media ads is in place to support targeted promotion of public health and corporate messages. Diversification of content is progressing, with production of videos, carousels, info cards, and behind the scenes photographs.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				The Executive Director's LinkedIn account is maintained and grown with posts on a wide range of topics.
Planning of communication activities and campaigns in key topic areas in the annually determined strategic business priority areas		Maximise public health impact of communication	**On track**	Communication plans for topics such as CTIS/ACT-EU, data, AI, cancer, shortages and the review of the EU pharmaceutical legislation are in place and implemented. Human and veterinary medicines highlights were published in January 2025. A press briefing on the highlights of approval of human medicines in 2025 with spotlight on mental health was held in January 2025. Annual report was drafted, agreed and published in an updated format. European Immunisation Week was commemorated with an EU-wide campaign Production of videos was agreed and contracts signed. The production will start in Q3. Two videos are foreseen for 2025.
Development of a European medicines web portal		High-quality product meeting both user and business needs, containing information on all medicines authorised in the European Union	**On track**	Preparations for user research to gather requirements ongoing.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Finalise strategy and implement step 2 of the CDP re-launch beyond COVID-19		Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs	**On track**	Strategy finalised and approved by MB at the end of 2024. Step 2 currently being implemented.
ePI: electronic product information for EU medicines		Generation of all tools and guidance needed for: • Updates to tools and processes based on pilot outcome • Implementation of ePI into business for CAPs and potentially some NAPs • Initiation of phased implementation across member states • Readiness for revision of the pharmaceutical legislation	**On track**	ePI pilot epic closed Business process group established with H-Div User Acceptance testing on FHIR import The public consultation on the 'Reflection paper on linking to ePI from EU medicine package' ended on 30 June Multiple procedure numbers functionality implemented Six Pharma Subject Matter Experts appointed to team
Contribute to the implementation of EMANS (European Medicines Agencies 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**	Finalization and publication of EMANS 2028 in March 2025. Hosting of a multi-stakeholder webinar for on EMANS 2028 in February 2025 following public consultation. Publication of analysis of outcome of public consultation on EMANS 2028

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Work underway to finalise the list of actions for EMANS 2028 on the basis of the strategy's goals and objectives
Implementation of scientific publication strategy		Maximise public health impact of communication	**On track**	Delivery of publications: 56 manuscripts reviewed internally and 56 manuscripts published by 1 July 2025, including 25 with EMA staff as leading author. 87% of papers published are Open Access. EMA covered the cost of 12 of these papers following internal evaluation. Median impact factor for Q1 and Q2 of 2025 publications is 6.3 (4.7 in 2024). Policy on publications by EMA staff and EMA scientific committee members on EMA's work (Policy 0015) came into effect in January 2025. Continued established collaboration with several high-impact journals, including BJCP (2 publications), Clinical Pharmacology & Therapeutics (7 publications), and Lancet Regional Health Europe (4 publications).
Collaboration with EC (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 with EC, HERA and ECDC counterparts held, continuous discussion of upcoming communication activities and alignment of messaging; Monthly meetings with the Heads of communication of the One Health agencies (ECHA, ECDC, EEA, EFSA, EMA) are taking place to identify areas for

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				cooperation and coordination and alignment of messages.
Work with Working Group of Communication Professionals (WGCP) to agree communication plans and appoint joint leads with EMA, as appropriate		Tailored communication at national level supported by strong co-ordination at EU level	**On track**	Bi-weekly meetings to coordinate network-wide communication planning are being held. A joint communication plan with WGCP is in place. A joint HMA/EMA LinkedIn live session was organised on evidence generation 2030, featuring speakers from EMA and HMA. EMA continues to explore possible bi- or multilateral communication activities with WGCP members. EMA supports WGCP campaign on safe use of OTC medicines.
Develop a more proactive approach to countering misinformation		Better and earlier awareness of mis- and/or disinformation, enabling tailored counter-information/ transparency	**On track**	Delivered a process and reporting for infodemic management and stakeholders listening on specific issues; currently evaluating its utility via a consultation with management for supporting different EMA activities. Collaboration with partners on tackling mis- and disinformation is ongoing, e.g. with One Health agencies, DG Sante. Additional trust-building measures are being developed (see above in social media section: e.g. ambassadors programme, thought leaders programme, work with influencers, podcasts, etc.)

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Established a collaboration with the European Academy of Paediatrics (EAP) to enhance vaccine science literacy; delivered a scientific publication on meningococcal B vaccines (coauthored by EAP and Emer) and also produced the first Vaccine Fact Box on meningococcal B vaccines. The fact box has been endorsed by EAP and consultation is currently ongoing with HCPs, PCO and academics to determine its utility. Maintaining up to date the LTT on COVID-19 and LTT on long COVID-19.
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 2025. Coordination of activities for crisis preparedness and monitoring of issues that may potentially evolve into crises has been ensured. Preparations for a crisis exercise in Q4 2025 are ongoing. Awareness of crisis management principles raised at EMA All managers meeting.
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's crisis communication plan endorsed by Crisis Preparedness and Response Steering Group and EXB for implementation in 2025 Participation in EU crisis exercise in June 2025
Develop EU regulatory framework to encourage generation and use of patient experience data (PED) in		CHMP assessment report template updated to include a specific section on PED	**On track**	Revised CHMP AR template published

