EUROPEAN MEDICINES AGENCY
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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Key developments

In the first half of 2026, the European Medicines Agency (EMA) made substantial progress in the main focus areas in the Single Programming Document (SPD) 2026-2028. This section highlights achievements in these areas, as well as other key developments that occurred over this period.

The work in these focus areas builds on the European medicines agencies network strategy to 2028 and is guided by the Agency's vision of creating a fast path from innovation to safe and effective medicines.

Main focus areas

Focus area 1 - 'Reimagining EMA'

In 're-imagining EMA', the Agency took steps to deliver on its expanding responsibilities at a time of rapid regulatory and technological change.

On 11 December 2025, the European Commission, European Parliament and the Council reached a provisional political agreement on the comprehensive reform of the EU pharmaceutical legislation. The agreement on the new pharmaceutical legislation (NPL) represents the most significant overhaul of the regulatory framework in over two decades and will modernise how medicines are developed, authorised and made available to patients across the EU.

Under the **NPL EMA management board governance structure**, adopted in December 2025, the Agency has been preparing for the implementation of the new legislation across the different delivery streams, and the **NPL Oversight Group** has endorsed a model to ensure involvement of experts from across the European medicines regulatory network. A dedicated page on EMA's corporate website was created to provide regular updates on the implementation of the landmark legislation.

Another major legislative development was the provisional agreement on the **Critical Medicines Act (CMA)** reached on 12 May 2026 by the Council and the European Parliament. The CMA represents an important step in strengthening the resilience, security and sustainability of the European Union’s supply of critical medicines.

The Agency has also been preparing for the implementation of the CMA, which foresees a role for EMA’s Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) in carrying out supply chain vulnerability assessments to help address structural vulnerabilities in the supply chain of critical medicines. This work will also help to strengthen supply chains of critical medicines under the new pharmaceutical legislation.

In preparation for the implementation of both the CMA and the new pharmaceutical legislation, the MSSG is evaluating vulnerabilities in the supply chains of a first set of medicines included in the Union list of critical medicines. This list contains over 200 active substances of medicines for human use that are considered critical for healthcare systems across the EU. The CMA also recognises and strengthens the role of the Quality Innovation Expert Group (QIG) which EMA established in 2022 to support developers of innovative technologies.

As part of these efforts to address supply chain vulnerabilities, EMA is also expanding the functionalities of the European Shortages Monitoring Platform (ESMP), a digital tool designed to enable faster, more consistent and more data-driven exchange of information about potential medicines shortages between industry and regulators.

Focus area 2 - Supporting innovation for public and animal health

In the first half of 2026, the Agency strengthened its support for innovation through its work with developers and initiatives on clinical trials and the use of real-world evidence.

After the completion of a two-year pilot, EMA launched three **major new features of PRIority MEdicines (PRIME)**, the Agency's scheme to support developers of medicines targeting an unmet medical need.

The first feature, the regulatory roadmap and product development tracker, helps chart a medicine's progress and flag potential issues early, making it easier for developers and EMA to stay aligned throughout development. The second, the expedited scientific advice, is a fast-track route for developers to receive timely and focused regulatory input on focused questions that are critical for the development process. The third, the submission readiness meeting, is a dedicated check-in, about a year before submission, where EMA and developers discuss the progress of the development programme and identify remaining evidence gaps to ensure that a comprehensive data package is available for a thorough evaluation by the Committee for Medicines for Human Use (CHMP).

Another milestone in supporting the timely patient access to medicines was reached through the application of the **HTA Regulation**, with publication on 9 June 2026 of the first joint clinical assessment (JCA) by the Health Technology Assessment Coordination Group.

In the area of clinical trials, the Agency – together with the European Commission and the Heads of Medicines Agencies (HMA) published the revised Accelerating Clinical Trials in the EU (ACT EU) workplan for 2026 to 2027. This is aligned with the updated **ACT EU objectives** and informed by key EU legislative and policy initiatives shaping the clinical trials environment, including the proposed Biotech Act, the Clinical Research Investment Plan (part of the Strategy for European Life Sciences) and the EU4Health initiatives.

Under ACT EU EMA/EC/HMA published Monitoring the European clinical trials environment, the first progress report tracking the **EU's new clinical trial targets**. Covering activities in the first quarter of 2026, the report highlights early progress. Preliminary data collected as of June 2026 indicate a continuing positive increase across key indicators, suggesting further progress towards the EU targets.

Established in 2025, these targets aim to strengthen the European Union's (EU) position as a leading destination for clinical research while improving patients' timely access to innovative medicines. The new clinical trial targets are aligned with the EU **Biotech Act** proposed by the EC. One of the key changes under the Biotech Act is the acceleration of clinical trial authorisation processes. Complementary network initiatives, notably FAST EU, are also contributing to these targets.

The ACT EU initiative also published a draft guidance document outlining how clinical trials should be conducted during public health emergencies (PHEs) in March 2026. It recommends a harmonised approach to ensure that clinical trials can be initiated, adapted and continued efficiently and safely when public health emergencies arise.

Meanwhile, **DARWIN EU®**, the EU network for generating real-world evidence on medicines, grew to 40 data partners across 18 European countries, covering over 250 million European patients. Since setup it has delivered more than 110 studies on disease epidemiology, drug utilisation and the safety and effectiveness of medicines, supporting the European Medicines Regulatory Network (EMRN) with timely real-world evidence (RWE) for regulatory decisions.

The Agency also published the 4th report on the experience gained with regulator-led studies, Real-world evidence framework to support EU regulatory decision-making. The report highlights the continued progress in integrating RWE into regulatory decision-making, aligned with the European

medicines regulatory network (EMRN) strategy to 2028 and in anticipation of the provisions from the new pharmaceutical legislation.