Action	MAWP strategic goal	Expected result	Status	Achievements / results
medicines development, evaluation and use		Publication of a Reflection Paper on PED		Drafted reflection paper on Patient Experience Data, endorsement by working parties and committees and submitted to Guideline Consistency Group Supported and delivered presentations on PED to different stakeholders (DIA, industry etc)

6. Information Management Division

Workload indicators

Procedure							2025 annual forecast			
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change	
	Number of information services/IT systems provided by EMA	33	28	28	-	-	33	33	0	0%

Performance indicators

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Satisfaction of EMA internal and external users	80%	97.30%	96.18%	95.00%	96%	96%
	Availability of IT systems	98%	99.99%	99.17%	98.00%	98.20%	99.50%

Achievements

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Centralising Data Standards	2.1 (ECP 1 A new plan for Europe)	Enable semantic interoperability and exchange of data through the use of standards, terminologies and master data across EMRN and stakeholders	**On track**	Active contribution and/or leadership in international data standardisation efforts across key Standards Development Organisations (SDOs) and stakeholders. Leadership role within ISO/TC 215 WG6 focused on the development of International Organisation for Standardisation (ISO) Identification of Medicinal Products (IDMP) data standards. Ongoing participation in HL7 (Health Level Seven) FHIR (Fast Healthcare Interoperability Resources) standardisation initiatives to ensure alignment with regulatory use cases. Engagement in HL7 FHIR Connectathons, contributing to interoperability testing under Vulcan/UDP (Utilizing the Digital protocol), Gravitate Health-ePI-GIDWG (Gravitate Health - electronic product information for EU medicines - Global Identification Working Group), and Evidence-Based Medicine tracks. Establishment of four GIDWG Focus Groups (Pharmacovigilance, Cross-border, Shortages, Hospital Prescription) to evaluate the impact of IDMP Business Rules on global use cases

Action	MAWP strategic goal	Expected result	Status	Achievements / results
Develop and maintain EMA and EMRN Enterprise Architectures	2.2 (ECP 1 A new plan for Europe)	Business-driven and strategic Enterprise Architecture supporting implementation of the legislative priorities, security and technology landscape modernisation, data-driven initiatives, and ensuring operational efficiency of the Network	**On track**	The Enterprise Architecture Board has endorsed the modernisation of CTIS and legacy applications, leveraging the modernisation framework and Amazon Web Services (AWS) standards. A Data Platform concept has been introduced to support integration and governance needs, and to accelerate modernisation by decoupling system transitions. Vulnerability Management practices have been rolled out to development teams, with plans to embed security-by-design guidance into DevSecOps processes. The Enterprise Architecture Working Group (EAWG) has supported impact assessments for NPL, EHDS, and the migration to eCDTv4, and has developed target technology proposals for modernised applications.
Records management	2.4	Ensuring the efficient and systematic control of all EMA records throughout their entire life cycle, regardless of format, location, or hosting system, while maintaining regulatory compliance, operational efficiency, and the preservation of institutional memory	**On track**	Revised Records Management and Archives Policy approved on 15 April 2025. Records Management intranet re-launched to support awareness and access to resources. A mandatory e-learning course on Records Management fundamentals is now available for all staff.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Ongoing support for the implementation of DREAM 2.0 (Electronic Document and Records Management System).
Cybersecurity and Security Operation Centre	2.4	Enhancement of the EMA cyber security posture Efficient monitoring of Agency's perimeter and systems Fast adaptation on mitigating the risks stemming from the continuously changing threat landscape	**On track**	The Security Operations Centre (SOC) has consolidated all log monitoring under a single Security Information and Event Management (SIEM) system following the completion of multi-cloud integration. SOC has significantly expanded its monitoring capabilities by broadening the monitoring perimeter.
Data Management Services Data Stewardship Data Quality services Data related customer service Data Governance Activities	2.1 (ECP 1 A new plan for Europe)	EMA stakeholders have data registered in time and as needed to support their regulatory processes and qualified data that can be reliably used for decision making EMA stakeholders and users are informed and their questions in relation to data are answered Effective and Efficient Managing of enterprise/network data	**On track**	Delivered efficient and effective regulatory data services, meeting Service Level Agreements and Service Quality Indicators for Substances, Organisations, and Referentials. Managed a 2–3x increase in workload for Medicinal Product Management System (PMS) and XEVMPD. Enhanced customer satisfaction through updated guidance (SMS Guidance v3.0) and stakeholder engagement (PMS Info Day – 21 May 2025). Advanced data and information management modernisation with: • PMS UI Enrichment go-live in January

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				• Initiation of XEVMPD web UI replacement
Administration of Cloud services	2.2 (ECP 1 A new plan for Europe)	Effective and efficient Delivery and Acceleration of Cloud Services EMA stakeholders get reliable and continuous access to the Cloud services Allow EMA to further transform its business and way of working in support of its mission towards public and animal health in the EU	**On track**	Azure non-production tenant decommissioned, simplifying governance through a consolidated landing zone. Oracle non-database workloads migrated from VMware Cloud on AWS to native AWS EC2, eliminating VMware Cloud on AWS (VMC) infrastructure and improving cost efficiency. Security and compliance enhanced via Azure Arc integration and deployment of Microsoft Defender for Cloud across all cloud-connected Windows servers. Achieved full Security Operation Centre (SOC) visibility across the multi-cloud environment, boosting threat detection and response. Advanced FinOps maturity by embedding cost optimisation practices, improving cost visibility, and increasing stakeholder accountability.
Administration of digital productivity and collaboration services – Service Desk	2.2 (ECP 1 A new plan for Europe)	Quicker and more effective fulfilment of EMA services to its stakeholders Service desk as operational excellence (SLAs, customer satisfaction) – provide high quality end user services	**On track**	Customer satisfaction for the Service Desk consistently maintained above 85%. Supported adoption of collaboration platforms (e.g. MS 365) through: • SharePoint training sessions

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				• Pilot rollout of Copilot for Office applications
CTIS	II - Public health activities	Stakeholders (Public, Sponsors and National Competent Authorities) can use the CTIS for their intended purpose in line with the Clinical Trials Regulation	**On track**	System availability: 99.5% Performance of the system: OK, with improvements planned
Driving the communication with I-Div stakeholders [external]: Inter-agency collaboration and NCA IT Directors stakeholder engagement and NICTAC secretariat	2.2 (ECP 1 A new plan for Europe)	Foster positive relationship with the Network (NCAs and EU agencies) through regular engagement and communication to facilitate agency collaboration and NCA IT	**On track**	Inter-Agency Technology Innovation Workshop hosted by EFSA in Parma (April). Four NICTAC meetings, one face-to-face hosted by HPRA in Dublin (May). NCA IT Directors meeting hosted by EU Polish Presidency in Warsaw (March). Development of a NICTAC workplan to enhance collaboration on core priorities between the Network IT community.
Maintenance and optimisation of existing platforms	II - Strategies (EMANS and RSS)	Ensure platforms are performant, stable and resulting in fewer incidents	**On track**	User satisfaction rate reached 97.3% during the first semester of 2025. EMA systems maintained high stability and performance, with only 9 Priority 1 incidents reported.
Promotion of IT value	II - Strategies (EMANS and RSS)	Enhanced stakeholder understanding and advocacy for IT's role in driving business performance, optimizing regulatory processes, and supporting the strategic goals	**On track**	Improved stakeholder perception of IT service delivery following successful vendor transition for UPD, PMS, SMS, OMS, and RMS products. Initiated scoping and analysis for EudraGMDP and EV modernisation, aligned with NPL,

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				supporting target architecture and strategic business alignment. Formed cross-functional scrum teams with key roles (e.g. Business Analysts, Architects) to strengthen collaboration and ensure digital solutions meet regulatory and strategic needs. Increased IT engagement with business counterparts, fostering stronger relationships and positioning IT as a trusted strategic partner.
IT Demand management	II - Strategies (EMANS and RSS)	All IT demand coming from both Portfolio and Operations activities is appropriately captured, recorded and priorities, and EMA stakeholders have an overview of the demand	**On track**	Implemented a unified incident and change intake process for SAP Fieldglass, Business Technology Platform (BTP), and FIN modules, integrated with ServiceNow and Azure DevOps for real-time visibility. Established a governance structure for SAP Fieldglass, with regular meetings to stabilise production and manage KPIs and change backlog. Transitioned SAP FIN/BTP to Business-as-Usual (BAU) operations post-Hypercare, improving demand handling and business input. Rolled out a unified demand intake and triage process, enabling stakeholders to track demand status and priorities in real time.

Action	MAWP strategic goal	Expected result	Status	Achievements / results
				Strengthened IT demand identification and prioritisation through active collaboration with Value Stream Managers and Domain Architects, ensuring strategic and technically sound solutions. Enhanced stakeholder engagement and transparency, improving planning for current and future IT needs across the Agency.

7. Administration Division

Workload indicators

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	Total TA staff recruited against vacant posts	15	35	27	30	40	50	40	-10 -20%
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	1.60%	2.20%	3.10%	4%	3%	4%	4%	-1% -13%
	Total TA, CA, END at the Agency[46]	975	946	927	-	-	950	988	38 4%
	Onboarding of staff (TAs, CAs, ENDs) [47]	n/a	51	77	-	-	75	n/a	- -
	Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) [48]	17,034	24,000	-	-	-	67,000	37,000	-30,000 -45%
	Procurement procedures finalised[49]	16	28	11	-	-	46	46	0 0%
	Financial commitments initiated[50]	613	495	641	-	-	1,200	1,200	0 0%
	Payment transactions initiated[51]	21,579	10,094	16,066	-	-	41,116	41,116	0 0%
	Number of sales orders[52]	6,060	16,000	13,104	-	-	45,000	15,000	-30,000 -67%

[46] New indicator introduced in 2023 work programme.
[47] New indicator introduced in 2023 work programme.
[48] New indicator introduced in 2024 work programme.
[49] New indicator introduced in 2023 work programme.
[50] New indicator introduced in 2023 work programme.
[51] New indicator introduced in 2023 work programme.
[52] New indicator introduced in 2023 work programme.