In addition, EMA published the Data quality framework for EU medicines regulation: application to real-world data, adopted by CHMP. This framework provides recommendations specific to real-world data for the purpose of characterising and assessing the quality of data underpinning real-world evidence used in regulatory assessments. It also provides practical guidance on evaluating quality in relation to a specific research question, based on data quality metrics and evidence on the systems and processes underpinning the data.

Focus area 3 - Ensuring that we invest in our staff and the network of tomorrow

EMA and the Heads of Medicines Agencies (HMA) have updated the joint workplan Data and AI in medicines regulation for period 2026 to 2028. It 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 security and ethical standards. It also provides a framework for coordination to address new legislative initiatives in the European Union, notably the new pharmaceutical legislation, the European Health Data Space (EHDS), the Interoperable Europe Act and the AI Act.

The Agency has also been engaged in building visibility to **address mis- and disinformation**, and anti-scientific sentiments. In April 2026, EMA set up a new advisory group on vaccine confidence. The group includes over **20 high-level European and international experts** and will meet quarterly to advise the Agency on issues related to vaccine hesitancy.

The advisory group on vaccine confidence is part of **EMA's Vaccine Outreach Strategy**, a wider approach to increase knowledge and trust in the quality, safety and effectiveness of vaccines and to empower the EU public and healthcare professionals to take well-informed vaccination decisions. The activities of the group include identifying and addressing public concerns that may affect confidence, collaborating with healthcare professionals and public health initiatives, as well as developing communication materials and campaigns on vaccines.

The Agency is also collaborating with healthcare professional organisations and learned societies to develop a communication tool on vaccines, **'Vaccine Essentials'** which aims to help increase vaccine science literacy. It relies on vaccine science and regulation to address vaccine-related information gaps and concerns that healthcare professionals identify.

Other key developments and activities

One Health task force

In 2026, EMA is chairing the **One Health task force**. Established in 2023, this cross-agency task force helps EMA and its partner agencies – European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Environment Agency (EEA) and European Food Safety Authority (EFSA) – to work together to successfully implement the One Health approach in Europe.

In this role, EMA's work is focused on the task force's five objectives: facilitating strategic coordination, promoting research coordination, enhancing capacity building, strengthening communication and stakeholder engagement, and supporting partnerships and joint activities.

International cooperation and stakeholder engagement

EMA, in cooperation with EU national authorities, continued to support the establishment of the **African Medicines Agency (AMA),** with technical training and exchanges at national and regional levels. In January 2026, the official handover of responsibilities of the African Medicines Regulatory Harmonization (AMRH) and African Union Smart Safety Surveillance (AU-3S) programmes to the AMA took place in Lusaka, Zambia. In the same month, the inaugural Heads of National Regulatory Agencies and Regional Economic Communities Coordinators Forum was held in Kigali, Rwanda.

In the context of the Ebola virus disease outbreak caused by Bundibugyo virus in the Democratic Republic of Congo and Uganda, **EMA's Emergency Task Force (ETF)** has been engaging with the AMA, African national regulatory authorities, and the WHO-AFRO African Vaccines Regulatory Forum (AVAREF) to discuss possible clinical trial designs and medical countermeasures.

In the area of stakeholder engagement, the Agency published the Biennial report on stakeholder engagement activities 2024-2025. This report outlines the continued cooperation between the EMA and key stakeholder groups in the form of either multistakeholder dialogue or bilateral engagements during 2024 and 2025.

Legal developments

The number of judicial challenges against EMA and/or the European Commission in connection with alleged breaches of Union pharmaceutical law, transparency law or procedural irregularities remains high. During the first half of 2026, EMA was involved as a defendant or intervener in eleven cases before the Court of Justice of the European Union (CJEU), without recourse to external counsel.

Between January and June 2026, two cases proceeded to a judgment/order, which were delivered by the CJEU in favour of EMA.

First, in Case T-265/25, the General Court rejected as manifestly inadmissible an action seeking compensation against the European Commission and EMA for damages allegedly incurred following the administration of a COVID-19 vaccine. The case marks the first time that an action for non-contractual damages has been brought against EMA.

Second, in Case T-844/25 R, the President of the General Court sided with EMA in the context of interim relief proceedings concerning the partial publication of the withdrawal European Public Assessment Report (EPAR) for a candidate medicinal product. The ruling is significant as it constitutes the first time in which a pharmaceutical company has tried to obtain interim relief in respect of EMA's decision to publish a withdrawal EPAR, as required by its founding regulation, namely, Article 11 of Regulation (EC) No 726/2004.

Key figures

Assessment activities for human medicines

The total scientific advice and protocol assistance requests increased, compared to the first half of 2025, with 485 requests received in Q1/Q2 2026 (384 in Q1/Q2 2025). The annual forecast is revised to a total of 885 requests, an increase of 13%.

The total number of applications (orphan and non-orphan medicinal products) was equal to the previous year, with a total of 29 applications received. The total forecast is revised from a total of 78 to 74 applications for the full year.

The total number of variations remained relatively stable, with a total of 4,194 received in the first half of 2026 and a forecast of 8,949 for the full year.

A comparatively higher number of signals peer reviewed by EMA was reported in the first half of 2026, with a total of 850 compared to 716 in the first half of 2025.

Assessment activities for veterinary medicines

In the area of veterinary medicines, the total number of Scientific advice requests received and validated increased in comparison to the first half of 2025, with 17 requests received in 2026, in comparison to 7 requests received in the first half of 2025. The total forecast for the year is increased from 20 to 28 requests.

A total of 7 initial marketing authorisation applications has been received in the first half of 2026, the forecast is increased from 23 to 26 applications for the full year 2026.

The total number of variations received remains low with 133 in the first half of 2026, and the forecast is revised downwards from 320 to 287 for the full year.

Inspections and compliance

In the area of inspections, a high number of GMP (210) , GCP (71) as well as Pharmacovigilance inspections (10) was received in the first half of 2026, and the forecasts have been revised for GCP to 123 (from 111) and 16 Pharmacovigilance inspections (from 12) for the year 2026.