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	Number of registration activities[53]	6,252	6,566	6,319	-	-	14,000	6,252	-7,748 -55%
	PRE financial queries and disputes[54]	307	175	160	-	-	500	600	100 20%
	Receivable overdue for more than 30 days (including provision for bad debts)	7.44%	3.38%	3.76%	3.03%	2%	<10%	<10%	- -

Additional indicator

	Procedure						2025 annual forecast		
		2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1-Q2	2021 Q1–Q2	Initial	Revised	Change
	Number of new contracts TA, CA, SNE including contract changes (excluding renewals)	33	65	80	75	95	66	66	0 0%

[53] New indicator introduced in 2023 work programme.
[54] New indicator introduced in 2023 work programme.

Performance indicators

Performance indicators related to core business		Target 2025	Outcome at the end of				
			Q2 2025	Q2 2024	Q2 2023	Q2 2022	Q2 2021
	Posts on the Agency establishment plan filled	99%	98.00%	98.00%	97.00%	99.50%	97%[55]
	Average time to run selection procedures from the publication of the vacancy notice to establishment of reserve list - *reversal of traffic lights*	3 months	2.5 months	2.99 months	3.0 months	2.8 months	66% < 3 months
	Revenue appropriations implemented[56]	97%	41.00%	49.00%	42.00%	45%	45%
	Expenditure appropriations implemented	95%	79.00%	75.00%	71.00%	70%	67%
	Payments against appropriations carried over from year N-1	95%	84.00%	77.00%	61.00%	60%	70%
	The maximum rate of carryover to year N+1, of total commitments within the title:						
	Title 1	10%	-	-	-	-	-
	Title 2	20%	-	-	-	-	-
	Title 3	30%	-	-	-	-	-
	Payments within the regulation time limits	97%	87.89%	n/a	97.53%	97%	97%
	Value of the budget for the given year[57]	405	-	-	-	-	-

[55] The figure does not include the posts linked to the new mandate, which are subject to the development of the legislative process.
[56] Invoices issued.
[57] New indicator introduced in 2023.

Achievements

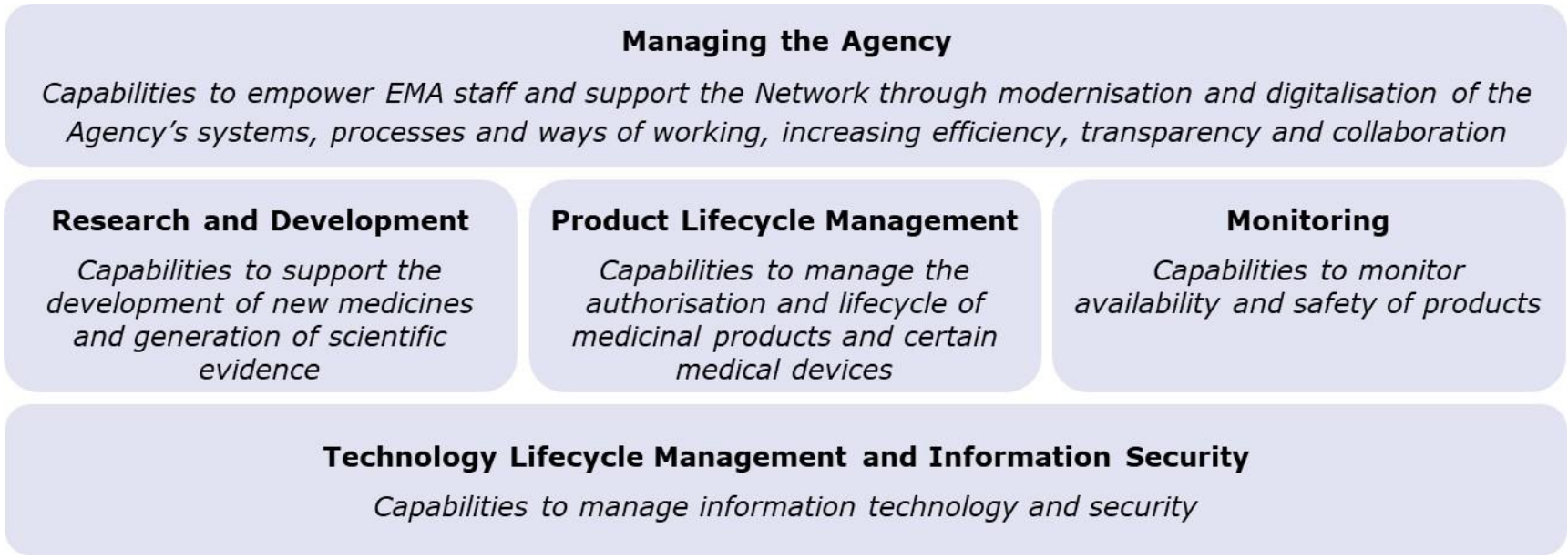
Action	MAWP strategic goal	Expected result	Activity Status (Mid-year 2025)	Achievements /results
Implementation of the HR strategy & priorities 2023-2025	6.2	The following improvements are expected by strategic ambition: Sustainable organisation will see improvement in resources and competencies needed 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 net promoter score Wellbeing activities will further improve staff wellbeing Staff and managers will show improved satisfaction with HR services	**On track**	On 12 May 2025, EMA hosted the first-ever EUAN-HR Strategy Conference, bringing together 110 participants from 45 EU Agencies and Joint Undertakings. This was the first-of-its-kind event marking a significant step in strengthening HR collaboration across EU agencies, with EMA at the forefront of shaping strategic dialogue and fostering a culture of shared progress. The conference has significantly reinforced EMA's position as a key driver of HR innovation and cooperation at EUAN level. Following the success of the event, exploratory discussions are now underway for the establishment of a dedicated EUAN-HR Strategy Working Group, further demonstrating EMA's leadership and continued commitment to advancing strategic HR initiatives across the network.
HQ efficiency	6.4	Environmental matters, campaigns, data collection, data analysis, reporting, improvement	**On track**	Data collection is in progress. Energy efficiency measures such as the increase of the building's temperature setpoint by one degree during the summer months were implemented.

Action	MAWP strategic goal	Expected result	Activity Status (Mid-year 2025)	Achievements /results
		identification, action implementation		Additional improvements have been identified and a plan of implementation is currently under development. Moreover, environmental campaigns such as the green days have been organised in cooperation with the catering team such as: • World bee day at the end of May • Introduced too good to go at the end of April (waste prevention) • World health day on 7 April • World pulses day on 10 Feb
Historical Archives - EMA 30th Anniversary		EMA Historical Archives identified and available at the European University Institute (EUI) from January 2025 at the anniversary of the Agency	**On track**	In January 2025, new internal rules were adopted for the application of Council Regulation (EEC, EURATOM) 354/83, as amended by Council Regulation (EU) 2015/496. These rules established a framework for the preservation and public access to historical archives, including guidelines for the protection of personal data. They also outlined procedures for depositing these archives at the European University Institute (EUI) in Florence. Following the adoption of these rules, the following activities were carried out during the first half of 2025: • Establishment of a records list: A list of records identified as historical was established in Q1 2025. • Physical and intellectual preparation of records:

Action	MAWP strategic goal	Expected result	Activity Status (Mid-year 2025)	Achievements /results
				This process involved a detailed review, physical preparation for preservation, digitization, and quality control. We also extracted metadata and drafted summary abstracts for the records. • Shipment of records: The shipment of these historical records to the Historical Archives of the European Union (HAEU) is planned for the end of September 2025.

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, with a designated 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 2025; progress and delivery as of 30 of June 2025 against what was planned in the work programme 2025 is reported using the following status:

On track
Delayed
Suspended
Achieved

Note 1: The budget figures for 2025 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) 2025	Status	Achievements/Results Q1/Q2 2025
Product Lifecycle Management Value Stream (PLM VS) *Capabilities to authorise and manage lifecycle of medicines and medical devices*						**Budget 2025 (M€) 13.6**
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	2027	Enable industry, through an application programming interface (API), to enrich PMS with ISO-IDMP compliant medicinal product data needed for European Shortages Monitoring Platform (ESMP) go-live Enable industry, through an API, to enrich PMS with ISO-IDMP compliant medicinal product data beyond the data fields needed for ESMP go-live Enable read access to PMS to the public through an API Perform analysis for a roadmap to replace and decommission the Art. 57/ eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)	On track	Implementation of a machine-to-machine solution (PMS API) to allow industry users to enrich PMS data needed for ESMP reporting is in progress. Analysis of PMS data enrichment beyond ESMP requirements is underway, including formulation of a SIAMED decommissioning strategy. Implementation of public read-only PMS API ongoing. Analysis is being conducted to draft a roadmap for XEVMPD decommissioning. Ongoing bug fixes and database maintenance to continuously enhance quality and reliability of PMS data.
Product Management System User Interface *(part of the Product Lifecycle Management portal)*		2023	2025	Enable industry, through the Product User Interface (PUI), to enrich medicinal product data in PMS needed for ESMP go-live Enable industry, through the PUI, to enrich medicinal product data in PMS beyond the data fields needed for ESMP go-live	On track	Functionality for industry users to edit non-centrally authorised products (non-CAPs) pack size and manufacturer data released in January 2025, ahead of ESMP go-live. The implementation of the bulk functionality, enabling updates across multiple products simultaneously, is ongoing. Ongoing maintenance and continuous improvements to the PUI to ensure optimal performance and usability.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results Q1/Q2 2025
Electronic Application Form (eAF) *(part of the Product Lifecycle Management portal)*		2021	2026	Go-live for eAF for human variations for non-CAPs Maintenance of the eAF for human variations for CAPs and non-CAPs	Achieved On track	Human variations web-based eAF live for non-centrally authorised products (non-CAPs) through the Product Lifecycle Management (PLM) portal since 11 February 2025. The eAF 'integrity stamp' feature launched on 6 March 2025. Maintenance of eAF for human variations ongoing.
Union Product Database (UPD)	Regulation (EU) 2019/6; associated implementing act	2021		UPD maintenance and improvements, i.e. enhance functionalities, usability and user experience for NCA and Industry	On track	Read-API for industry users to full product data and read-API for the public to non-confidential product data released in January. UPD maintenance and improvements ongoing. UPD updated to reflect Commission Implementing Regulation (EU) 2025/163 introducing 54 changes to variations not requiring assessment (VNRA), effective from 20 April 2025.
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2027	Go-live for the management of post-authorisation procedures (H & V) in IRIS and implementation of the New Fee Regulation Develop capability for procedure management of initial marketing authorisation applications (H & V) (+ Medicines for All & ancillary substances) in IRIS	Achieved On track	Post-authorisation procedures transitioned to IRIS in January and February 2025. Changes for new fee regulation completed. IRIS portal views and functionalities adjusted to enable collaboration for Network and industry users. Development of capability for initial marketing authorisation applications is ongoing.
Electronic Product Information (ePI) *(part of the Product Lifecycle Management portal)*		2022	2026	Implementation of features following findings from ePI pilot Development of functionalities that are essential for go-live	On track	Public Fast Healthcare Interoperability Resource (FHIR) import testing completed. Performed a public consultation on linking to ePI from EU medicine packages.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results Q1/Q2 2025
eCTD4 (eSubmissions incl. EURSnext/Common Repository)		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	Updated eCTD v4.0 specification and implementation guide (CAPs only) published, as outcome of the first phase of eCTD v4.0 technical pilot. Second phase of eCTD v4.0 technical pilot planned. Roll-out of EURSnext review tool to EMA users.
European Medicines Web Portal (EMWP)	Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2027	Perform user research and initial UX design to support the design and future development of EMWP	On track	Preparations for user research to gather requirements ongoing.
Research and Development Management Value Stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*						**Budget 2025 (M€) 13.6**
Regulatory Procedure Management (RPM) for R&D *(part of the IRIS portal)*		2023	2026	Pre-authorisation processes onboarding onto IRIS	On track	Changes for new fee regulation completed. Development of capability for pre-authorisation processes (eligibility request, intent to submit, pre-submission meeting and support, notification of change /withdrawal) ongoing (in parallel to the initial marketing applications).
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82	2014	tbc	CTIS maintenance and continuous improvements, further improve stability, usability and user satisfaction CTIS Public Portal maintenance and improvements Continue the simplification principles of CTIS functionalities in preparedness for CTIS modernisation in 2025 and beyond Deliver new epics based on business value to enable CTIS modernisation over time	On track	CTIS and CTIS Public Portal maintenance and continuous improvements ongoing. Simplification task force work ongoing. Review of modernisation roadmap, technology and architecture completed. Clinical trial map launched in the EU on 3 March and is accessible from the Clinical Trials Information System (CTIS) public website. CTIS BI maintenance and improvements ongoing.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results Q1/Q2 2025
				CTIS Business Intelligence (CTIS BI) maintenance, improvement and further development to ensure alignment with CTIS improvement activities		
Scientific Explorer		2020	2025	Scientific Explorer II to expand capabilities of Scientific Explorer I to bridge evidence generation and evaluation support	Delayed	European public assessment report (EPAR) ingestion completed. AI extraction capability expanded to include EPARs.
Knowledge Mining		2025	2025	Develop knowledge mining and AI capabilities for EMA and the Network (custom products)	Delayed	Collection of use cases and experimentation ongoing.
Monitoring Value Stream (MON VS) *Capabilities to monitor availability and safety of products*						**Budget 2025 (M€) 4.7**
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2025	ESMP minimum viable product (MVP) go-live in February 2025 allowing the entry into force of the regulation Maintenance and improvements to MVP	Achieved	ESMP fully deployed on 2 February 2025. Gap analysis and impact assessment for ESMP interoperability with European Medicines Verification System (EMVS) started.
Regulatory Procedure Management (RPM) for Monitoring *(part of the IRIS portal)*		2023	2025	Maintenance and improvements on inspections and parallel distribution, including new fee regulation (NFR)	Achieved	Inspections and parallel distribution updated in January to reflect new fee regulation.
Union Pharmacovigilance Database (UPhV, formerly EVVet3)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2024	Product development completed in 2024, maintenance to continue in 2025 European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) decommissioning	Achieved	UPhV maintenance and improvements ongoing. ESVAC decommissioning completed.
Antimicrobial Sales & Use (ASU)	Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578	2021	2024	Product development completed in 2024, maintenance to continue in 2025	Achieved	ASU maintenance and improvements ongoing.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results Q1/Q2 2025
	Commission Implementing act 2022/209					
Signal and Safety Analytics (SSA) [new]		2025	2025	SSA minimum viable product (MVP) go-live	On track	The project is progressing and aims to enter into operation for a limited number of NCAs in Q4/2025.
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 2025 (M€) 5.0**
SAP Finance replacement		2023	2026	Finalise analysis and technology selection	On track	Architecture analysis completed. Technology selection ongoing.
SAP HR replacement		2023	2025	SAP HR Core replacement	On track	Development and testing ongoing.
New Fee Regulation	Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency	2023	2025	Go-live in January 2025 Integration of latest regulatory processes with the new fee system	Achieved	All systems related to the new fee regulation (NFR) were successfully updated to reflect the regulation that entered into force on 1 January 2025.
Document Management System replacement		2023	2025	Implementation of document management system replacement	Achieved	Go-live of new document management system on 23 June 2025.
AskEMA replacement		2024	2025	AskEMA replacement implementation	Suspen-ded	
Anonymisation@EMA		2025	2025	Enable automated anonymisation of commercially confidential information (CCI) in large sets of documents	On track	Analysis and technology selection ongoing (personal/clinical data).
Customer Relationship Management (CRM) tool		2025	2026	Start analysis and technology selection	On track	Analysis started. Business consultancy tender process concluded.
Workplace Experience		2024	2027	Finalise analysis and technology selection	Delayed	Technology selection ongoing.
Early Notification System (ENS) [new]		2025	2025	Secure communication platform to deliver emerging safety information to	On track	Proof of concept completed; operationalisation ongoing.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Status	Achievements/Results Q1/Q2 2025
				NCAs, international partners and EMA staff.		
Technology Lifecycle Management and Information Security Value Stream (TLM VS) *Capabilities to manage information technology and security*						**Budget 2025 (M€) 3.0**
Information Security and Cyber Security enhancements		2022	2025	Cyber & Information Security enhancements Operational Security enhancements Application Security enhancements	On track	Continuous improvements to information security and cyber security.
Legacy application modernisation		2023	2025	Horizon 25 Modernisation Factory: move the legacy applications that are running on outdated technologies into a modern, stable and secure environment ("re-platforming")	Delayed	Legacy modernisation activities ongoing.