Horizontal public and animal health activities

In the area of public and animal health activities, the number of ETF meetings was significantly higher than the forecast, with 25 meetings held in the first half of 2026. The number of EU NTC training events advertised to the Network was also significantly higher than the forecast, with 69 events out of 75 events planned for the full year.

Performance indicators

Out of 49 performance indicators, 1 indicator is flagged as red, 'Average clock-stop for new active substances and biosimilars'. 13 performance indicators are marked as blue, meaning achieving more than 110% of the target.

Human resources management

During the first half of 2026, the Agency issued 31 new TA contracts. The turnover rate (TA and CA) was 0.9% and the Agency reached full occupancy. The total number of staff at the Agency (TA, CA, SNE) was 991 at the end of Q2.

Year-end budget forecast

At mid-year, the overall budgetary status is on track. The forecast shows a healthy situation where expected increases in cost are potentially compensated by the revenue forecast. Currently, the year-end forecast shows a small surplus in the area of €2 million.

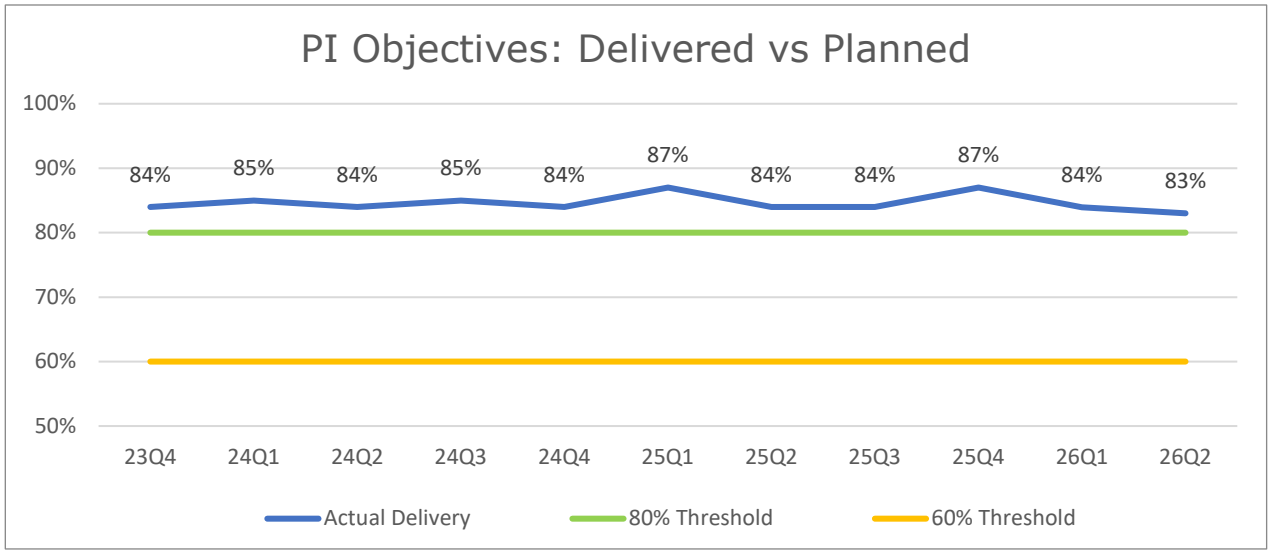
The revenues follow the trends highlighted above, and taking into account the evolution of the applications received, there is an expected upward revision in the area of €10 million.

The cost evolution is mainly driven by an expected increase in cost of the staff, taking into account the latest estimates of the European Commission regarding the adjustment of the remuneration. In addition, the revenue evolution triggers an increased remuneration to National competent authorities (NCA) of about €4 million. As communicated at the June Management Board meeting, the funding for CTIS acceleration is included in the budget.

Digitalisation initiatives and Network Portfolio

H1/2026 Network Portfolio highlights

The Network Portfolio continued to deliver in line with the Portfolio Objectives 2026-2028 and Network Portfolio Roadmap. 84% of the planned Planning Interval (PI) objectives were delivered in Q1/2026, and 83% in Q2/2026. As shown in the below graph, portfolio delivery has been consistently above the 80% 'green' delivery target threshold.



The Data Analytics Platform Business Intelligence (DAP BI) team launched a revamped IRIS NCA dashboard layout on 21 January to improve overall usability, simplify navigation, and make key information easier to access and understand.

As of 5 February, the Clinical Trials Information System Business Intelligence (CTIS BI) platform is available to NCA staff and the European Commission. The platform provides consolidated dashboards and analytical reporting to support monitoring and coordination activities related to CTIS.

CTIS Simplification Task Force has been repurposed into a CTIS Task Force, which will identify system changes needed to support the implementation of upcoming legislative updates (such as the Biotech Act), while helping to deliver benefits for innovation and patients.

The upgraded version of the current XEVMPD/Article 57 user interface, XEVMPDweb, was launched for MAH, sponsors and NCA users on 10 February. The upgraded version provides an improved user experience with easier access.

Since 3 March, the Scientific Explorer includes initial marketing authorisation procedures, including public assessment reports. This enhancement allows for more extensive search of regulatory precedents.

The European Shortages Monitoring Platform (ESMP) released two new functionalities for EMRN use in April and May. In the ESMP shortage monitoring and risk analysis tool (SMART), Member States can access CAP shortages reports and consult shortage data submitted by industry. The Voluntary

Solidarity Mechanism (VSM) functionality allows a Member State (MS) to submit requests for support from other MSs during critical shortages.

In line with the partial access granted on the basis of Article 13(5) of the Windsor Framework, the United Kingdom, acting in respect of Northern Ireland for veterinary medicines, was given partial read and write access to the Union Product Database (UPD) on 5 May 2026.

A beta version of the Product Management Service (PMS) public application programming interface (API) was launched on 12 June, enabling direct system-to-system access and supporting greater transparency and access to structured medicinal product data for wider audiences.

Legacy modernisation is progressing with go-live of Athena, a query-tracking tool, on 27 May. Athena records internal and external regulatory issues and queries raised at pre-submission meetings or in relation to Committees/Working Parties and organisational matters. The cloud-native modernised version provides improved security, scalability and monitoring.

The Anonymisation tool was launched on 11 June to help increase the accuracy and efficiency of the anonymisation and redaction of protected personal data contained in the public release of information through EMA's Access to Documents process.

More information about the delivery of Network Portfolio can be found in the quarterly Product Lifecycle Management Insights and Clinical Trials Highlights newsletters.

H1/2026 Digitalisation highlights

The Digitalisation programme continued to drive innovation, AI adoption, and business process transformation across EMA and the European medicines regulatory network during the first half of 2026. Through consolidation of an innovation portfolio, introduction of structured experimentation into the Network Portfolio and enablement of citizen development, the programme continues to accelerate the delivery of innovative tools and approaches with particular focus on customer-centricity, user experience (Ux) and increased ecosystem engagement.

Notable digital innovation highlights include:

- Experimentation Runway approach in the Network Portfolio firmly established, providing a structured framework to enable the exploration and delivery of digital innovation, with significant focus and progress on the AI enabled exploration and citizen development enablement. The Runway supported the identification and validation of process improvement opportunities through experimentation with emerging technologies, data analytics, automation, and AI, enabling evidence-based decisions on future implementation and scaling.

Multiple AI-focused proofs of concept and innovation initiatives were coordinated under the Knowledge Mining and AI Use Cases portfolio, examples include:

- Eureka pilot for Veterinary medicines: AI-enabled tool for signal detection of adverse reactions reports from the Summary of Product Characteristics (SmPC), streamlined with the approach in Human Domain
- Meeting Agenda Expert Screening and Restrictions Oversight (MAESTRO) pilot: AI-assisted support for the management of experts' declarations of interests and conflict-of-interest assessments.
- Quality Review Application internal pilot exploring how effective AI prompts can improve consistency and reduce manual effort in quality review activities of regulatory documents.
- InspectAI proof of concept, an AI-enabled tool that generates risk-based insights from GMP inspection report findings in support of inspection planning and regulatory oversight.

- Citizen Development, enablement initiatives, aiming to boost digital innovation in business teams, initial pilot on MS Power Platform, established. The pilot engaged a growing community of more than 20 business representatives and set the foundations for Citizen Development governance and enablement frameworks.

EMA, through the EU NTC/Digital academy, launched 20 new Network training courses on the topics of AI, data and digitalisation including the first AI literacy programme for the EMRN in March. The programme consists of micro eLearning modules that aim to meet the basics requirements for AI literacy to comply with the EU AI Act.

The User Experience (UX) hub developed a model approach for UX design at EMA and training on UX design basics.

EMA, NCAs and Industry engagement on critical transformative initiatives was boosted through RoG coordinated facilitation, progressing both the PMS Data Qualification process from feasibility assessment into process design and the optimisation of Type IA variations through a joint regulator–industry F2F workshop focused on future-state process simplification.

Annex 1 - Work programme indicators

This part of the report reflects the progress of implementing the adopted Annual work programme 2026.

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 the status against workload indicator forecasts and performance indicator targets. For workload indicators, the actuals reported are dependent mainly on external factors.

	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 2026'. For performance indicators that are expressed as a percentage or number of days per task, 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.

Work programme indicators

A) Statutory activities

1. Product related activities

1.1. Evaluation and supervision of human medicines

1.1.1. Pre-authorisation activities

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Total scientific-advice and protocol-assistance requests	485	384	402	348	470	785	885	100	13%
	Protocol-assistance and follow-up requests	85	69	80	59	75	140	164	24	17%

1.1.2. Initial evaluation

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Total initial evaluations	29	29	30	25	26	78	74	-4	-5%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	% of initial marketing authorisation applications that had received centralised scientific advice	65%	63.80%	68.90%	-	43.00%	60.00%
	Average assessment time for new active substances and biosimilars[1]	205	196.18	189.97	203.75	190.00	199.00
	Average clock-stop for new active substances and biosimilars[2]	150	210.36	132.97	239.00	185.00	229.00
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	50%	50.00%	33.33%	66.66%	50%	33%

1.1.3. Post-authorisation activities

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Total variations	4,194	3,914	3,838	4,010	4,001	8,954	8,949	-5	0%

[1] Reversal of traffic lights.
[2] Reversal of traffic lights

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Average assessment time for variations that include an extension of indication[3]	180	159.00	178.48	191.73	177.51	171.00

1.1.4. Referrals

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Total referral procedures	1	3	3	4	4	11	9	-2	-18%

1.1.5. Pharmacovigilance activities

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Signals peer-reviewed by EMA	850	716	792	822	1,126	1,100	1,100	0	0%

1.1.6. Cooperation with the HTA Coordination Group

Workload indicator for this area of work is covered in 1.1.1.

[3] Reversal of traffic lights.

1.2. Evaluation and supervision of veterinary medicines

1.2.1. Pre-authorisation activities

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Scientific advice requests received and validated	17	7	14	3	18	20	28	8	40%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Scientific advice procedures completed within set timeframes	100%	100.00%	100.00%	100.00%	100.00%	100.00%

1.2.2. Initial evaluation

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Initial marketing authorisation applications	7	12	11	15	9	23	26	3	13%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Initial procedures completed within legal timeframes	100%	100.00%	100.00%	100.00%	100.00%	100.00%

1.2.3. Post-authorisation activities

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Total variations	133	132	139	147	-	320	287	-33	-10%
	Transfers of marketing authorisations	0	0	1	1	0	1	1	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Post-authorisation applications evaluated within the legal timeframes	100%	100.00%	100.00%	100.00%	100%	100%

1.2.4. Arbitrations and referrals

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Total arbitrations and referrals	0	1	1	0	3	3	3	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Referral procedures managed within the legal timelines	100%	100.00%	n/a	100.00%	100.00%	-

1.2.5. Pharmacovigilance activities

Performance indicators

	Performance indicators related to core business[4]	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Annual statements submitted by MAHs	100%	98.00%	-	-	-	-
	G.I.19 submitted by MAHs further to regulator's signal management recommendation	100%	100.00%	-	-	-	-
	Unrecorded AEs out of the total number of AEs reported[5]	4%	3.25%	-	-	-	-

[4] New indicators introduced in 2026 work programme.
[5] Reversal of traffic lights.

1.3. Horizontal and other product related activities

1.3.1. Inspections and compliance

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	GMP (excluding PMF)	210	114	189	210	89	396	410	14	4%
	GCP	71	41	53	47	53	111	123	12	11%
	Pharmacovigilance	10	5	12	13	10	12	16	4	33%
	Notifications of suspected quality defects	207	248	108	127	131	450	414	-36	-8%
	Parallel distribution initial notifications	1,772	1,548	1,365	1,038	1,012	2,860	3,000	140	5%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Standard certificates issued within the established timelines (30 working days)	90%	100.00%	100.00%	100.00%	100%	100%
	Average days to issue standard certificate[6]	15	5.40	14.70	5.00	4.80	3.00
	Urgent certificates issued within established timelines (2 working days)	98%	99.80%	98.00%	99.00%	100%	100%

[6] Reversal of traffic lights.

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Parallel distribution initial notifications checked for compliance within the established timeline	98%	99.90%	99.00%	99.00%	99%	99%

1.3.2. Committees, working parties, and expert management

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of reimbursed meetings	152	139	151	151	24	334	334	0	0%

1.3.3. Medical devices

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of CECPs and PECPs[7]	57	-	-	-	-	85	85	0	0%

[7] New indicators added in the 2026 work programme.

1.3.4. Data governance and data management

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of data board activities supported[8]	10	-	-	-	-	20	20	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines[9]	90%	90.00%	-	-	-	-
	Percentage of monthly updates of the ADR report website performed according to the timelines	90%	100.00%	100.00%	100.00%	-	-
	Percentage of EV QAT Service Desk requests addressed according to set timelines[10]	90%	94.00%	-	-	-	-
	Percentage of Data Asset entry completion in the EMA Data Catalogue[11]	90%	90.00%	-	-	-	-
	Percentage of completion of mandatory metadata fields of entered Data Assets in the EMA Data Catalogue[12]	100%	80.00%	-	-	-	-

[8] New indicator added in the 2026 work programme. NDSG Meetings, Data Board Meetings, Data Strategy Area Leads Meetings, Data Community Meetings.
[9] New indicators added in the 2026 work programme.
[10] New indicators added in the 2026 work programme.
[11] New indicators added in the 2026 work programme.
[12] New indicators added in the 2026 work programme.

1.3.5. Strengthening methodology and decision making

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Number of methodological advice provided on product procedures	73	38	92	-	-	90	120	30	33%
	Number of methodological contributions to guidelines led by other committees and working parties	8	7	12	-	-	15	10	-5	-33%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Product procedure requests for methodological support completed as per timelines	90%	100.00%	100.00%	100.00%	-	-
	Planned MWP contribution to guidelines led by other committees and working parties	75%	100.00%	100.00%	100.00%	-	-

1.3.6. Clinical trials

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Number of business validation for CTIS releases	8	5	11	-	-	18	12	-6	-33%

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of EudraCT reports and number of CTIS data analyses and reporting[13]	62	95	36	-	-	110	110	0	0%
	Number of ACT EU multi-stakeholder workshops[14]	8	5	9	-	-	12	12	0	0%
	Number of CT highlights newsletters	6	14	16	-	-	11	11	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	90%	79.00%	97.80%	89.00%	-	-
	WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	90%	100%	100%	100.00%	-	-
	ACT EU multi-stakeholder workshops organised according to workplan	80%	100.0%	80.0%	90.00%	-	-
	Support to the secretariat for CTCG and physical hosting 4 times per year	100%	100.00%	100.00%	100.00%	-	-
	Provide secretariat for CTCG weekly assessors round table	100%	100.00%	100.00%	100.00%	-	-

[13] Including ad-hoc and regular reporting (weekly dashboards for bi-weekly newsflash, MB monthly reports, ACT EU KPI reports, CTCG).
[14] Led and co-organised events; including multi-stakeholder platform (MSP) advisory group

1.3.7. Real-world evidence

Workload indicators

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Number of non-interventional studies performed (on-going or completed)[15]	79	44	15	-	-	60	90	30 50%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Studies performed within less than 26 weeks[16]	60%	76.00%	80.00%	44.40%	-	-
	Non-Interventional Study (NIS) protocols and summary results registered in HMA/EMA Catalogue of RWD studies within a month after finalisation	90%	86.00%	100.00%	92.00%	-	-

[15] This is a special year for DARWIN EU, as it is the final year of the current contract. Consequently, all studies must be completed before the end of the contractual period (i.e. by February 2027). Most of the studies reported under this KPI are already ongoing in 2026, with only a limited number expected to be added during the second half of the year. For additional context, 27 studies initiated in 2025 were completed in 2026, while only 2 studies were both initiated and completed in 2026. Furthermore, 50 studies were ongoing during the first part of 2026.
[16] Excluding framework contract studies.

1.3.8. Small and medium sized enterprises

Workload indicators

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Regulatory assistance delivered[17]	116	-	-	-	-	255	255	0 0%

1.3.9. International cooperation

Workload indicators

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	120	126	151	127	-	250	250	0 0%

1.3.10. Communication activities

Workload indicators

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Number of documents published on EMA website	4,233	4,695	3,766	3,834	3,787	7,500	7,500	0 0%

[17] New indicators added in the 2026 work programme.

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Number of press releases and news items published	51	69	66	64	87	120	100	-20 -17%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Average rating of pages on corporate website during the year	3.9	3.2	3.0	-	3.8	3.1

1.3.11. Public and stakeholder engagement

Workload indicators

	Procedure						2026 annual forecast		
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change
	Number of messages circulated via 'Early Notification System'	271	290	271	277	329	500	500	0 0%
	Requests for information received	3,065	3,671	3,835	3,624	4,559	8,000	7,000	-1000 -13%
	Number of medicines overview and medicines overview updates published	110	110	116	81	97	180	180	0 0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	75%	68.00%	76.5%	76.00%	73.00%	68.00%
	Triage of incoming requests received via AskEMA within set timelines	100%	99.00%	99.80%	99.60%	99%	99%
	Responses to RFI within set timelines (for EMA)	95%	84.00%	84.75%	84.00%	82%	89%

1.3.12. Transparency

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Access to documents, requests received	356	401	254	416	375	750	750	0	0%
	Access to documents, documents released	598	641	605	652	497	2,000	1,200	-800	-40%
	Clinical Data Publication (CDP), Procedures published	99	38	40	27	-	120	120	0	0%
	Clinical Data Publication (CDP), Documents published	5,178	2,354	3,271	471	-	10,000	10,000	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Responses to ATD within set timelines[18]	90%	96.10%	97.14%	98.60%	91%	89%

2. Horizontal public and animal health activities

2.1. Innovation and development

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Innovation Task Force briefing meetings conducted	15	15	16	17	16	35	35	0	0%
	Portfolio and Technology meetings conducted	9	9	-	-	-	20	16	-4	-20%
	Number of European Union Innovation Network plenary and subgroup meetings	19	-	-	-	-	25	25	0	0%
	Number of Innovation Task Force briefing meeting requests received	50	-	-	-	-	90	90	0	0%

[18] 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.

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Percentage of Innovation Task Force briefing meeting requests triaged[19]	100%	100.00%	-	-	-	-
	Number of presentations to Committees, Working Parties, lunch talks to disseminate business intelligence compiled via the Innovation Task Force, the Business Analysis Forecasting function[20]	60	40	-	-	-	-

2.2. Regulatory science and academia

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Academia briefing meetings conducted	10	14	-	-	-	20	20	0	0%

2.3. Supply and availability of medicines and medical devices

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Number of MSSG meetings	6	3	6	-	-	12	12	0	0%

[19] New indicators added in the 2026 work programme.
[20] New indicators added in the 2026 work programme.

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of Vulnerability Analysis and MSSG recommendations	2	-	-	-	-	10	10	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Percentage of CAP shortages processed[21]	100%	100.00%	-	-	-	-
	Percentage of notifications of critical shortages (CAPs and NAPs, human + vet) managed[22]	100%	100.00%	-	-	-	-

2.4. Public health threats

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of ETF meetings[23]	22	-	-	-	-	30	30	0	0%

2.6. EMRN capacity and capability building

Workload indicators

[21] New indicators introduced in the 2026 work programme.
[22] New indicators introduced in the 2026 work programme.
[23] New indicators introduced in the 2026 work programme.

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	New or updated EU NTC training curricula related to scientific, regulatory and digital topics[24]	2	-	-	-	-	2	300%	1	50%

2.8. Competitiveness

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of biotech hubs/TTOs engaged through collaboration programme[25]	23	-	-	-	-	20	20	0	0%

3.4. Information management

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	EMA Community: Total Number of Users[26]	64,700	-	-	-	-	79,275	79,275	0	0%

[24] New indicators introduced in the 2026 work programme.
[25] New indicators introduced in the 2026 work programme.
[26] New indicators introduced in the 2026 work programme.

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Satisfaction of EMA internal and external users	80%	98.30%	97.30%	96.18%	95.00%	96.00%
	Average Time to Detect and Respond to Security Incident (hours)[27]	4	4.00	-	-	-	-

3.6. Administrative activities

3.6.1. Human resources

Workload indicators

	Procedure	2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	2026 annual forecast Initial	Revised	Change	
	Staff turnover rate (staff leaving against total no. of staff TA & CA)[28]	0.90%	1.60%	2.20%	3.10%	4.00%	5.00%	5.00%	0	0%

[27] New indicator introduced in the 2026 work programme. Reversal of traffic lights.
[28] Reversal of traffic lights.

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Posts on the Agency establishment plan filled	99%	100.70%[29]	98.00%	98.00%	97.00%	99.50%

3.6.2. Finance

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Revenue appropriations implemented	97%	44.00%	44.00%[30]	49.00%	42.00%	45.00%
	Expenditure appropriations implemented	95%	82.00%	79.00%	75.00%	71.00%	70.00%
	Payments against appropriations carried over from year N-1	95%	83.00%	84.00%	77.00%	61.00%	60.00%
	Payment transactions within the Financial Regulation's time limits	97%	96.58%	87.89%	n/a	97.53%	97.00%

[29] EMA makes use of article 38(2) FR to offset workforce loss through part-time work undertaken by TA staff. Mid 2026 the average part-time loss was -11 FTE, allowing for the appointment of 5 additional staff.
[30] Value corrected.

B) Strategic transformation initiatives

2. Digitalisation initiatives and Network Portfolio

2.1. Digitalisation

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of new digital tools delivered from Innovation portfolio[31]	3	-	-	-	-	5	5	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Number of Business process redesigned as a result of Innovation Portfolio[32]	3	4.00	-	-	-	-

[31] New indicators introduced in the 2026 work programme.
[32] New indicators introduced in the 2026 work programme.

2.2. Network Portfolio

Workload indicators

	Procedure						2026 annual forecast			
		2026 Q1-Q2	2025 Q1-Q2	2024 Q1-Q2	2023 Q1-Q2	2022 Q1–Q2	Initial	Revised	Change	
	Number of epics completed or ongoing	19	19	25	-	-	33	33	0	0%

Performance indicators

	Performance indicators related to core business	Target 2026	Outcome at the end of				
			Q2 2026	Q2 2025	Q2 2024	Q2 2023	Q2 2022
	Overall stakeholder satisfaction with change management support	SES: N/A	-	-	-	-	-
	Number of features demonstrated in Public system demos	115	n/a	-	-	-	-
	Number of products involved in the demos[33]	23	17	-	-	-	-

[33] Indicator in the process of being refined (estimates).

Annex 2: Strategic Transformation initiatives

EMANS 2028 implementation

Theme 1: Strategic goal 1.1 Optimise the path to accessibility by working with other decision makers (HTA bodies and payers)	
1.1.1 Contribute to the successful implementation of the HTA Regulation whilst preserving the remits of regulators and HTA bodies, respectively	**On Track (All Good)**
1.1.2 Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers)	**On Track (All Good)**
1.1.3 Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes	**On Track (All Good)**

Theme 1: Strategic goal 1.2 Deepen engagement with healthcare policy makers on initiatives and research relevant to sustain health technology accessibility	
1.2.1 Contribute to initiatives exploring the perspective different stakeholders have about unmet medical needs and how they inform considerations about clinical significance, significant benefit and major contributions to patient care	**On Track (All Good)**
1.2.2 Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes	**On Track (All Good)**
1.2.3 Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments	**On Track (All Good)**

Theme 2: Strategic goal 2.1 Maximise the generation, interoperability, use and exchange of data to support EU decision-making in the context of key EU legislative initiatives (notably the European Health Data Space and new pharmaceutical legislation)	
2.1.1 Embed the use of healthcare data from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)	**On Track (All Good)**
2.1.2 Ensure a high level of interoperability (including through the use of master data), standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed	**On Track (All Good)**

Theme 2: Strategic goal 2.2. Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes	
2.2.1 Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes	**On Track (All Good)**
2.2.2 Foster a culture of continuous experimentation and innovation across the network	**On Track (All Good)**

Theme 2: Strategic goal 2.3 Realise the Network vision on AI across all EMANS focus areas	
2.3.1 Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network	**On Track (All Good)**
2.3.2 Harness the potential of AI throughout the medicines' lifecycle	**On Track (All Good)**

Theme 3: Strategic goal 3.1 Promote the future proofing of the EU innovation ecosystem by monitoring and integrating advancing science and technology in medicines development and manufacturing	
3.1.1 Continue to support innovation and enable rapid integration and adaptation of scientific and technological advancements in the development of human and veterinary medicines in a timely manner	**On Track (All Good)**
3.1.2 In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines to inform the development of regulatory tools and approaches and identify areas where additional expertise is needed	**On Track (All Good)**
3.1.3 Facilitate the development and implementation of novel manufacturing technologies and analytical techniques, including with a view to facilitating the adoption of more sustainable practices with a reduced carbon footprint	**Caution (Needs Monitoring)**

Theme 3: Strategic goal 3.2 Foster generation of high quality and impactful evidence with particular focus on clinical trials	
3.2.1 Support the generation of high-quality evidence in quality, non-clinical (including non-animal methods) and clinical domains by researchers and sponsors from early development stages and provide timely and more accessible scientific and/or regulatory advice	**On Track (All Good)**
3.2.2. Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation (including the integration of real-world data) in conjunction with activities related to theme 2	**On Track (All Good)**
3.2.3 Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions (e.g. the Joint Research Centre) and align approaches internationally (e.g. with ICMRA)	**On Track (All Good)**

Theme 3: Strategic goal 3.3 Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness	
3.3.1 Develop network-led partnerships with key stakeholders (e.g. academia, and industry and funding bodies) to deliver impactful progress in regulatory science and research and provide training	**On Track (All Good)**
3.3.2 Enhance the regulatory competence of researchers and developers from academia, hospitals and small and medium-sized enterprises (SMEs) to facilitate the translation of research into innovative medicines through direct support and pre-competitive research collaborations	**On Track (All Good)**
3.3.3 Increase collaboration with medical device experts, notified bodies, ethics committees and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network in conjunction with the European Commission to support development and authorisation of combination products	**On Track (All Good)**

Theme 4: Strategic goal 4.1 Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach	
4.1.1 Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals and for improving access to information and data and communicating the findings	**On Track (All Good)**
4.1.2 Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices. For human medicines, take account of ongoing initiatives, while incorporating relevant new provisions in the new pharmaceutical legislation	**On Track (All Good)**
4.1.3 In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests	**Caution (Needs Monitoring)**
4.1.4 Develop, update, and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also supporting the development, implementation and uptake of guidance for human medicines	**On Track (All Good)**

Theme 4: Strategic goal 4.2 Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners	
4.2.1 Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders	**On Track (All Good)**
4.2.2 Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products	**On Track (All Good)**
4.2.3 Provide systematic support to developers of new antimicrobials for human use, including vaccines, antibacterials and alternatives to the use of antimicrobials, mainly through the ETF, and for veterinary medicines through the Innovation Task Force (ITF) and veterinary medicines Scientific Advice Working Party	**On Track (All Good)**
4.2.4 Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment	**On Track (All Good)**

Theme 4: Strategic goal 4.3 Strengthen regulatory preparedness for health threats	
4.3.1 Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies	**On Track (All Good)**
4.3.2 Respond to health threats that could be related to climate and environmental changes, using the One Health approach, as defined by OHHLEP, when applicable and in close collaboration with other Union agencies	**On Track (All Good)**
4.3.3 Expand the international alignment on regulatory requirements from Quadrilateral (US FDA Health Canada-PMDA-EMA) agreements to achieve more global consensus	**On Track (All Good)**
4.3.4 Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats	**Caution (Needs Monitoring)**
4.3.5 Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system	**On Track (All Good)**

Theme 5: Strategic goal 5.1 Strengthen the availability of medicines to protect public and animal health	
5.1.1 Identify specific root causes of shortages for human and veterinary medicines and develop harmonised strategies to improve the prevention and management of shortages, particularly for critical medicines	**On Track (All Good)**
5.1.2 Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners	**On Track (All Good)**
5.1.3 Work with the European Commission to coordinate national and EU strategies for human medicines, including stockpiling, to reduce the possible impact of national measures on availability of medicines in other countries	**On Track (All Good)**
5.1.4 Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies	**On Track (All Good)**

Theme 5: Strategic goal 5.2 Reinforce the oversight and protection of the supply chain and increase inspector capacity	
5.2.1 Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties.	**On Track (All Good)**
5.2.2 Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chain, including for key finished product and API manufacturers.	**On Track (All Good)**
5.2.3 Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain	**On Track (All Good)**
5.2.4 Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, AI and other technological systems)	**On Track (All Good)**
5.2.5 Improve and inter-link information in current databases (e.g. EudraGMDP)	**On Track (All Good)**

Theme 6: Strategic goal 6.1 Reinforce the scientific and regulatory capacity and capability of the network	
6.1.1 Ensure the network has the capacity and capability to support innovation and the use of new methodologies, AI and data analytics and to be equipped for the new pharmaceutical legislation	**On Track (All Good)**
6.1.2 Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically	**On Track (All Good)**
6.1.3 Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, knowledge management, ways of working and tools	**On Track (All Good)**

Theme 6: Strategic goal 6.2 Establish a shared operating model to support network activities and collaboration	
6.2.1 For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems	**On Track (All Good)**
6.2.2 For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors	**On Track (All Good)**
6.2.3 Explore opportunities for shared data, process and technology initiatives including AI and establish a model for joint EMA/HMA sponsorship for such initiatives	**On Track (All Good)**
6.2.4 Contribute to the implementation of the new EMA fee regulation and regularly monitor and adjust the cost-based system for fees and NCA remuneration	**On Track (All Good)**

Theme 6: Strategic goal 6.3 Strengthen public and stakeholder engagement and global convergence with international partners	
6.3.1 Enhance capacity of the network through international convergence, information and work sharing and multilateral cooperation	**On Track (All Good)**

6.3.2 Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and to face global challenges related to new methodologies and continuous manufacturing	**On Track (All Good)**
6.3.3 Strengthen cooperation between European and international partners and support regulatory systems in EU candidate countries and the African Medicines Agency	**On Track (All Good)**
6.3.4 Develop and implement a framework for communication and stakeholder engagement to address information needs of the public and counter mis/disinformation	**On Track (All Good)**

Annex 3: Terms and abbreviations

Term/abbreviation	Definition
3Rs	3Rs principles -Replace, Reduce and Refine- for the ethical use of animals in medicine testing across the European Union
3S	African Union Smart Safety Surveillance
ACT EU	Accelerating Clinical Trials in the EU
ADR	Adverse Drug Reaction
AE	Adverse Event
AI	Acceptable Intake
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonisation initiative
API	Active Pharmaceutical Ingredient
ATD	EMA Access to Documents
AU	African Union
AVAREF	African Vaccine Regulatory Forum
BI	Business Intelligence
CA	Contract agent
CAP	Centrally Authorised Product
CDP	EMA Clinical Data Publication
CECP	Clinical Evaluation Consultation Procedure
CHMP	EMA Committee for Medicinal Products for Human Use
CJEU	Court of Justice of the European Union
CMA	Conditional Marketing Authorisation
CT	Clinical Trial
CTCG	Clinical Trial Coordination Group
CTIS	Clinical Trials Information System
DAP	Data Analytics Platform
DARWIN	Data Analytics and Real World Interrogation Network
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
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
EPAR	European Public Assessment Report
ESMP	European Shortages Monitoring Platform
ETF	EMA Emergency Task Force
EU	European Union
EU4H	EU4Health programme
EV	EudraVigilance

Term/abbreviation	Definition
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMDP	Good manufacturing and distribution practice
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
IA	International Affairs
ICMRA	International Coalition of Medicines Regulatory Authorities
IRIS	Not an abbreviation. Refers to the regulatory & scientific information management platform between EMA and stakeholders
JCA	Joint Clinical Assessment
MAA	Marketing Authorisation Application
MAESTRO	Meeting Agenda Expert Screening and Restrictions Oversight
MAH	Marketing Authorisation Holder
MS	Member State of the European Union
MSSG	EMA Medicines Shortages Steering Group
MWP	EMA CHMP Methodology Working Party
NAP	Nationally Authorised Product
NCA	National Competent Authority
NIS	Non-Interventional Study
NPL	New pharmaceutical legislation
NTC	EU Network training centre
OHHLEP	One Health High-Level Expert Panel
PECP	Performance Evaluation Consultation Procedure
PHE	Public Health Emergency
PI	Product Information
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMF	Plasma Master File
PMS	Post-Marketing Surveillance
PRIME	EMA Priority Medicines scheme
Q	Quarter
QAT	Quality control, assurance and acceptance testing
QIG	Quality Innovation Group
RFI	EMA Request for Information
RWD	Real World Data
RWE	Real World Evidence
SES	staff engagement survey
SMART	Specific Measurable Achievable Relevant Time-based
SME	Subject Matter Expert
SmPC	Summary of product characteristics
SoHO	Substance of Human origin
SPD	Single Programming Document

Term/abbreviation	Definition
TA	Temporary agent
TTO	Technology Transfer Offices
UPD	Union Product Database
US	United States of America
UX	user experience
VSM	Voluntary solidarity mechanism
WHO	World Health Organization
XEVMPD	Extended EudraVigilance medicinal product dictionary
XML	Extensible Markup Language