Annex 3: Terms and abbreviations

Term/abbreviation	Definition
ACT EU	Accelerate Clinical Trials in the EU
ADR	Adverse Drug Reaction
ADRA project	Dosage review and adjustment of selected veterinary antibiotics
AER	Adverse Event Report
AI	Artificial Intelligence
AM	Additional Monitoring
AMA	African Medicines Agency
AMEG	EMA CHMP/CVMP Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
AMRH	African Medicines Regulatory Harmonisation initiative
API	Active Pharmaceutical Ingredient
AR	Assessment Report
ASR	Annual Safety Reports
ASU	Antimicrobial sales and use
ATD	EMA Access to Documents
ATMP	Advanced Therapy Medicinal Product
AUDA NEPAD	African Union Development Agency
AWS	Amazon Web Services
BAU	Business as usual
BE	Bioequivalence
BI	Business intelligence
BJCP	British Journal of Clinical Pharmacology
BTP	SAP Business Technology Platform
CAP	Centrally Authorised Product
CBRN	Chemical, Biological, Radiological and Nuclear
CCI	Commercially Confidential Information
CDDF	Clinical Data Interchange Standards Consortium
CDP	EMA Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CDT	Centre de Traduction
CHMP	EMA Committee for Medicinal Products for Human Use
CMC	Chemistry Manufacturing and Controls
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
COA	Certificate of Analysis
CRM	Customer Relationship Management
CRP	Collaborative Registration Procedure
CT	Clinical Trial
CTA	Clinical Trial Application
CTCG	Clinical Trial Coordination Group
CTD	Common technical document

Term/abbreviation	Definition
CTIS	Clinical Trials Information System
CTR	Clinical Trial Regulation
CVMP	EMA Committee for Veterinary Medicinal Products
DALT	Digital Acceleration Leadership Team
DAP	Data Analytics Platform
DARWIN EU®	Data Analysis and Real World Interrogation Network
DG	Directorate-General
DG INTPA	European Commission Directorate-General for International Partnerships
DIA	Drug Information Association
DPC	Data Protection Coordinator
DPO	Data Protection Officer
DREAM	Document Records Electronic Archive Management system
EAC	East African Community Region
EAP	European Academy of Paediatrics
EAWG	Enterprise Architecture Working Group
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission priority
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EEA	European Environment Agency
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EMA	European Medicines Agency
EMANS	European Medicines Agencies Network Strategy
EMRN	European Medicines Regulatory Network
EMVS	European Medicines Verification System
EMWP	European Medicines Web Portal
END	Seconded national expert (Experts nationaux détachés)
ENS	Early Notification System
EPAR	European Public Assessment Report
ePI	electronic product information for EU medicines
ERA	Environmental Risk Assessment
ERATO	Enhanced Review of Abstracts with Transformer Models
ESEC	EMA European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicine
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	EMA Emergency Task Force
EU	European Union
EUAN	European Union Agencies Network
EUI	European University Institute

Term/abbreviation	Definition
EUM4all	EU Medicines for all
EUNTC	EU Network Training Centre
EurEKA	EU product information Entity Extraction and Knowledge Acquisition project
EURS	European Review System for eCTDs
EV	EudraVigilance
EVV	Union Pharmacovigilance Database
EWP	Efficacy Working Party
EXB	EMA Executive Board
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FVE	Federation of Veterinarians of Europe
GCP	Good Clinical Practice
GIDWG	Global Identification Working Group
GIREX	Group for Internal Rules on Extensions of Clock Stops
GL	Guideline
GLP	Good Laboratory Practice
GMDP	Good manufacturing and distribution practice
GMP	Good Manufacturing Practice
HAEU	Historical Archives of the European Union
HCIN	Heads of Communication and Information Network
HCP	Healthcare Professional
HCPWP	EMA Healthcare Professionals' Working Party
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMA MG	Heads of Medicines Agencies Management Group
HPRA	Health Products Regulatory Authority (Ireland)
HQ	Headquarters
HTA	Health Technology Assessment
ICH	International Conference on Harmonisation of Technical Requirements for
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	Individual Case Safety Report
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IGAD	Intergovernmental Authority on Development
IHD	Instant Health Data
IMPDQ	Medicinal Product Dossier Quality
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme

Term/abbreviation	Definition
IRIS	Not an abbreviation. Refers to the regulatory & scientific information management platform between EMA and stakeholders
ISO	International Organisation for Standardisation
ITF	EMA Innovation Task Force
IVD	In vitro Diagnostics
IVDR	EU In vitro Diagnostic medical devices Regulation
IVMAB	ECDC/EMA Immunisation and Vaccine Monitoring Advisory Board
IWG	Inspectors Working Group
JAMRAI	Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections
JCA	Joint Controllership Agreement
JCASG	Joint Clinical Assessment subgroup
JIACRA	Joint Inter-agency Antimicrobial Consumption and Resistance Analysis
JSC	Joint Scientific Consultation
KPI	Key Performance Indicator
LLFG	EMA Listen and Learn Focus Group
LMS	Learning Management System
LTT	Lines to take [internal EMA document usually not for publication]
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MAWP	Multi-annual Work Plan
MB	EMA Management Board
MD	Medical Device
MDCG	EU Medical Device Coordination Group
MDR	EU Medical Devices Regulation
ML	Machine learning
MP	Medicinal Product
MRA	Mutual Recognition Agreement
MRL	Maximum Residue Limit
MS	Member State of the European Union
MSSG	EMA Medicines Shortages Steering Group
MUMS	Minor Use, Minor Species
MVP	Minimum viable product
MWP	EMA CHMP Methodology Working Party
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDSG	Network Data Steering Group
NFR	New Fee Regulation
NICTAC	Network ICT Advisory Committee
NIS	Non-Interventional Study
NITAG	National Immunisation Technical Advisory Group
NLP	Natural language processing
NPL	New pharmaceutical legislation

Term/abbreviation	Definition
NRA	WHO National Regulatory Authority
OMS	Organisation Management Service
OoNM	Qualification of Novel Methodologies
OPEN	Opening our Procedures at EMA to Non-EU authorities
OTC	Over-the-counter
PACMP	post approval change management protocols
PCO	Patients' and Consumers' Organisations
PCWP	EMA Patients' and Consumers' Working Party
PED	Patient Experience Data
PHE	Public Health Emergency
PHE EAG	Public Health Emergencies Ethics Advisory Group
PI	Planning Interval
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PLCM	Product Lifecycle Management
PLM	Product Lifecycle Management
PMF	Plasma Master File
PMS	Post-Marketing Surveillance
PMSV	Post-market surveillance and vigilance
PQ	Pre-qualification
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	EMA Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure
Pre-SIG	Pre-submission Interaction Group
PRIME	EMA Priority Medicines scheme
PSUR	Periodic Safety Update Report
PUI	Product User Interface
QAT	Quality control, assurance and acceptance testing
RAPS	Regulatory Affairs Professionals Society
RECs	Regional Economic Communities
RFI	EMA Request for Information
RMS	Risk Management System
ROG	Regulatory Optimisation Group
RPM	Regulatory Procedure Management
RSS	EMA Regulatory Science Strategy
RWD	Real World Data
RWE	Real World Evidence
SA	Scientific Advice
SAFE	Scaled Agile Framework
SAWP	EMA CHMP Scientific Advice Working Party
SDO	Standards Development Organisations
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SIEM	Security Information and Event Management

Term/abbreviation	Definition
SLA	service level agreement
SME	Small and Medium-sized Enterprises
SMS	Substance Management Service
SNE	Seconded national expert (Experts nationaux détachés)
SOC	Standard of care
SPD	Single Programming Document
SPMP	Shortage prevention and mitigation plan
SPOC	Single Point of Contact
SRA	WHO Stringent Regulatory Authority
SSA	EMA Signal and Safety Analytics
SWP-V	EMA CVMP Safety Working Party
TA	Temporary agent
TB	Tuberculosis
TC	Technical Committee
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TF	Task force
TFAAM	HMA-EMA Task Force on Availability of Medicines
TIG	Technical Implementation Guide
TRS	EMA Regulatory Science and Innovation Task Force
TWG1	Thematic working group
UDP	Utilizing the Digital protocol
UI	Unique Identifier
UPD	Union Product Database
UPhV	Union Pharmacovigilance Database
US	United States of America
UX	user experience
VE	Vaccine Effectiveness
VMC	VMware Cloud on AWS
VMP	ECDC/EMA Vaccine Monitoring Platform
VNRA	Variation Not Requiring Assessment
VOG	Vaccine Outreach Group
VS	Value Stream
VWP	EMA CHMP Vaccines Working Party
WG	Working Group
WGCP	Working Group of Communication Professionals
WHO	World Health Organization
WLA	WHO-Listed Authority
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary