EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's biennial report on stakeholder engagement activities

2024-2025

An agency of the European Union

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Foreword by Emer Cooke

Emer Cooke, Executive Director, European Medicines Agency

The years 2024 and 2025 marked an intense period of collaboration between EMA and its stakeholders, with focused discussions around medicines evaluation, and on shaping future regulatory frameworks to embrace the changes and opportunities brought by innovation.

"Ensuring a fast path from innovation to safe and effective medicines" remained the core vision that shaped the Agency's activities and initiatives. Maintaining a dialogue with our stakeholders is key to delivering on this vision. We have consulted and involved stakeholders to hear their views and gain insights into multiple and diverse matters.

This report provides highlights of the key areas where active involvement of organisations representing patients, healthcare professionals, academia and industry has been essential to the Agency's core activities and instrumental in shaping together the future of medicines regulation in the EU. A clear example of the importance that the Agency places on engaging with stakeholders at both strategic and operational level is the integration of their feedback into the European medicines agencies network strategy (EMANS) to 2028[1].

In 2025, the European Medicines Agency (EMA) celebrated its 30th anniversary: 30 years of a centralised procedure for medicines in the EU. This would not have been possible without continued engagement and transparent communication with our stakeholders. I would like to express my gratitude to each and every one of them and reaffirm our commitment to continuing our collaboration in the future.

[1] https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf

Executive summary

Stakeholders play a central role in the Agency's activities: the views of patients, healthcare professionals, academia and industry and the open dialogue with regulators are fundamental to the Agency's daily work.

During 2024 and 2025, stakeholders have continued to contribute to the Agency's core business of evaluating medicines and monitoring their safety. In addition, stakeholder discussions have contributed to shaping the future of the European pharmaceutical environment by participating in several initiatives. It is therefore key that the engagement and contributions of stakeholders to EMA's work are reflected in this report.

An example of stakeholders' contribution to the activities of the Agency is the incorporation of their feedback into the EMANS to 2028. Their views helped in shaping the overarching strategy guiding the work of the whole EU medicines regulatory network and was reflected into both EMA and HMA multiannual workplans.

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.

Multistakeholder approach

During the review 2 year period, the Agency engaged patients, consumers, healthcare professionals, academia, and industry representatives on key topics of relevance to the whole regulatory ecosystem, actively promoting dialogue among them. This multilateral exchange created a dynamic platform to explore diverse stakeholder perspectives, needs, and expectations, while fostering collaboration in identifying practical solutions to existing challenges.

A recurring theme across all stakeholder groups was the central role of patients throughout the lifecycle of medicines. There was strong consensus on the importance of integrating patient lived experiences and perspectives into the medicine lifecycle (from development and clinical trials to authorisation and post-marketing monitoring).

The launch of an open call for patient and healthcare professional experts in 2024 marked an important step in making remuneration for involvement in EMA activities possible.

The Agency has ensured broad participation in public and targeted consultations on key guidance documents, strategic frameworks and workplans. This has helped to identify sector-specific challenges and opportunities for improvement including the fostering of a more responsive and adaptive regulatory environment.

Stakeholders were invited to contribute to several initiatives, including the development of strategies under the EMANS framework, the ethical and effective use of artificial intelligence (AI) and digitalisation tools, the reflection paper on patient experience data (PED) and the improvement of the current clinical trial landscape via the ACT EU multistakeholder platform. Additionally, discussions on the availability and accessibility of medicines benefited from diverse stakeholder input, helping to shape practical methodologies and solutions.

This collaborative model reflects the Agency's commitment to dialogue and knowledge exchange between regulators and key stakeholder groups.

Engagement with patients and consumers

To systematically capture patient perspectives in medicines evaluation and enhance transparency, the CHMP public assessment report template was revised to include dedicated sections to reflect patient and healthcare professional input on EMA assessments, including the CHMP early dialogue and to capture patient experience data submitted in applications. EMA introduced a response form to facilitate and systematically capture patient input to scientific advice.

The Patients and Consumers' Working Party (PCWP) was increased from 22 to 25 member organisations, reflecting the increasing number of eligible organisations and the continued importance and interest in this platform.

Engagement with healthcare professionals

Progress has been made in reviewing the engagement framework, which confirmed the validity of its principles and working methods, while identifying opportunities for simplification and alignment with the revised framework for engagement with patient and consumer organisations[2]. The revised framework is expected to be published in 2026.

EMA has further consolidated the CHMP early dialogue with healthcare professional organisations and strengthened bilateral meetings with them over the past two years, establishing these as important engagement methods.

The Healthcare Professionals' Working Party (HCPWP) was also increased from 22 to 25 member organisations. In parallel, the healthcare professional organisations' Policy Officers Group continued to play a key role by complementing the HCPWP and serving as a bridge to the broader network of eligible organisations.

Engagement with academia

A significant portion of the scientific research leading to new medicines, including therapies addressing unmet medical needs and non-commercially viable medical conditions, originates from academia. Therefore, EMA has strengthened support for academic research and reinforced collaboration with academic stakeholders over the past two years.

During 2024-2025, the Academia Briefing meetings (ABMs) continued to support the dialogue between EMA and academic developers on development and research related challenges.

In addition to ABMs, Innovation Task Force (ITF) meetings focused on innovation topics, and engaged academic medicine or method developers to address regulatory, technical and scientific concerns. Additionally, as of 2025, developers from the not-for-profit sector began benefitting from a full fee reduction when applying for scientific advice, qualification of novel methodologies and protocol assistance (scientific advice for orphan-designated medicinal products).

[2] https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-and-patients-consumers-and-their-organisations_en.pdf

This type of support offered to academia is aimed at facilitating the transition from research to development that may ultimately support marketing authorisation.

During the reporting period, EMA actively engaged in research initiatives and participated in externally funded projects to address research gaps. In 2024-2025, through the Collaboration management meetings (CMM), EMA agreed to join several externally funded projects, consortia or partnerships. In addition, EMA published a substantial update of the Regulatory Science Research Needs document, which outlines existing gaps in regulatory science that require research-driven solutions.

In 2025, EMA and the Heads of Medicines Agencies (HMA) launched the European Platform for Regulatory Science Research to foster dialogue and collaboration between academic researchers and regulators, to advance regulatory science and translate research into practical solutions for regulators and developers. Since its launch, around 250 academic researchers participated in the platform to discuss a variety of research and cross-cutting topics.

Finally, as part of EMA's work to support training with academia, in 2025, EMA published the learning needs of academia and micro, small and medium-sized enterprises (SMEs) involved in clinical research. These findings will inform the development of a clinical trial learning ecosystem for these stakeholders.

Engagement with industry

Throughout the reporting period, EMA maintained regular dialogue with organisations representing the human and veterinary pharmaceutical and medical device industry, as well as medicines distributors. This engagement took place through strategic meetings of the Industry Standing Group (ISG) and bilateral exchanges with individual stakeholder organisations. In addition, operational meetings were held, such as interested parties' meetings and stakeholder platform meetings on research and development support, the centralised procedure for human medicines and the operation of the EU pharmacovigilance.

EMA has maintained close interaction with industry (including SMEs) to support implementation of new legislative requirements (such as EMA's extended mandate, the Health Technology Assessment Regulation, the Clinical Trials Regulation, the EC new strategy for EU life sciences) and in understanding the interlinks and impact of cross-sectorial legislation and regulatory requirements (such as the Medical Device Regulation, the In vitro diagnostic regulation, and the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals).

EMA monitored the effectiveness of the "Framework for interaction between the European Medicines Agency and industry stakeholders"[3] via a number of activities (i.e. "Industry stakeholders and EU network expert surveys on early engagement fostering innovation"[4] and the "Industry stakeholders feedback on engagement and communication activities"). Feedback received confirmed the importance of EMA's activities in supporting innovation and ensuring effective communication and active stakeholder engagement.

[3] https://www.ema.europa.eu/en/documents/other/framework-interaction-between-european-medicines-agency-and-industry-stakeholders_en.pdf

[4] https://www.ema.europa.eu/en/documents/report/report-industry-stakeholders-eu-network-experts-surveys-early-engagement-fostering-innovation_en.pdf

Conclusions

This report provides an overview of EMA's interaction with its main stakeholder groups during 2024 and 2025, highlighting key outputs achieved through both multistakeholder engagement and bilateral interactions.

Through structured dialogue, targeted consultations, and collaborative platforms, the Agency ensured that the perspectives of patients, healthcare professionals, academia, and industry were included into its strategic and operational activities.

Specific and tangible outputs have been delivered such as the integration of stakeholder views into EMANS to 2028, through active discussions at the PCWP, HCPWP, ISG and through the establishment of the European Platform for Regulatory Science Research.

The multistakeholder approach remained key for identifying shared challenges and exploring practical solutions, particularly in areas such as medicines availability, clinical trials, and digital transformation. In parallel, targeted engagement with organisations representing the unique perspectives of European patients, consumers, healthcare professionals, academics and industry provided valuable opportunities for deeper, sector-specific reflections on priorities and emerging trends.

Looking ahead, the Agency remains fully committed to strengthening the engagement with its stakeholders to ensure the availability of high quality, safe and effective medicines across the EU. Stakeholder voices will continue to play a central role in shaping medicines regulation, guiding implementation of new regulatory requirements, and driving sustainable innovation.

The next 2 years will provide opportunities to strengthen multistakeholder engagement, notably as we must work together to implement the new pharmaceutical legislation. Collaboration with patients, consumers and healthcare professionals will remain key to identifying expert needs and the promotion of expert remuneration. Similarly, the Agency will continue supporting academia in translating research outputs into medicines. Finally, given the rapid pace of scientific and technological innovation, evolving geopolitical dynamics and the upcoming changes to the EU pharmaceutical legislation, EMA will explore enhanced dialogue with senior leadership from the pharmaceutical industry.

Multistakeholder engagement

> Engaging at a multistakeholder level ensures that diverse perspectives are shared and considered into the Agency's work. A practical example of this is the delivery of European Medicines Agencies Network Strategy (EMANS) to 2028, where stakeholders feedback helped shape the network's priorities.
>
> **Melanie Carr**,
> Head of Stakeholders and Communications

During 2024 and 2025, many of the Agency's key initiatives advanced through simultaneous involvement of all stakeholder groups, with open dialogue and shared proposals to progress various areas of regulatory work. The following section outlines these initiatives, including the main events held to celebrate EMA's 30th anniversary with EU citizens, highlighting the strong collaboration of the EU network with all stakeholders in medicines regulation.

Celebrating the EMA's 30th anniversary

EMA Open Door Day

On Europe Day, 9 May 2025, EMA hosted its first public open-door day to celebrate its 30th anniversary. This symbolic date was chosen as it marks the anniversary of the Schuman Declaration, which laid the foundation of today's European Union.

The aim of the open-door day was to bring EU citizens closer to EMA's mission: ensuring medicines work and are safe for both EU citizens and animals. Visitors were guided through

the building and attended expert-led sessions on how medicines are evaluated, authorised and monitored for safety, covering both human and veterinary medicines.

One hundred and twenty visitors representing the general public, patients, healthcare professionals, academia, university students and industry stakeholders had the opportunity to step inside EMA's decision-making spaces. They visited the rooms where EMA's scientific committee meetings are held, and where key decisions are made on EU medicines for millions of citizens and animals across the EU.

Visitors also explored EMA's historical archives, which showcased the evolution of EMA from the pre-digital era, where scientific submissions were paper based to today's modern processes.

Overall feedback was very positive, with most visitors leaving with a better understanding of EMA's role and expressing interest in engaging with the Agency in the future.

Scientific conference on EMA's 30th anniversary

In June 2025, EMA marked its 30th anniversary with a scientific conference that brought together patient and healthcare professional organisations, industry organisations, Dutch government and EU and international regulatory agencies. The conference, opened by His Majesty King Willem-Alexander of the Netherlands, reflected on three decades of groundbreaking achievements and progress in medicine and regulatory science. This was illustrated by a keynote presentation by Dr Holst on the discovery of the gut hormone GLP-1.

Key achievement

30th year anniversary celebrated with the first EMA Open Door Day and scientific conference.

European Medicines Agencies Network Strategy (EMANS) to 2028

A pivotal moment in the preparation of the EMANS 2028 was the public consultation and subsequent workshop to gather stakeholder views on the proposals. Valuable feedback from patients, healthcare professionals, academics, and industry representatives significantly refined the network priorities and ensured that all sectors and perspectives were included. Stakeholder engagement was recognised as an essential function in shaping and delivering the six priorities set out in the EMANS 2028.

Key achievement

Stakeholder input shaped the EMANS 2028 through a public consultation and multistakeholder workshop.

Accessibility

Regulatory/Health Technology Assessment Interface

Health Technology Assessments (HTAs) play a critical role in making new medicines accessible to patients. They ensure that new therapies are evaluated not only for clinical effectiveness but also their added value compared to existing therapies.

The HTA Regulation (HTAR)[5] established a new EU framework for the assessment of medicines and medical devices by strengthening collaboration between regulators and HTA bodies. EMA worked closely with the European Commission's HTA secretariat and with the Member State Coordination Group on HTA (HTACG) to establish the processes required by HTAR. Engagement with stakeholders such as patients, healthcare professionals, methodologists and industry, was crucial in these discussions. Since June 2024, applicants can state in the letter of intent if their application is expected to fall under a Joint Clinical Assessment (JCA). In support to this, the Agency was tasked to provide to the HTA secretariat information related to marketing authorisation applications and extension of indications. In addition, developers now have the option to request a Joint Scientific Consultation (JSC) at the same time as seeking scientific advice from the agency on their evidence generation plans.

During 2024 EMA contributed to the implementation activities of the new HTA regulation by giving regular progress updates and training for stakeholders on the newly established JCA and JSC processes. Specifically the Agency contributed actively to multiple events such as the HTA Stakeholder Network, the regional information sessions organised by the European Commission (EC) throughout the year, and scientific conferences (such as ISPOR).

EMA also provided regular progress updates on the implementation of HTAR to industry stakeholders at the SME Info Day in October 2024 and at the ISG meetings in 2024 and 2025.

Since the entry into force of the new legislation in January 2025, the focus gradually shifted to operational updates and related training. Nevertheless, engagement with stakeholders in existing forums and the maintenance of a dedicated webpage continued to ensure best support to developers and experts (clinicians, patients).

In September 2025, EMA and the HTA Secretariat hosted a workshop to discuss the establishment and maintaining of operations of the new processes. In terms of evidence requirements to support decision making, EMA worked with HTA bodies through a series of workshops in 2024/2025. This culminated in a Joint HTA workshop on regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions, as reference for future technical work.

Key achievement

Successful integration of multistakeholder perspectives on evidence generation to support implementation of HTA regulation.

[5] Regulation (EU) 2021/2282 on Health Technology Assessment (HTA)

Availability and supply

During the reported period, the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) continued its activities to ensure a robust response to medicines' supply issues, in line with its new legal mandate (Regulation 2022/123)[6].

Continued engagement with stakeholders was central to these activities, with direct interaction from patient, consumer and healthcare professional organisations through inclusion of observers from the Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) in the composition of the MSSG.

Additionally, key stakeholder groups (including patients, healthcare professionals and industry) were consulted and kept informed on several activities:

- In 2024 and 2025, the EU medicines regulatory network carried out a targeted revision of the Union list of critical medicines, in consultation with stakeholders' representatives. This revision aimed at identifying additional critical medicines whose supply disruption would put patients in danger. In addition, the Working group of the MSSG on the vulnerability analysis methodology was established to develop a common methodology to identify critical medicines and to evaluate vulnerabilities in their supply chains. This work included feedback from industry stakeholders and the MSSG endorsed the methodology in October 2025.
- In 2024, EMA also contributed to discussions of the Working Groups of Critical Medicines Alliance by providing information on existing activities and advising on feasibility of proposed activities.
- In April 2024, the MSSG published Recommendations to strengthen supply chains of critical medicinal products, which outlines possible measures for MSSG to consider such as the recommendation to marketing authorisation holders to diversify suppliers and ensure regulatory flexibilities are deployed when needed..
- Targeted consultation with relevant experts and stakeholders also contributed to shape further recommendations by the MSSG for specific medicines:
  - Recommendations to address vulnerabilities in the supply chain of radiopharmaceuticals (April 2025).
  - Recommendations to address anti-D immunoglobulin supply chain vulnerabilities (June 2025).
- In 2024 and 2025, Member States continued to use the Voluntary Solidarity Mechanism[7] as a last resort to identify supply of medicines subject to critical shortages, when Member States had exhausted other possibilities. Information on the solidarity mechanism is published as part of the minutes of the MSSG meetings to inform relevant stakeholders.
- In July 2024, following the publication of Recommendations on the shortage of Glucagon-Like Peptide-1 (GLP-1) receptor agonists, EMA held a multistakeholder workshop on GLP1-RA shortages, which brought together patient, consumer and healthcare

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2022:020:TOC

[7] https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf

professional organisations, marketing authorisation holders and EU/ EEA and international regulatory bodies. Stakeholders discussed their experiences and suggested actions to mitigate shortages of these medicines, including through communication. In 2025, EMA contributed to an international Drug Utilisation Study on GLP-1 RAs, which includes involvement of EU and international regulators, academic institutions and patient and healthcare professional representatives.

- In early 2025, EMA successfully launched the European Shortages Monitoring Platform (ESMP). This platform enables information exchange between the Agency, NCAs and Industry stakeholders for better prevention, identification and management of shortages, as well as communication to ensure availability of medicines for patients during public health emergencies and major events. The development of the ESMP was supported by the continued dialogue and cooperation with stakeholders, specifically industry. Stakeholder participation was supported by a series of training events and guidance.
- In October 2024, EMA launched a pilot implementing the Medicine Shortages Communication (MSC), a new procedure to communicate on shortages to healthcare professionals. The MSC replaces Direct healthcare professional communications (DHPCs) for shortages not related to a quality, safety or efficacy issue. Feedback will be collected from SPOC WP and industry stakeholders to adapt the template. In December 2024, EMA launched a 6-month pilot for implementing the Shortage Prevention Plans (SPPs) and Shortage Mitigation Plans (SMPs). The feedback collected from industry stakeholders will be used to further refine templates and ensure an optimal use of the SPPs and SMPs as tools for early identification of vulnerabilities in the supply chain to prevent shortages.
- In 2025, EMA hosted a webinar for both patients and healthcare professionals to provide practical insights into EU medicine shortages activities. In parallel, in partnership with European healthcare professional and consumer organisations, EMA launched a social media campaign (#ItTakesATeam) to raise awareness about medicine shortages, highlighting the importance of shared responsibility and collaboration.

Key achievements

- Stakeholder input into the update of the Union list of critical medicines
- Launch of the ESMP, developed with stakeholder input
- Endorsement of the first vulnerability assessment methodology to identify vulnerabilities in the supply chains of critical medicines
- Strengthened public engagement through dedicated webinar on EU shortage activities for patients and healthcare professionals
- Launch of co-created #ItTakesATeam campaign with European healthcare professional and consumer organisations

Leveraging data, digitalisation and artificial intelligence

The EMANS 2028 recognises "data" as a strategic asset for regulatory authorities, reflecting its transformative potential in shaping the future of medicines regulation. In an increasingly complex and data-rich environment, the ability to collect, analyse, and interpret high-quality data is essential for informed, timely, and transparent decision-making. During 2024-2025 the Agency launched a series of initiatives, often involving stakeholders, aimed at identifying ways to maximise the use of data and evidence generation in support of decision making, and at exploring how to safely and ethically use emerging technologies, such as artificial intelligence.

Network Data Steering Group

The Network Data Steering Group (NDSG) was established in 2024 by the HMA and EMA. Its aim is to optimise how data are used and managed in regulatory processes and decision-making, helping safe, effective and high-quality medicines reach patients and animals faster. The group brings together multidisciplinary expertise and perspectives from regulatory partners and stakeholders across Europe. Its work is guided by a multiannual workplan 2025-2028 which is reviewed and updated annually.

One of the key priorities of the NDSG is leveraging real-world data (RWD) and integrating real-world evidence (RWE) to support regulatory decision making, thereby complementing data from clinical trials.

Recognising that collaboration with stakeholders is essential to the successful delivery of the workplan, the NDSG actively engaged stakeholders through 2024 and 2025. Contributions to inform and deliver the workplan were gathered during the annual big data stakeholder forum. Dedicated multistakeholder events by the NDSG were also held on the following topics:

- Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries

  The event brought together representatives of registry holders, regulatory agencies, pharmaceutical companies, patients, healthcare professionals, academia, and health technology assessment bodies to discuss the EMA qualification procedures for patient registries with the aim to clarify the benefits, identify current limitations and propose measures to optimise the process.

- Joint EC/HMA/EMA multistakeholder workshop on pharmacogenomics

  The workshop aimed at discussing aspects such as promotion of clinical implementation of pharmacogenomics, uptake of genomics by national healthcare systems and leverage of genomic data linked to real-world data sources to inform the creation of a roadmap towards the clinical implementation of pharmacogenomics in Europe.

- Joint HMA/EMA Big Data Steering Group workshop on real-world evidence (RWE) methods

  The event aimed at gathering views from regulatory agencies, pharmaceutical companies, patients, healthcare professionals, academia, and health technology assessment bodies on the draft RWE reflection paper and on the priorities for further regulatory guidance development.

- Multistakeholder workshop on Data Quality Framework for Adverse Drug Reaction reporting

  The workshop aimed at consulting stakeholders involved in adverse drug reaction (ADRs) reporting on guidance and standards' needs for human and veterinary ADRs arising from all sources (e.g. spontaneous reports, medical literature, non-interventional studies and interventional clinical trials).

- First EMA/HMA multistakeholder forum on EudraVigilance and signal detection

  The event was aimed to inform stakeholders on ongoing and forthcoming developments in international guidance, ADR case processing, signal management and data analysis in EudraVigilance, and to foster stakeholder engagement and collaboration to further strengthen these areas. The forum included several stakeholder groups including EU regulators and companies.

- Mechanistic models for regulatory assessment and AI

  The workplan also strengthened the collaboration with patient organisation representatives. Their involvement supported efforts to leverage patient experience data, real-world data and clinical study data to enhance regulatory decisions on medicines. Stakeholders were also invited to participate in public consultations on the European medicines agencies network data strategy as well as on topics related to real-world data (see the Real-World Evidence section for more information).

Real World Data and Real-World Evidence

Several public consultations on RWD/RWE guidance were launched and multistakeholder workshops were held throughout 2024 and 2025 to gather insights and exchange views:

- The reflection paper on use of RWD in non-interventional studies to generate RWE for regulatory purposes[8] was published in March 2025.
- A public consultation on the RWD chapter of the Data Quality Framework was conducted in February 2025.
- The ICH M14 scientific guideline on general principles on plan, design and analysis of pharmacoepidemiological studies that utilise real-world data for safety assessment of medicines[9] was published in September 2025.

Furthermore, the multistakeholder DARWIN EU Advisory board continued to regularly provide oversight and advice on the delivery of RWD studies through DARWIN EU.

Patient and healthcare professional organisations were actively involved in the development and review of protocols and reports of studies conducted through DARWIN EU. Recent examples include studies on immunoglobulin use, cystic fibrosis and GLP-1 receptor agonists.

[8] https://www.ema.europa.eu/en/reflection-paper-use-real-world-data-non-interventional-studies-generate-real-world-evidence-scientific-guideline

[9] https://www.ema.europa.eu/en/ich-m14-guideline-general-principles-plan-design-analysis-pharmacoepidemiological-studies-utilize-real-world-data-safety-assessment-medicines-scientific-guideline

These studies are publicly available in the HMA-EMA catalogues of real-world data sources and studies.

Veterinary Big Data Stakeholder Forum

The Veterinary Big Data Stakeholder Forum facilitates strategic collaboration among regulators, academia, industry, and technology partners to advance the EU Veterinary Big Data Strategy. Key activities in 2024-2025 with multistakeholder participation included:

- exploration of artificial intelligence applications in veterinary medicine
- application of innovative data technologies to improve animal health and welfare
- the integration of digital tools into regulatory processes

Multistakeholder engagement is instrumental in aligning priorities, identifying data governance challenges, and promoting interoperability across systems. These efforts contributed to a more cohesive and forward-looking veterinary data ecosystem, supporting innovation, transparency, and improved decision-making in public and animal health.

Artificial Intelligence for regulatory use

The regulatory use of artificial intelligence (AI) was a key topic in discussions with all EMA stakeholders. AI has the potential to enable smarter regulation by improving systems' efficiency, enhancing data insights and strengthening decision-making.

In September 2024, following a public consultation, EMA published its reflection paper on the use of AI in the medicine's lifecycle. To shape future priorities, stakeholders were invited in September 2025 to participate in a survey aimed at identifying research needs for AI in the development and evaluation of medicines. Furthermore, two multistakeholder workshops took place in 2024 and 2025, allowing stakeholders' to exchange views on the latest developments in AI, on shaping the AI workplan and exploring use cases across the medicines' lifecycle.

Patient experience data

During 2024-25, the Agency worked on developing a refection paper which was a key deliverable from the 2022 Workshop on Patient Experience Data (PED). This document aims to encourage stakeholders to include PED in medicines development programs and regulatory submissions. It also highlights scientific advice and other EMA support mechanisms as opportunities for early dialogue with regulators on how to generate and use PED. The draft reflection paper was prepared by a multidisciplinary expert group that included representatives from patients, consumers and healthcare professionals, and was published for public consultation. In particular, stakeholders played a key role in shaping the section on patient engagement and in illustrating the challenges of systematically implementing these types of data.

Other ongoing work on PED were feedback from stakeholders is pivotal, includes a survey to stakeholders (patients/consumers, healthcare professionals, industry, NCAs/HTAs) to define gaps and priorities for the use of PED in different therapeutic areas.

Key user group for EMA corporate website

In May 2025, EMA re-established the key user group for the EMA Corporate Website (KUG), following a period of inactivity during the COVID-19 pandemic. The KUG serves as a forum for regular interaction between EMA and the main users of EMA's corporate website. All members of the KUG are representatives of EMA's network of patient, consumer, healthcare-professional and industry organisations.

In 2025, EMA held two KUG meetings, in May and in September; discussions centred around the process to identify updates to webpages and documents, and enhancing the website's search tool.

The insights gathered through this interaction supported the ongoing improvement of the website, enabling further alignment with its key users' needs.

Key achievements

- Reflection paper on patient experience data released for public consultation.
- Final reflection paper on the Use of Artificial Intelligence (AI) in the medicinal product lifecycle published after public consultation.

Regulatory science, innovation and competitiveness

The Agency continues its activities in bridging the translational research gap and in providing regulatory support and scientific advice to academia and developers, including small and medium enterprises.

European Platform for Regulatory Science Research

EMA and HMA launched in 2025 the European Platform for Regulatory Science Research. The platform brings together academia and regulators, to advance and accelerate research in regulatory science on questions of common interest, support uptake of solutions into the work of regulators and medicines developers and strengthen research impact on medicines development and evaluation. In September 2025, a call was launched to appoint an industry observer, ensuring representation of this stakeholder group in future meetings. Since the launch of the platform, 250 researchers from academia and non-for-profit research organisations are participating. To date there was high engagement with participants sharing direct insights, experiences from ongoing work and proposals to advance the regulatory science research agenda. In addition, European funding opportunities and reflections of regulatory involvement in research projects were also highlighted.

Key achievement

Launch of the EMA/HMA European Platform for Regulatory Science Research.

Innovating the clinical trial landscape through ACT EU

The flagship initiative on clinical trials, Accelerating Clinical Trials in the EU (ACT EU), jointly led by HMA, the European Commission and EMA, established a Multistakeholder Platform Advisory Group (MSP AG) in March 2024. This group provides both strategic and operational guidance and includes representatives from key stakeholder groups involved in clinical trial activities in the EU.

Insights from the advisory group, particularly on implementing the Clinical Trials Regulation, contributed to the revision of the ACT EU workplan for 2025-2026. Additionally, annual meetings of the MSP organised in 2024 and 2025 provided an opportunity to review achievements, to identify priority areas for further development and to initiate a dialogue on innovative approaches. These discussions covered patient-oriented research, use of AI and digitalisation in clinical research, methodological and biotechnology advances, as well as ethics and regulatory preparedness.

To foster collaboration and gather input, ACT EU also hosted several multistakeholder workshops on key topics. Following requests raised during the January 2024 workshop on clinical trial analytics, ACT EU launched a clinical trial map to help patients and healthcare professionals locate trials of interest in Europe.

In September 2024, new features were introduced on the CTIS public portal, following an extensive consultation with stakeholders, including patients and healthcare professionals. These enhancements improve the accessibility and usability of publicly available information on clinical trials in the EU and EEA.

In early 2025, ACT EU carried out a survey among academia and SMEs to assess their clinical trial training needs. The findings will inform the mapping and signposting of existing training opportunities and support the development of new training materials.

The EMA set up in 2025, under the auspices of the MSP AG, several stakeholder focus groups to work with partners across the European Medicines Regulatory Network and develop joint solutions:

Table 1. Overview of ACT EU multi-stakeholder focus groups

Focus group	Group scope and key deliverable
Redesign of CTIS and CTR training material	• Established with representatives of CTIS users, academia, SMEs, industry, and Member States. The group defined the strategy for revising the existing material and, subsequently, reviewed progress and validated content updates. In July 2025, the redesigned CTIS sponsor

Focus group	Group scope and key deliverable
	handbook[10] was published, consolidating previously scattered documents into a single comprehensive source of reference.
Risk based approaches in clinical trials	• Established with representatives from patients, healthcare professionals, industry and academia. It aims to support the revision of the 2017 Recommendation Paper on risk-proportionate approaches in clinical trials and the planning of a dedicated workshop, foreseen in early 2026.
Clinical trials training for academia and SMEs	• Established with representatives from academia, SME and healthcare professionals. The group aims to support the development of a sustainable clinical trials training ecosystem for academia and SMEs, foreseen in 2026.

Innovating manufacturing

EMA continued its efforts to support the development and implementation of advanced manufacturing technologies through its Quality Innovation Group (QIG). These innovations will foster agility and flexibility in the manufacturing sector, strengthen the robustness of supply chains and medicines availability, ultimately benefiting patients in the EU. As part of this commitment, QIG has held several Listen and Learn Focus Group (LLFG) meetings with stakeholders (industry and academia) offering a forum to discuss scientific and regulatory challenges related to specific technologies, propose solutions, and identify concrete follow up actions.

In 2024 and 2025, LLFG meetings focused on pharmaceutical process models, platform technologies and personalised medicines (including ATMPs, next generation sequencing, antisense oligonucleotides, and 3D printing, among others).

Supporting Micro, Small and Medium Sized Enterprises

To mark the 20th anniversary of the SME Regulation, EMA and members of the EU medicines regulatory network hosted in October 2025 a roundtable meeting with stakeholders from across the pharmaceutical and MedTech sectors (including public and private investors, life science incubators, patient organisations, and industry representatives).

Participants exchanged views on current challenges and future opportunities to foster innovation and strengthen support for SMEs.

[10] https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf

Evidence generation and treatment optimisation in oncology

The cancer pathfinder was introduced in 2023 to address the increasing burden of cancer in the EU. This project aims to expedite and optimise the development and approval of cancer medicines.

The Cancer Medicines Forum (CMF), co-chaired by EMA and the European Organisation for Research and Treatment of Cancer (EORTC), promotes collaboration among academic organisations to facilitate research into optimising cancer treatment and uphold high standards of care within the EU. The CMF supported discussions on pragmatic and risk-proportionate trial designs and incentives for optimising research. Examples include optimisation trials, such as studies on treatment duration in prostate and bladder cancer and therapy de-escalation strategies (DE-ESCALATE and STARBUST). Ongoing discussions include how to address regulatory challenges for academic sponsors.

Key achievements

- 2024: workshop where CMF launched treatment optimisation discussions with key stakeholders.
- 2025: CMF workshop where consensus was reached on early, continuous, collaborative, and well-funded optimisation supported by pragmatic trials.
- Agreement of CMF mandate by HCPWP/PCWP in 2025.
- Publication of monthly European Regulatory Oncology Newsletter (ERON) since October 2024.

- **Patient-reported outcomes**

To support treatment optimisation, a joint EMA–EORTC workshop on patient-reported outcomes (PROs) and health-related quality of life (HRQoL) was held in February 2024.

The event helped to establish a shared understanding of how patient perspectives can better inform regulatory and HTAs decision-making. Participants highlighted the need for consistent use of validated PRO instruments and harmonised core outcome sets across oncology trials. The workshop underscored the value of longitudinal PRO collection beyond treatment discontinuation to capture full patient experience. Stakeholders recognised that PRO data must be used to enable fair comparisons between studies to support HTA and payer assessments. Methodological initiatives such as Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data (SISAQoL) were showcased as pathways to greater analytical consistency. Case studies illustrated how PROs can reveal trade-offs not captured by traditional endpoints. HTA representatives stressed the importance of long-term, comparable data for meaningful benefit evaluation. The workshop called for strengthened collaboration among patients, regulators, industry, and academia.

Future priorities include standardisation, digital innovation, and integration of PROs in evidence generation and regulatory submissions.[11] [12] [13]

- **Cancer treatments for older adults – How to optimise and tailor anti-cancer agents?**

The meeting held in April 2025 discussed common challenges in designing cancer clinical trials for older patients focusing on endpoints, methodology, and patient input. Participants agreed on shared objectives to optimise oncology treatments for older adults. The outcome of this workshop will inform the ongoing revision of EMA's anti-cancer guideline and future discussions within the CMF. Effective communication is essential with public health organisations and industries to advance treatment optimisation for oncology treatments for older adults. In addition, patients experience and preference is also important to take into consideration when designing clinical trials.

- **Personalised medicines in oncology**

During the reported period, EMA continued to offer opportunities to developers of personalised medicines in oncology for early dialogue and consultation before submitting a marketing authorisation application. This includes the scientific assessment of the applications by EMA's Committee for Medicinal products for Human Use (CHMP) which leads to a recommendation on whether a medicine should be marketed or not.

The EMA published guidance in 2024 on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics - Revision 1 and in 2025 the Questions & answers - Practical arrangements on the companion diagnostics consultation procedure to the European Medicines Agency by notified bodies.

The CHMP also provides a scientific opinion on the suitability of a companion diagnostic for a specific medicine, in line with the *In Vitro* Diagnostics Regulation.

[11] https://www.iqwig.de/en/presse/press-releases/press-releases-detailpage_145152.html

[12] https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(25)00150-0/abstract

[13] https://www.sciencedirect.com/science/article/pii/S1470204525001512

Key achievement

The EMA–EORTC workshop on soft tissue and bone sarcomas strengthened collaboration between regulators, healthcare professionals, researchers, and patients to advance innovation in ultra-rare cancers. Discussions focused on flexible trial designs, enhanced use of real-world data and harmonised clinical endpoints. A shared roadmap[14] was developed to improve research infrastructure and foster data sharing across Europe. The workshop highlighted the importance of methodological rigour and patient engagement in evidence generation. Ongoing dialogue between EMA and the sarcoma research and patient community will support regulatory alignment and sustainable innovation. These initiatives represent a key step toward improving effective treatments for patients with ultra-rare sarcomas and have been taken into consideration to draft the report of the repurposing pilot initiative[15].

Expanding innovation to other therapeutic areas

The Agency held dedicated discussions with stakeholders on specific areas of unmet medical needs and rare diseases where more guidance on evidence generation and clinical requirements has enabled innovation to help identify even more therapies.

A series of workshops were held to foster dialogue on challenges linked to the development, regulation and clinical practice of specific therapeutic areas:

Table 2. Overview of workshops organised

Workshop	Summary
EMA workshop on challenges in drug development, regulation, and clinical practice in haemoglobinopathies	• During the event, regulators, clinicians, researchers, patients, bioethicist, and industry representatives shared perspectives on drug development, regulation, and clinical practice in haemoglobinopathies, focusing on sickle cell disease and thalassaemia including gene editing medicines. Participants highlighted the importance of natural history studies and registries to strengthen evidence generation. Innovative trial methodologies, including adaptive and platform designs, were recognised as key enablers for rare disease research. Early engagement among regulators, HTA bodies, and developers was considered essential to align evidence expectations. A shared roadmap was outlined to foster collaboration, harmonise guidance, and build sustainable research infrastructure.

[14] https://www.sciencedirect.com/science/article/abs/pii/S0305737225001252

[15] https://www.sciencedirect.com/science/article/abs/pii/S0305737225001252

Workshop	Summary
EMA workshop on challenges in drug development, regulation, and clinical practice in immunoglobulins	• The Haematology Working Party convened a multi-stakeholder workshop to review the clinical development, regulatory requirements, and therapeutic use of immunoglobulins. The event brought together healthcare professionals, industry and HTA bodies to get a perspective on the use of immunoglobulins and their view on established and new indications. The workshop collectively provided a comprehensive overview of current challenges in the development, regulation, and clinical application of immunoglobulin therapies, highlighting the critical importance of multi-stakeholder collaboration in addressing these complex challenges.

Medicines used in children and adolescents

During 2024-25, multistakeholder engagement played a critical role in advancing research and innovation to support high-quality paediatric clinical studies and increase the availability of paediatric medicines.

EMA continued its support for the European Network of Paediatric Research (EnprEMA) by hosting annual stakeholder events. These meetings brought together relevant stakeholders and discussed ongoing priorities, including strengthening the role of paediatric research nurses and improving cross-border access for paediatric patients to participate in clinical trials. Further efforts are also underway to support academic sponsors under the ACT EU initiative and to refine best practices for patient recruitment and the involvement of children, adolescents, and their families in clinical trial planning.

As part of the ACT EU initiative, a dedicated multistakeholder workshop for assessors of paediatric clinical trials was held in July 2025, to identify challenges in reviewing paediatric clinical trials within the EU/EEA. Real-life case studies of trials submitted via the Clinical Trials Information System (CTIS) and assessed under the Clinical Trials Regulation (CTR) were reviewed to foster a shared understanding of different regulatory and decision-making processes. Key outcomes included proposals to develop joint guidance on interpreting the CTR and addressing issues to ensure a harmonised approach across EU member states.

The Accelerate platform, set-up in collaboration with EMA, is an important initiative fostering international dialogue among stakeholders to advance the development of medicines for childhood cancers. In both 2024 and 2025, the platform hosted annual conferences as well as strategic forums. These biannual forums, alternating between Europe and the US, focus on specific disease areas or product classes and provide opportunities for stakeholders, including HTA bodies, to reach consensus on priority topics for future development. The aim is to ensure that paediatric cancer medicine development is targeted, effective and responsive to public health needs. The 15th Paediatric Forum, held in June 2025, focused on antibody-drug conjugates.

Antimicrobial resistance and other health threats

During 2024-2025 the Agency intensified its efforts to ensure the correct use of antibiotics and to promote the development of new antimicrobials, to advance the fight against antimicrobial resistance (AMR).

Crisis preparedness and addressing antimicrobial resistance

The Emergency Task Force (ETF) provides scientific support to facilitate clinical trials of medicines treating pathogens, as listed within its scope in the consolidated 3-year work plan (such as Influenza viruses, *Bacillus anthracis*, Clostridium botulinum toxin, Staphylococcal enterotoxin B, *Mycobacterium tuberculosis species*).

In 2024-25, the ETF raised awareness across stakeholders (via the Industry Standing Group (ISG) and ACT EU Multi-Stakeholder Platform Advisory Group (ACT EU MSP AG)) about available support activities, including initiatives to promote harmonisation of clinical trial and marketing authorisation applications across Member States. These efforts included appointing two ETF coordinators, establishing a dedicated forum of concerned member states and an Ethics Advisory Group.

EMA/FVE info session on restrictions for use of certain antimicrobials in animals

The fight against AMR also involves promoting the responsible use of antibiotics in animals. Widespread use of antibiotics in livestock can contribute to AMR, as resistant bacteria may spread to humans through meat consumption or the environment. Therefore veterinarians are the first line of defence against emerging diseases and play a key role in mitigating AMR development. The Agency supported measures introduced in the veterinary regulation (EU) 2019/5[16] to ensure the prudent use of antimicrobials in animals. EMA also contributes by monitoring and evaluating the risk factors associated with the use of antibiotics in animals, and by providing guidance on their impact on both animal and public health.

The Federation of Veterinarians of Europe (FVE), together with the Agency and members of the CVMP, organised webinars on the veterinary regulation to clarify and enhance understanding of the new rules among veterinarians, EU medicines regulatory agencies and other stakeholders. Topics discussed included the list of antimicrobials reserved for human use and the conditions under which certain antimicrobials can be used in exceptional circumstances.

Sustainability of the EU medicines regulatory network

The efficient use of the EU medicines regulatory network resources is linked to the number and timing of submissions of marketing authorisation applications received. In line with the need to increase predictability, streamline processes and ensure availability of the right expertise, the Agency and HMA have conducted several awareness initiatives involving stakeholders.

- In 2025 a webinar was held to raise awareness of the work of European Medicines Regulatory Network (EMRN) among non-commercial experts (i.e. not affiliated with the

[16] https://eur-lex.europa.eu/eli/reg/2019/5/oj

pharmaceutical industry), including healthcare and regulatory professionals with experience in clinical medicine, pharmacology, toxicology, inspections and other aspects of medicines research, development, manufacturing and surveillance, both within the EU and internationally, and to encourage broader expert participation in EMRN's activities by external experts.

- Importantly, the Agency has increased involvement of patients and healthcare professionals in its activities. In September 2024 an open call was launched to create a pool of patient and healthcare professional experts who can be contracted by EMA for a selected list of tasks and remunerated for their involvement. The call remains open for the period of 2024-2029. Since then, 178 applications were assessed, 88 of these were included in the pool of experts, 68 contracted and 77 tasks have been assigned to contracted experts. The pools of patient, consumer and healthcare professional experts are published on EMA's website and updated on a regular basis.
  - Pool of patient and consumer experts list for 2024-2029
  - Pool of healthcare professional experts list for 2024-2029

In this context, EMA revised Policy 044 on the handling of competing interests of scientific committees' members and experts which became effective in May 2025. This updated policy further strengthens impartiality on medical devices in line with new responsibilities of the Agency.

Key achievements

- In 2024**,** launch of open call aimed at remunerating patients, consumers and HCP experts for their collaboration with EMA.
- In 2025, first experts contracted and remunerated.

Other engagement activities

All stakeholders registered in the EMA stakeholders database were kept informed of key activities via targeted communications, to raise awareness on relevant published news and to promote participation in other events, public consultations, surveys and calls for expression of interest.

Additionally, the Agency published newsletters periodically to ensure that specific information and updates on various topics reached a wider audience.

Targeted engagement with patients and consumers

> The PCWP is a model of how patients and consumers can meaningfully contribute to the work of EMA, ensuring the patient voice is heard across the breadth of the Agency's activities. At a time when the role of civil society and patient organisations is increasingly called into question, it is more important than ever to strengthen the PCWP and demonstrate the added value of our involvement at the regulatory level.
>
> **Marco Greco**,
> PCWP Co-Chair

Patients contribute to EMA's work in a number of ways – both collectively through eligible organisations and the Patients and Consumers' Working Party (PCWP), and as individual experts. In December 2025, there were a total of 42 eligible patient and consumer organisations. The PCWP expanded to 25 member organisations, reflecting the continued interest in this platform. At the same time, 219 patient / consumer representatives with a valid declaration of interests were listed in the database of European Experts; forming a pool of patient and consumer experts who can be called upon to participate in EMA activities.

There are two patient representatives on EMA's Management Board, and patients also have representation on several scientific committees:

- Committee for Orphan Medicinal Products (COMP) – 3 members
- Paediatric Committee (PDCO) – 3 members and 3 alternates
- Committee for Advanced Therapies (CAT) – 2 members and 2 alternates

- Pharmacovigilance Risk Assessment Committee (PRAC) – 1 member and 1 alternate.

Patients and consumers are also represented in several EMA working groups and task forces, which include the Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG) and the Emergency Task Force (ETF). In addition they are involved in the DARWIN EU Advisory Board, the Network Data Steering Group (NDSG), the Drafting Group on Digital Support Tools to Risk Minimisation Measures, the Network Advisory Group on Raw Data, ENCePP Steering Group, Enpr-EMA, QRD working subgroup on the PL improvement project, PRAC multistakeholder working group on digital Support Tools to Risk Minimisation Measures (RMM) and the ACT EU Multistakeholder Platform Advisory Group.

EMA's relationship with its patient and consumer stakeholders is formalised in a dedicated engagement framework that describes the objectives, methodologies and overarching principles for engagement.

Patients and Consumers' Working Party

The Patients and Consumers' Working Party (PCWP) provides a platform for exchange of information and discussion of issues of common interest between EMA and patients and consumers. The working party was launched in 2006 and will celebrate its 20th anniversary in 2026.

The PCWP's work is guided by its workplan. A joint PCWP/HCPWP workplan for the term 2025-2028 is being developed involving volunteers from both PCWP and HCPWP building upon the PCWP/HCPWP workplan 2022-2025 and the European medicines agencies network strategy (EMANS) to 2028.

Table 3 provides an overview of the topics in which the PCWP was involved during 2024 and 2025. Many of the meetings are held in conjunction with the corresponding HCPWP as several subjects covered are of mutual interest and relevance. This is not only consistent with our multistakeholder approach but also results in better outcomes. Meeting summaries and presentations are systematically published after the meetings.

New co-chair of the PCWP

In September 2025, the Patients and Consumers Working Party (PCWP) elected Marco Greco as its new co-chair. Marco Greco is a lawyer by training and has extensive advocacy experience. He is a longstanding PCWP member and has served two terms on both the Pharmacovigilance Risk Assessment Committee (PRAC) and EMA's Management Board. Mr Greco is also the President of the Board of the European Patients' Forum and brings many years of experience advocating for patients within EMA and across Europe. He follows Marko Korenjak in the role of co-chair of the PCWP.

Together with Juan Garcia Burgos, Head of Public and Stakeholder Engagement at EMA, and Dr Piotr Szymanski, co-chair of the Healthcare Professionals Working Party (HCPWP), Marco Greco will co-chair the meetings of their respective working parties for the 2025–2028 mandate.

Table 3. PCWP meeting topics during 2024 and 2025

2024	2025
February Third-party interventions • Activities in cancer • Patient experience data • Pharmacovigilance • Shortages • Policy on competing interests • EMA working party operations	April EMA 30th anniversary • Clinical trials • EMANS to 2028 • Electronic product information • Shortages and the shortages platform • DARWIN EU • Revised EMA policy on competing interests • PED • Communication campaigns
July EMANS to 2028 • Clinical trials • Product information • Lactation • Transparency • Shortages • Vaccine updates • Biosimilar medicines • Patient engagement updates	September Election of new co-chairs • Assessment of medicines • 30th anniversary scientific conference • EMA's first public Open Door Day • Engagement with other stakeholders • Medicine safety campaign • Risk Minimisation Measures
November Clinical trials • Sustainability of the network • Shortages • Medical devices • Data-related initiatives and digitalisation • Artificial intelligence • Communication activities	November New Pharmaceutical legislation • Clinical trials • Training activities • International activities • Availability and supply of medicines • Product information • Communications • Members' voice

Interactions with FDA supporting patient engagement

EMA continued its collaboration with FDA to support patient engagement through various activities. The Patient Engagement Cluster, established in 2016 to enable both agencies to share initiatives and best practices for involving patients in discussions on medicines, continued to meet virtually two to three times a year.

In addition, the PCWP meets annually with the Patient Engagement Collaborative (PEC), a joint project between the FDA and the Clinical Trials Transformation Initiative (CTTI), to discuss topics of public health interest, such as patient information, communication and youth engagement. In 2024, the topic of the joint meetings was patient reported outcomes and quality of life questionnaires, while in 2025 the focus was on how medicines shortages are handled by regulators.

In collaboration with the FDA Oncology Center of Excellence, three public panel discussions under the title 'Conversations on Cancer' were held. The three topics included Transforming Patient Lives by Therapeutic and Regulatory Innovations (1 February 2024), Paediatric Cancers: Navigating the Challenges Together (19 November 2024) and Cervical Cancer Treatment Innovation: A Collaborative Discussion (14 January 2025). Each panel featured

speakers with a range of perspectives on the cancer under discussion and addressed the various elements relating to therapies and innovations in treatment. Additional information can be found under Patient engagement in Oncology.

Bilateral meetings

Bilateral meetings can be organised upon request by an eligible patient or consumer organisation to discuss issues of common interest. These meetings allow EMA to listen to stakeholders' concerns and provide additional information or clarifications. They complement discussions within the PCWP and offer an opportunity to explore a specific organisation's priorities in greater depth. Confidential and product-specific discussions are out of scope.

In 2025, EMA colleagues met with representatives of the European Consumer Organisation (BEUC) to discuss product information, medicine shortages, medical devices and clinical trials.

Contributions to patient organisations' meetings

As described in its framework of engagement, EMA contributed regularly to trainings and conferences organised by patient and consumer organisations to increase their awareness of EMA's activities and encourage the participation of organisations in the Agency's work.

Selected examples include:

- EURORDIS Open Academy
- Myeloma Platform Europe Advocate Development Programme
- Retina International Education Hub
- 1st European Pulmonary Fibrosis Patient Advocacy Forum

Patient contribution to the evaluation of medicines

Whenever possible, EMA involves patients as individual experts in expert meetings such as scientific advice and scientific advisory group or ad hoc expert group meetings. EMA also involves patients collectively through their representative organisations via the CHMP early dialogue and in stakeholder meetings in conjunction with the PRAC.

Scientific advice and protocol assistance

At any stage of a medicine's development, a developer can ask EMA for guidance on the best method for generating robust evidence of a medicine's benefits and risks. This is called scientific advice or, in the case of orphan medicines, protocol assistance. The added value of patient input in these procedures has been well demonstrated, as this has helped enhance the quality of the advice provided.

In 2024, 70 patients and carers participated in 67 scientific advice, protocol assistance and qualification of new methodologies procedures. In 2025, 53 patients and carers participated in 53 procedures.

Key achievement

Improvement of the scientific advice submission template (clear-language summary of questions for patients) and introduction of a response form to facilitate patient input.

Scientific advisory and ad hoc expert groups

Scientific advisory groups (SAG) or ad hoc expert groups (AHEG) are expert groups that are convened to answer questions raised during a medicine's assessment. SAGs are usually requested by the human medicines committee (CHMP), the safety committee (PRAC), or the committee for advanced therapies (CAT). In some disease areas, there are core SAGs. When a request arises for a medicine where there is no core SAG, an *ad-hoc* expert group is organised.

In 2024, 27 patients and carers participated in 16 SAG or ad hoc expert group meetings, and in 2025, 14 patients and carers participated in 10 such meetings.

Scientific committee consultations

During the review of a medicine, EMA's scientific committees may need to reach out to patients with experience of the condition being treated to obtain specific information. Patients were regularly consulted in 2024 and 2025 and invited to provide comments in person, in virtual meetings or in writing (see table 4, below).

Table 4. Scientific committee consultations

Year	Committee	No. of consultations	No. of patients consulted
2024	COMP	3	81*
	CHMP	14	21
	PDCO	4	317*
	PRAC	2	18
2025	COMP	5	5
	CHMP	6	11
	PDCO	5	409*
	PRAC	3	20

** meetings and written consultations, including surveys*

CHMP early dialogue with patient organisations

At the start of the evaluation of marketing authorisation applications for certain medicines, EMA invites patient organisations to provide input on their experiences and concerns about the condition and highlight key aspects that are important to them. This early dialogue with patient organisations is an additional and complementary approach to other engagement

methods. It primarily targets organisations representing patients, consumers or healthcare professionals that meet EMA's eligibility criteria.

Input was received on new active substances for initial marketing authorisation applications. In 2024, there were 27 early dialogue procedure requests, resulting in input from 21 organisation. In 2025, there were 23 requests, with input received from 19 organisations.

Review of documents targeted to the public

Before publication, patients review documents intended for patients and the general public, such as the package leaflet the medicine overview or the public health communication. The suggestions and comments made by patients help to ensure that the documents address the target audience and use the right language to ensure the message is clear and understandable.

In 2024, patients reviewed 25 package leaflets, 47 medicine overviews and 10 public health communications. In 2025, patients reviewed 55 package leaflets, 53 medicine overviews and four public health communications.

Key achievement

Changes to the European public assessment report (EPAR) template to reflect input from patients and healthcare professionals gathered during CHMP early dialogue as well as patient experience data.

Contribution of patients to guideline development

In 2024, EMA held a virtual stakeholder meeting to seek input from patients and healthcare professionals on the revision of the Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension (PAH). These guidelines are aimed to define the clinical requirements for obtaining marketing authorisation.

Promoting further outreach of safety information

EMA collaborated with individual patients and healthcare professionals in the development and publication of a new booklet on medicine safety monitoring. This booklet offers a comprehensive overview of how EMA and EU Member States work together to ensure the safety of medicines used across Europe throughout their lifecycle.

Contributions to communication campaigns

The campaign on shortages #ItTakesATeam was co-created with PCWP and HCPWP members and showcases the work that is going at EU level to manage medicine shortages. The campaign includes regulators, national agencies, patient and healthcare professional organisations and aims to highlight the role of different stakeholders in supporting patients affected by medicines shortages.

Targeted engagement with healthcare professionals

> Early and sustained engagement with healthcare professional organisations - across areas such as medicines development, clinical trials, pharmacovigilance, digital tools, and access to medicines - is essential to ensure that regulatory initiatives effectively meet patients' needs and continuously foster trust in scientific methods.

Piotr Szymański,
HCPWP Co-Chair

Similarly to patients, healthcare professionals (HCPs) play an important role at EMA by participating in every aspect of the regulatory lifecycle of a medicine. Their involvement spans pre-submission and evaluation processes, as well as post-authorisation activities. HCPs participate in committee and expert meetings, and provide clinical expertise directly into scientific regulatory discussions, helping to ensure that medicines are safe, effective, and of high quality. Between 2024 and 2025, EMA strengthened its collaboration with HCPs, recognising their essential role in shaping regulatory decisions that reflect real-world clinical practice.

Some of the indicators of a successful cooperation between EMA and HCPs are the increasing number of experts registering in the EMA's expert's database to provide scientific expertise, as well as the continued active role of the Healthcare Professional's Working Party (HCPWP) and HCP Policy Officers Group (POG). These groups serve as valuable complementary platforms to strengthen engagement of eligible healthcare professional organisations with EMA activities.

Between 2024 and 2025, EMA accepted four new eligible organisations: International Society on Thrombosis and Haemostasis (ISTH), European Society of Contraception (ESC), European Wound Management Association (EWMA) and European Network of Teratology Information Services (ENTIS), and welcome back the World Family Doctors (WONCA EUROPE). As of December 2025, there were 44 healthcare professional's organisations eligible to engage with EMA.

The HCPWP expanded to 25 member organisations, reflecting the continued interest in and importance of this platform. Additionally, by the end of 2025, the number of healthcare professionals representatives with a valid declaration of interests in the database of European Experts was 101. These experts can be called upon to contribute their expertise to EMA activities

Healthcare professionals are represented by two members at EMA's Management Board representing and one member representing veterinarians HCPs are represented on several EMA scientific committees:

- Pharmacovigilance Risk Assessment Committee (PRAC) - 1 member and 1 alternate
- Committee for Advanced Therapies (CAT) – 2 members and 2 alternates
- Paediatric Committee (PDCO) – 3 members and 3 alternates

In addition, HCPs are actively represented in several EMA working groups and task forces, contributing their expertise to a wide range of regulatory and scientific initiatives. These include DARWIN EU Advisory Board, the Network Data Steering Group (NDSG), Emergency Task Force (ETF), European Network of Paediatric Research (Enpr-EMA), ACT EU Multi-Stakeholder Platform Advisory Group (MSP AG), Cancer Medicines Forum (CMF), QRD working subgroup on the PL improvement project, PRAC multistakeholder working group on digital Support Tools to Risk Minimisation Measures (RMM) and Drafting Group on Digital Support Tools to Risk Minimisation Measures, as well as observers at Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG).

EMA's relationship with HCPs is formalised in a dedicated engagement framework that describes the objectives, methodologies and overarching principles for engagement. In 2024, EMA continued its reflection to review the current framework of interaction with HCPs and their organisations, with the goal of completing this review by 2026. This update aims to incorporate lessons learned since the framework's last revision in 2016 and address emerging challenges and opportunities.

Healthcare Professionals' Working Party (HCPWP)

Between 2024 and 2025, the HCPWP continued to serve as an important platform for structured dialogue between EMA and eligible healthcare professional organisations. In 2025, EMA welcomed newly elected representatives for the new three year's term.

As previously, the HCPWP's work is guided by its workplan. A joint PCWP/HCPWP workplan for the term 2025-2028 is being developed involving volunteers from both PCWP and HCPWP building upon the PCWP/HCPWP workplan 2022-2025 and the European medicines agencies network strategy (EMANS) to 2028.

Throughout 2024-2025 various topics were discussed and progressed and meeting summaries and presentations were systematically published after the meetings.

The table below provides an overview of the topics in which the HCPWP was involved during 2024 and 2025. Many of the meetings were held in conjunction with the corresponding PCWP, as several subjects addressed were of shared interest and relevance. This is not only consistent with EMA's multistakeholder approach but also contributes to achieving more effective and impactful outcomes.

Table 5. HCPWP involvement during 2024 and 2025

2024	2025
February Third-party interventions • Activities in cancer • Patient experience data • Pharmacovigilance • Shortages • Policy on competing interests • EMA working party operations July EMANS to 2028 • Clinical trials • Product information • Lactation • Transparency • Update on framework of interaction with HCPs • Update on CHMP early dialogue process with HCPs • Update on HCP POG drafting groups • Shortages • Vaccine updates • Biosimilar medicines • Patient engagement updates November Clinical trials • Sustainability of the network • Shortages • Medical devices • Data-related initiatives and digitalisation • Artificial intelligence • Communication activities	April EMA 30th anniversary • Clinical trials • EMANS to 2028 • electronic product information • Shortages and the shortages platform • DARWIN EU • Revised EMA policy on competing interests • PED • Communication campaigns September Election of new co-chairs • 30th anniversary scientific conference • EMA's first public Open Door Day • Engagement with other stakeholders • Medicine safety campaign • Risk Minimisation Measures • Draft work plan for 2025-2028 • Update of framework of interaction with HCP November New Pharmaceutical legislation • Clinical trials • Training activities • International activities • Availability and supply of medicines • Ecosystem information management • Product information • Communications • Members' voice

New co-chair of the HCPWP elected

In September 2025, the Healthcare Professionals' Working Party (HCPWP) elected Dr. Piotr Szymański as its new co-chair. Dr. Szymański has been a member of the HCPWP since 2022, representing the European Society of Cardiology, where he also serves as a Board Member and Chair of the Regulatory Affairs Committee. In this capacity, he has played a key role in coordinating input from diverse clinical communities, building consensus, and fostering constructive dialogue with regulators. He succeeds Dr. Rosa Giuliani in the co-chair role. Together with Juan Garcia Burgos, Head of Public and Stakeholder Engagement at EMA, and Marco Greco, co-chair of the Patients' and Consumers' Working Party (PCWP), Dr. Szymański will co-chair the meetings of their respective working parties for the 2025–2028 mandate.

Healthcare professional policy officer's group

The EMA Healthcare Professional Policy Officers' Group (HCP POG) brings together representatives from eligible healthcare professional (HCP) organisations to discuss policy and regulatory matters with EMA. It complements the HCPWP by enabling broader participation from eligible organisations. In 2025 the HCP POG marked its fourth year of operation. Interest among representatives grew significantly during the reporting period bringing the total number of representatives to 60. The group met six times in 2024 and five times in 2025.

Between 2024 and 2025, the HCP POG meetings focused on a variety of recurring and evolving themes. These included updates on clinical trials, such as ACT EU initiatives and its multistakeholder platform, CTIS developments, priority actions on clinical trials during public health emergencies, the implementation of novel complex and innovative trials, and the Cancer Medicines Forum. Additional topics included updates on medicine shortages, the use of artificial intelligence in healthcare and associated healthcare professional organisations' position papers, engagement with academia, scientific publication strategies, the European Vaccination Portal, and communication activities, including the development of misinformation frameworks. Specific points raised by organisations were discussed during meetings, as well as recent/upcoming events and recent publications of interest or public consultations. Members also had the opportunity to present their organisations' activities and key areas of policy work.

Bilateral meetings

Bilateral stakeholder meetings can be organised upon request by healthcare professional organisations to discuss issues of common interest. These meetings allow EMA to listen to stakeholders' concerns and provide additional information or clarifications. They complement discussions within the HCPWP and offer an opportunity to explore a specific organisation's priorities in greater depth. Confidential and product-specific discussions are out of scope.

Priority is given to EMA eligible organisations, which have been assessed against eligibility criteria endorsed by EMA's Management Board – these include, among others, transparency regarding funding sources.

Throughout the reporting period, bilateral meetings were held with five healthcare professional organisations (EAHP, ESC, EASD, EAU and ERS), as well as a joint meeting with organisations representing general practitioners (UEMO, EFPC and WONCA EUROPE). These meetings aimed to address specific concerns, explore areas of mutual interest, identify opportunities for joint sessions at professional congresses, and promote transparency through the publication of meeting summaries.

Key achievement

During 2024-2025, EMA held its first formal bilateral meetings with several EMA eligible healthcare professional organisations:

- the European Society of Cardiology (ESC), the European Association for the Study of Diabetes (EASD), the European Association of Urology (EAU) and European Respiratory Society (ERS).

Contributions to healthcare professional organisations' meetings

The Agency regularly contributes to events such as congresses, workshops, and courses organised by eligible organisations. This is in line with the corresponding engagement framework and aims to raise awareness of the Agency's activities and encourage and facilitate the participation of healthcare professional organisations in the Agency's work.

Selected examples include:

- CPME-PGEU joint event in June 2024
- The European Society for Medical Oncology (ESMO) annual congress in October 2024
- 6th EORTC Quality of Life in Cancer Clinical Trial conference in May 2025
- The European Midwives Association (EMA) annual conference in October 2025
- the European Association of Hospital Pharmacists (EAHP) congress in November 2025

Healthcare professional contribution to the evaluation of medicines

Healthcare professionals play a key role as experts in the evaluation of medicines. The involvement of practicing clinicians, specialised nurses and pharmacists is critical for assessing the clinical benefits of candidate medicines, those currently in use, and their real-world application. Their perspective helps ensure that regulatory decisions translate effectively into clinical practice. Healthcare professionals can contribute at various stages of the evaluation process and throughout a medicine's entire lifecycle. Healthcare professionals can be involved at different stages during the evaluation process and throughout a medicine's lifecycle.

Scientific committee consultations

During the review of a medicine, EMA scientific committees may need to reach out to healthcare professionals with expertise in the relevant therapeutic areas to obtain specific

information. Several healthcare professional organisations (HCPOs) were consulted in 2024 and 2025 and invited to provide comments in writing (see table 6, below).

Table 6. Scientific committee consultations

Year	Committee/ Working Party	No. of consultations	No. of HCPOs consulted
2024	PRAC	2	24
	CHMP/QWP	1	2
2025	PRAC	3	31
	PDCO	4	9

CHMP early dialogue with healthcare professional organisations

Once a marketing authorisation application is submitted and the EMA begins its evaluation, the Agency may invite healthcare professional organisations to share their insights on various aspects of the condition, the currently available treatments, and their clinical experiences in managing the condition. CHMP early dialogue is additional and complementary to other engagement methods.

In 2024, EMA published the 1-year report on Early dialogue with healthcare professional organisations for marketing authorisation applications. Following the successful completion of the first year of engagement with HCP organisations, a consultation with healthcare professionals will now systematically be considered for all new applications involving new active substances. In 2024, there were 33 early dialogue procedure requests, and inputs were received from 32 HCP organisations. In 2025, there were 27 early dialogue procedure requests, with inputs received from 30 organisations.

Key achievement

- 1-year report on early dialogue with healthcare professional organisations for marketing authorisation applications.
- Changes to the European public assessment report (EPAR) template to reflect healthcare professional and patient input to CHMP early dialogue.

Scientific advisory and *ad hoc* expert groups

Scientific advisory groups (SAG) or *ad hoc* expert groups (AHEG) are expert groups convened to address specific questions that arise during the assessment of medicines. SAGs are usually requested by the human medicines committee (CHMP), the safety committee (PRAC), or the committee for advanced therapies (CAT). For some therapeutic areas, there are permanent SAGs. These groups are composed of independent European experts selected according to their specific expertise. The SAG consists of a core group of experts, and other individual experts who may be called upon to participate in a specific meeting when their

specialised expertise is required. In those where there is no SAG, an *ad hoc* expert group can be organised. In 2024, a total of 186[17] healthcare professionals participated in 19 SAG or *ad hoc* expert group meetings, while in 2025, 117* healthcare professionals participated in 10 such meetings.

Review of documents targeted to healthcare professionals

Healthcare professionals are involved in the review of safety communications, including Direct Healthcare Professional Communications (DHPCs) and Public Health Communications (PHCs). They are also involved in communications related to medicine shortages, such as MSSG recommendations, shortage catalogue entries, medicine shortage communication, where applicable.

Healthcare professionals reviewed 32 safety communications and 11 shortage communications in 2024. In 2025, healthcare professionals reviewed 15 safety communications and 22 shortage communications.

Promoting further outreach of safety information

During the reporting period, EMA collaborated with representatives from various healthcare professional organisations and learned societies including European Association of Urology (EAU), European Academy of Paediatrics (EAP), as well as general practitioner (GPs) organisations (Union Européenne des Médecins Omnipraticiens / European Union of General Practitioners (UEMO), European Forum for Primary Care (EFPC) and World Organization of Family Doctors (European Region) (WONCA EUROPE)), to co-author three scientific publications:

The article titled: "*A call to prevent inappropriate prescribing of fluoroquinolones from the European Medicines Agency (EMA) and the EAU Guidelines*" co-authored by EMA in collaboration with the European Association of Urology (EAU).

The article titled: "*Meningococcal B Vaccines as a Paradigm of Safe and Effective Vaccines for Children*" co-authored by EMA in collaboration with European Academy of Paediatrics (EAP).

The article titled: "*The case for more prudent prescribing of fluoroquinolones in primary care*" co-authored by EMA in collaboration with EAU and GPs organisations (WONCA EUROPE, UEMO, and EFPC).

These publications align with the EMA's scientific publication strategy, which aims to enhance the impact of its scientific output, particularly those with significant clinical relevance.

In addition, EMA has collaborated with individual patients and healthcare professionals on a booklet on medicine safety monitoring. It offers a comprehensive overview of how EMA and EU Member States work together to ensure the safety of medicines used across Europe throughout their lifecycle.

Contribution of healthcare professionals to guideline development

In 2024, EMA held a virtual stakeholder meeting to seek input from healthcare professionals and patients on the revision of the Paediatric addendum to the guideline on clinical

[17] These figures include all healthcare professionals involved in SAGs, including core group members and individual experts.

investigation of medicinal products for the treatment of pulmonary arterial hypertension (PAH). These guidelines are aimed to define the clinical requirements for obtaining marketing authorisation.

Contributions to communication campaigns

The campaign on shortages #ItTakesATeam was co-created with PCWP and HCPWP members and showcases the work that is going on at the EU level to fight medicine shortages. The campaign includes regulators, national agencies, patient and healthcare professional organisations and aims to highlight the role of different stakeholders in supporting patients in case of a shortage.

Targeted engagement with academia

> Our partnership with academia is essential to advancing regulatory science and achieving our vision of a fast track from innovation to safe, effective medicines. Over the past two years, an increasing number of bi-directional exchanges and joint research have strengthened our shared sense of purpose and reinforced Europe's position as a global leader in human and animal health.

Emmanuel Cormier,
Head of Regulatory Science and Innovation

Academia includes universities, public or private not-for-profit organisations or higher education establishments pursuing research, consortia funded under public research programmes and individual researchers pursuing research independent from commercial control. Academic developers or researchers are actors from the academic sector involved in the development of medicinal products, methodologies or drug development tools.

The EMA is committed to a close working relationship with researchers and developers from academia as this collaboration with benefits the Agency in multiple ways. It supports the gathering of information that helps prepare the Agency for future challenges, facilitates the identification of scientific and technological advancements relevant to regulatory science, and ensures that such innovations are directed towards improving public health.

A broad range of activities is conducted for, and in collaboration with academia, learned societies and research groups. These can be broadly grouped into three categories:

regulatory offerings and support, engagement in research and training initiatives with academia.

Strengthening engagement with academia through regulatory support

The academic sector plays an important role in the development of medicinal products. Academic developers are at the forefront of research that may address unmet medical needs and develop treatments for patient groups affected by health conditions that may not attract commercial interest, as well as those for which there is a wider interest. To ensure that these early-stage innovations held by an academic institution can successfully transition to industry or progress towards a marketing authorisation, early engagement with regulators is needed.

Academia briefing meetings (ABM)

Academia briefing meetings (ABM) offer researchers and academic developers a platform for early dialogue with EMA. These meetings facilitate early discussion of research needs, promote mutual understanding and supports alignment on scientific challenges and research issues. They offer academics and academic developers the opportunity to receive strategic guidance on relevant EMA services, experience and priorities. They also serve as a forum for discussing scientific plans and involvement of different disciplines. ABMs are free of charge and require only minimal preparation for the academic researchers and developers taking part.

During 2024-25, the EMA held 33 ABMs, covering a wide range of topics, such as gene therapy, patient reported outcomes, repurposing of medicinal products, and vaccines.

Innovation Task Force (ITF) Meeting

Academics can also be invited to Innovation Task Force (ITF) meetings, briefing meetings to support developers in their development programmes. Similarly to ABMs, ITF meetings are free-of-charge and cover regulatory, technical and scientific issues linked to the development of innovative medicines, new technologies and borderline products. In 2024-2025, 14 ITF meetings with academic developers were held.

ABMs and ITF meetings are the coordinated early point of contact support system for academic developers and researchers. They do not replace scientific advice, protocol assistance or qualification advice. They help academic developers and researchers to verify the suitability of tests, study designs, methodologies or other relevant aspects for marketing authorisation applications of medicinal products.

To further encourage academic researchers and developers, EMA can provide fee reductions for certain scientific advice requests by certain non-for-profit entities, upon validation of the application. These reductions also cover novel methodology qualification and protocol assistance. This is in line with the new fee Regulation (EU) 2024/568, which entered into force on 1 January 2025.

Key achievement

A fee waiver for scientific advice can be requested by not-for-profit entities in line with the Working arrangements for Regulation (EU) 2024/568 on fees and charges payable to EMA.

Pilot Programmes Supporting Academic Developers

EMA has previously launched pilot programs to support academic developers on specific regulatory development pathways and products, namely the repurposing pilot and the advanced therapy medicinal products (ATMP) pilot.

The repurposing pilot started in October 2021 and offered tailored scientific advice to not-for-profit organizations and academia conducting research to repurpose authorised medicines for new therapeutic uses. In July 2025, a milestone was reached with the publication of the repurposing pilot report. The report highlights the importance for academic developers to seek regulatory support early in their programs and recommends the continued provision of tailored support services to academia, including ABMs and free-of-charge scientific advice.

The ATMPs support pilot for academic developers was launched in 2022 and currently includes three ATMPs under development:

- ARI-0001 by Hospital Clínic de Barcelona,
- TregTacRes by Berlin Center for Advanced Therapies (BeCAT) – Charité and
- etuvetidigene autotemcel by Fondazione Telethon.

While the pilot does not introduce any new regulatory tools, it helps developers make optimal use of existing regulatory tools and development support measures.

Engagement in research

EMA engages in a broad range of pre-competitive research initiatives and collaborates with academia to advance scientific knowledge. Research in regulatory science contributes to improving regulatory standards and helps to translate research outcomes into benefits for patients, healthcare professionals, and health systems. Engagement with academic stakeholders takes multiple forms, including support to researchers for grant applications, participation in externally funded European and global research consortia, partnerships and projects, either as an advisor, associate partner or beneficiary. Most external research projects in which EMA participates are funded through Horizon Europe and the Innovative Health Initiative (IHI). In the years 2024 and 2025, EMA was involved in different ways in about 30 externally funded projects, consortia or partnerships.

To engage in research EMA implements a range of initiatives, including structured project engagement mechanisms such as Collaboration Management Meetings (CMMs), the European Platform for Regulatory Science Research, continuous monitoring of gaps and emerging needs in regulatory science, and the nomination of collaborating experts to support specialised scientific activities.

Potential EMA involvement in externally funded research projects is explored through collaboration management meetings (CMM). These meetings help identify suitable projects and support academic researchers preparing grant applications or participating in pre competitive regulatory science initiatives. CMMs aim to clarify project objectives, discuss scientific and regulatory challenges, and highlight relevant EMA services.

During 2024 and 2025, EMA held 16 CMMs, covering topics such as green pharmaceuticals, rare diseases, patient reported outcomes, inclusion of under-represented and under-served populations in clinical research, real world data, non-clinical safety, personalised medicine, biomarkers, and paediatric population aspects.

In addition to joining external projects, EMA also monitors gaps in regulatory science and medicine development and identifies potential research questions that can help advance science. These are published periodically as a list of regulatory science research needs. Researchers from academia and industry, as well as funders are invited to address the identified research needs in their work, grant applications, consortia and programmes. As a result of proactive work involving monitoring of multiple sources, the latest list of Regulatory Science Research Needs was published in July 2025.

Key achievement

Following a cross-Agency effort and an external consultation, EMA published the latest list of Regulatory Science Research Needs in July 2025.

In 2025, EMA and HMA launched the European Platform for Regulatory Science Research, a forum bringing together academia and regulators. The platform aims to support medicines developers and enhance regulatory decision making by accelerating research in regulatory science and uptake of scientific and methodological solutions. Activities include discussions of regulatory science research needs, sharing methodological insights and best practices, and promoting the translation of findings into practical applications.

Since its launch, 250 researchers from academia and non-for-profit research organisations are participating in the platform. The first two platform meetings took place in 2025 and were attended by about 150 researchers and regulators. Sessions focused on exchange of experiences from ongoing work and discussions on proposals to advance the research agenda, highlighting funding opportunities and reflections of regulatory involvement in research projects. To continue advancing specific research and methodological topics, ad hoc working groups have been established to develop concrete outputs and next steps.

Key achievement

The EMA/HMA European Platform for Regulatory Science Research was launched in 2025, and attracted substantial interest from numerous stakeholders, including academic researchers.

To address regulatory science research questions, EMA also works closely with research funding bodies, including the European Commission, executive research agencies, and national funding organisations. EMA provides input on funding calls and recommendations on regulatory and scientific aspects of planned initiatives.

EMA can also host collaborating experts interested in collaborative research projects related to EMA's scientific work. Collaborating experts may self-nominate themselves, or vacancy notes for collaborating experts may be posted on EMA website. Collaborating expert work needs to align with the regulatory science research needs. In 2024-2025, EMA onboarded 21 collaborating experts.

Training with academia

The needs of the regulatory system for access to appropriate expertise is defined by ACT EU Priority Action (PA 10) which aims to develop a learning ecosystem for academia and micro, small and medium-sized enterprises (SMEs) involved in randomized controlled trials in Europe. In 2025, a milestone was reached, with the publication of a report summarising the learning needs of academia and SMEs based on a survey with responses from more than 400 participants. Stakeholders involved in clinical research highlighted, amongst other challenges, difficulties in identifying relevant training opportunities. The PA10 team continues to address the gap, with the next step of the project focused on mapping and signposting externally available trainings in the learning ecosystem.

In 2025, EMA developed a dedicated training on EMA Scientific Advice to guide academic researchers and developers on how to request, prepare for and make effective use of Scientific Advice to generate a robust benefit–risk evidence package. The training also covers support tools such as protocol assistance, qualification of novel methodologies, academia briefing meetings, and Innovation Task Force briefing meetings.

Targeted engagement with industry

> The role of industry stakeholders in delivering innovative solutions to patients and animals is essential. This is why maintaining regular dialogue with them remains a priority. In recent years, the industry standing group has become an important forum for strategic discussions on regulatory aspects, as well as on the challenges and opportunities encountered when implementing regulatory requirements. It complements existing platforms, along with bilateral meetings with interested parties, all of which foster dialogue to facilitate research, support navigation of regulatory pathways, and ensure effective monitoring of medicines.
>
> **Juan Garcia Burgos,**
> ISG chair, Head of Public and Stakeholder Engagement Department

Engagement with industry stakeholders follows the principles outlined in the established framework for interaction[18] and is carried out through continuous and open dialogue with not-for-profit organisations representing industrial sectors (such as innovators, generics, small and medium sized companies, distributors, wholesalers, medical devices/in vitro diagnostics manufacturers).

[18] https://www.ema.europa.eu/en/documents/other/criteria-be-fulfilled-industry-stakeholder-organisations-involved-european-medicines-agency-activities_en.pdf

In line with the working methodology outlined in the framework, following evaluation against a set of eligibility criteria[19] two additional organisations (Diagnostics for Animals and PHUSE) were accepted as eligible industry organisations.

In addition to the engagement with industry stakeholders' organisations, EMA also interacts with individual companies as part of its core regulatory activities. This includes activities in support to (early) development of innovative therapies and technologies, handling of product specific applications and the ongoing marketing authorisations.

In 2024, the EMA gathered feedback from industry stakeholders through a survey focused on early engagement activities that support innovation[20] (i.e. Innovation Task Force briefing meetings; Portfolio and technology meetings; Quality Innovation Group meetings (Listen and learn focus group and 1:1 meetings) and SMEs briefing meetings). The survey assessed stakeholders' experiences with the meeting request process, discussion quality, outputs, and overall communication. Respondents highlighted the high value of these interactions for advancing innovation, while also noting areas for improvement, including clearer and updated guidance, more streamlined timelines, and enhanced support.

In 2025, EMA conducted a second survey to evaluate the effectiveness of the Agency's engagement and communication with industry stakeholders. The feedback confirmed the positive impact of EMA activities in promoting transparency, understanding, and active involvement, while also identifying opportunities to further improve interactions.

Engagement at strategic level

Industry Standing Group (ISG)

Since its establishment in June 2022, the ISG has become a forum for strategic discussion and, with the approval of the revised pharmaceutical legislation and related acts, is expected to further develop into the main forum for discussion of key implementation activities and requirements.

The benefits of this group were acknowledged by its members through periodic surveys.

In 2024 and 2025, the ISG[21] met quarterly, with discussions focusing on the implementation of EMA's extended mandate. Discussions covered the methodology and impact of the Union list of critical medicines, preparations for the launch of ESMP, participation in the medical device expert panels pilots and the Emergency Task Force scientific advice procedures.

The ISG also served as a platform to exchange on the implementation of key legislations (such as the Health Technology Assessment Regulation, the new fee regulation and the Critical Medicines Act) as well as other topics of cross-industry interest (digitalisation, artificial intelligence, misinformation and disinformation, clinical trials, OneHealth; etc.).

[19] https://www.ema.europa.eu/en/documents/other/criteria-be-fulfilled-industry-stakeholder-organisations-involved-european-medicines-agency-activities_en.pdf

[20] https://www.ema.europa.eu/en/documents/report/report-industry-stakeholders-eu-network-experts-surveys-early-engagement-fostering-innovation_en.pdf

[21] https://www.ema.europa.eu/en/partners-networks/pharmaceutical-industry/industry-standing-group/industry-standing-group-meetings

Table 7. Overview of ISG focus group

Focus group	Group scope and key deliverable
Regulatory science research translation	• Established in January 2024 with volunteers from the ISG to identify elements for moving scientific discoveries into practical regulatory frameworks and real-world healthcare and for maximising the impact of outputs of public-private partnerships for regulatory science. The group concluded its activities in September 2025 with a report providing recommendations, priorities and approaches for enhancing the translation of regulatory science research outputs into practical application in regulatory practice as well as in research and development.

Key achievements

- ISG became the main point of reference for industry to ensure timely implementation of the revised pharmaceutical legislation and related acts.
- ISG focus group on regulatory science research translation published the report on Regulatory Science Research Needs.

Annual bilateral interactions

The possibility to interact with the Agency bilaterally[22] is a strategic opportunity enabling eligible industry organisations[23] to share sector specific perspectives, priorities and challenges in a confidential and open dialogue.

During 2024 and 2025, EMA held a total of 22 single bilateral meetings with industry organisations.

An overview of the key topics discussed is available in the following table.

Table 8. Overview of key topics discussed during bilateral meetings

Eligible organisation	Key topics discussed
Association of Clinical Research Organizations (ACRO)	• Improving attractiveness of EU clinical trials; AI/machine learning in clinical research.

[22] https://www.ema.europa.eu/en/partners-networks/pharmaceutical-industry/industry-annual-bilateral-meetings

[23] https://www.ema.europa.eu/en/documents/other/list-eligible-industry-stakeholder-organisations_en.pdf

Eligible organisation	Key topics discussed
Association of the European Self-Care Industry (AESGP)	• Position on 'One substance one assessment'; combination products; ePI; views on variation regulation.
Affordable Medicines	• Views on the revised pharmaceutical legislation; QR codes and ePI; Parallel Distribution submissions; new fee regulation; safety update procedure; Windsor agreement.
Alliance for Regenerative Medicines	• EU-US regulatory convergence for ATMPs; Views on the revised pharmaceutical legislation; platform technologies and gene editing.
Animal Health Europe	• EMANS to 2028; views on new veterinary regulation; preparedness activities for vaccines availability in emerging diseases.
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)	• Medical devices related activities; European Health Data Space (EHDS) impact analysis; EU views on AI act implementation.
The European Federation of Pharmaceutical Industries and Associations (EFPIA)	• Vulnerability assessment and solidarity mechanism; views on the revised pharmaceutical legislation; EU network resource sustainability; Clinical trials ecosystem; position on cumulative impact assessment on green-related files; EU medicines shortages; HTA implementation; interface between medical device and pharmaceutical legislation.
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	• Views on EU Biotech Act and life science strategy; views on the revised pharmaceutical legislation; Health Technology Assessment implementation; ACT EU.

Eligible organisation	Key topics discussed
European Association for Bioindustries (EuropaBio)	• ACT EU and CTR implementation; views on variation regulation and guidelines.
International Plasma and Fractionation Association (IPFA) and Plasma Protein Therapeutics Association (PPTA)	• Views on the revised pharmaceutical legislation; impact analysis on Substances of Human Origin (SoHO; Immunoglobulins.
Medicines for Europe	• Priorities for the implementation of the revised pharmaceutical legislation; Union list of critical medicines; repurposing of medicines; EMANS to 2028; biosimilars in the international context.
MedTech Europe	• Views on MD/IVR regulation and AI act; feedback on expert panels for orphan and paediatric medicines; feedback on HTA interface; combination products regulatory pathway; international activities.
Nuclear Medicines Europe	• Views on the revised pharmaceutical legislation; dual nature of radiopharmaceuticals.
Transcelerate	• Embedded clinical trial elements at point of care (pragmatic trials); operationalization of translational safety; modernisation of clinical trial conduct and individual case safety reporting; optimizing data collection; protocol digitalisation/EHR connectivity.
Vaccines Europe	• Vaccines pipelines; Global harmonisation of vaccines licensing; vaccine confidence; Emergency Task Force; Views on the revised pharmaceutical legislation; EMA-ECDC-Vaccines MAHs cooperation.

Key achievement

A total of 22 annual bilateral meetings (13 in 2024; 8 in 2025) between EMA and industry eligible organisations enabled exchange of views and proposals on sector specific matters of mutual interest.

Engagement at operational level

EMA has various platforms and stakeholder groups in place that allow for discussion on operational aspects linked to technical and specific aspects related to innovative medicines and technologies. The goal is to boost mutual understanding of the regulatory requirements, identify opportunities to streamline procedures and discuss guidance needs.

In addition, each platform/group can establish a dedicated focus group with nominated experts from industry aiming at developing on specific proposals that are then presented and agreed during formal interactions.

Industry stakeholder platform meetings

EMA currently hosts three types of platform meetings: Research and Development (R&D), Centralised Procedures (CP) and Pharmacovigilance (PhV). The platforms meet twice a year (R&D, CP) or once a year (PhV) and discuss operational aspects linked to research and development support, centralised procedures and pharmacovigilance.

R&D platform

Four face-to-face meetings of the R&D platform were held during the reporting period. Topics generally concerned evidence generation along the medicine's lifecycle and support activities related to product-development, such as scientific advice and qualification, as well as specifics for paediatric and orphan medicines.

During the reporting period the focus was on the following topics:

- the development support for programme-specific evidence planning, including provision of scientific advice on paediatric developments and piloting of scientific advice on clinical trial design (SAWP-CTCG pilots);
- experience with the new features of the PRIME scheme;
- evidence planning for medicinal products with medical devices and/or companion diagnostics;
- action plan for future-proofing the qualification of novel methodologies platform; moving the stepwise Paediatric Investigation Plan (sPIP) concept from pilot to operation; piloting of the Development Support Coordinator;
- EMA survey on early engagement meetings that foster innovation;
- focus group to explore opportunities for the use of RWD and the generation RWE;
- experience with Portfolio and Technology meetings (PTMs);

- establishment of potential alternatives to animal testing in line with the 3Rs principles; implementation of the new fee regulation;
- completion of onboarding of R&D processes onto the IRIS platform.

Table 9. Overview of R&D platform focus groups

Focus group	Group scope and key deliverable
Use of RWD and generation of RWE	• Share knowledge and experience with use of RWD and generation of RWE to advance integration of relevant and reliable RWE in regulatory decision making.
Scientific advice and PRIME (sounding board)	• Options on better use of discussion meetings; support to the survey on the three PRIME pilots (expedited scientific advice, development tracker, submission readiness meetings); review of the requirements for paediatric scientific advice; consultation on the Development Support Coordinator concept.
Qualification of Novel Methodologies (sounding board)	• Contribution to the action plan on future-proofing the Qualification of Novel Methodologies platform (Action plan); supporting the delivery of the action plan
Paediatrics (sounding board)	• Consultation on the report on the stepwise PIP pilot; contribute to establishing a monitoring system for follow-up on agreed sPIP applications in terms of life-cycle management; review of the requirements for paediatric scientific advice

CP platform

Four face-to-face meetings of the platform on the CP were held during the reporting period. Topics includied pre-submission activities, evaluation and post authorisation.

The focus during the reporting period was on the following topics:

- implementation of the new variation regulation and related classification guideline;
- patient engagement and use of PED in regulatory procedures;
- regulatory challenges for combination products and dynamic regulatory assessment and lifecycle management of combination products at post-authorisation.
- international cooperation programs such as OPEN, ICMRA pilots on collaborative assessment; promotion of EMA documents for reliance;

- process improvement and initiatives on the centralised procedure including improving pre-submission interactions, submission predictability, clock stops and changes to EPAR with the provision of track-changes version of the product information;
- digitalisation activities such as the implementation of IRIS for post authorisation procedures; the establishment of Product Management Service (PMS); the electronic Application form and the optimal submission of the CTD 4.0; ePI pilot outcomes; EMA website;
- initiatives to increase network capacity, such as IncreaseNet;
- regulatory interactions for cancer medicines and Cancer Medicines Pathfinder industry focus group;
- preparedness for good manufacturing practice (GMP) submissions;
- public consultation on the QRD template for product information, and next steps for clinical data publication;
- challenges for biological medicinal products for human use and ongoing follow-up on clinical study data initiatives;
- implementation of the SEND (Standard for exchange if non-clinical data) proof of concept study;
- review EMA activities and regulatory challenges related to the Instrument for Pre-accession Assistance (IPA).

Table 10. Overview of CP platform focus groups

Focus group	Group scope and key deliverable
Regulatory reliance	• The focus group was set up as part of the 9th Platform meeting on the Centralised procedure in Nov 2022. It includes members from the different EU trade associations and EMA International Affairs and Human Medicines Division. The group meets 3-4 times a year. The goals include: – to get a better understanding of EMA as reference regulatory authority (RRA) in global submissions, – outline the current challenges based on EMA as RRA, – suggest recommendations and actions needed to implement unilateral reliance. • The group organised a webinar on 'Regulatory Reliance Tools Unveiled: A practical guide by EMA' on 19 March 2024. '1478 participants from 48 countries, speakers from WHO, EMA, EDA-Egypt and industry covered a number of topics including: WHO considerations on reliance pathways, the EMA assessment outputs for centralised procedures and GMP inspections that can

Focus group	Group scope and key deliverable
	be used for reliance, the experience from an authority on unilateral reliance based on EMA documents. • The group organised a second webinar 'Unlocking efficiency through reliance: Navigating the EMA post-authorisation framework' with participation of WHO, EMA, EDA-Egypt, Industry, on 3 April 2025 with 1,600 participants from across the regulatory and healthcare community worldwide. Very high interest and satisfaction from participants. A Q&A was published afterwards. • A publication 'Reliance into action. Understanding EMA documents to streamline reliance for marketing authorisation applications'[24] was published in Therapeutic Innovation & Regulatory Science. • This joint article highlights the importance and value of reliance pathways in regulatory processes. It highlights how these pathways can facilitate and accelerate access to quality-assured, effective and safe medicinal products while also conserving resources and reducing duplication of regulatory efforts. The article further explores the role of EMA in supporting global implementation of reliance through various cooperation initiatives along with recommendations for achieving broader and more effective adoption of reliance practices. Among these is the need for a more thorough analysis of the different documents provided to relying authorities to identify which ones are essential, supportive or redundant. This analysis aims to streamline the reliance process and avoid duplication of requirements. • The article provides recommendations for implementing reliance, including the use of core documents like the Eudra GMP certificate, approval letter, and European Public Assessment Report (EPAR) as primary sources of information. The accessibility and public availability of these documents enhance transparency and foster trust in EMA's operations.
Pre-submission predictability	• Implementation of a system to collect information from applicants and monitor submissions. • EMA organised a webinar to increase awareness on the importance of early engagement and timely reporting of changes to submission timelines.

[24] https://link.springer.com/article/10.1007/s43441-025-00824-9

Focus group	Group scope and key deliverable
Pre-submission interactions (Pre-SIG)	• Streamline and simplify the EU regulatory processes, with the aim of accelerating the approval timelines.
Proof of concept raw data pilot	• The pilot, a key activity of the joint HMA-EMA Network Data Steering Group, aims to assess whether submitting raw clinical study data and letting regulators assess these can help speed up and improve the medicine-evaluation process and improve patients' access to innovative medicines. • Collaboration with industry remains central, with the renamed "Industry Group on Clinical Study Data" focusing on four key areas: transparency, standardised analyses, IT development, and data standards. Industry feedback highlighted both the benefits (e.g. fewer questions, faster approvals) and barriers (e.g. workload, data privacy concerns) to participation. EMA will continue to engage with stakeholders, expand group membership, and address industry recommendations to support broader involvement and readiness for future regulatory requirements.
Cancer medicines path finder regulatory interactions	• To improve access to cancer medicines for patients in Europe by implementing efficiencies in the centralised authorisation procedure. The focus group was set-up in January 2025 with wide representation from industry associations.

Key achievement

Joint HMA/EMA multi-stakeholder workshop on submission predictability: the event brought together representatives from NCAs, industry, and EMA, to focus on submission predictability and how it can be improved.

PhV platform

The PhV platform held two virtual meetings on the operation of pharmacovigilance activities during the reported period (2024/205). Topics included several aspects related to post-authorisation monitoring activities of medicinal products, such as the management of spontaneous reporting systems in the EudraVigilance (EV) database (development of a masking policy for personal data, proposals for improving case follow-up and reducing

duplication of Individual Case Safety Reports, and compliance reporting to EV) as well as principles for EV monitoring and signal detection.

A recurrent topic was the Periodic Safety Update Report (PSUR), with aspects related to the restructuring of the format of the PSUR assessment report, affecting the extrapolation of safety outcomes. This included alignment of the PSURs' submission dates, i.e. the EURD list, with criteria for PSUR submission for well-established medicinal products.

The forum regularly discussed changes to EU guidance, including ongoing and completed updates to good pharmacovigilance practices. Modules published during the period were:

- Introductory cover note, last updated with final Addendum I to Module XVI on minimising embryo-foetal risks of medicines,
- Annex I – Definitions (Rev. 5),
- Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance,
- Module XVI – Risk minimisation measures (Rev. 3),
- Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-foetal risks

Following the amendments to EC Implementing Regulation (IR) 520/2012 on the performance of pharmacovigilance activities, the pilot of continuous monitoring of EV by MAHs has been carried out. Emerging topics in pharmacovigilance guidance included non-fixed drug combinations as well as drug-device fixed combinations for reporting ADRs.

The forum discussed the expanding use of RWE in regulatory decisions using the DARWIN EU system and EMA in-house studies, as relevant for post-authorisation procedures, PSURs, and signals, as well as the use of the RW metadata catalogue. The use of Artificial Intelligence in pharmacovigilance activities, including in the HMA work plan, the report of the CIOMS Working Group "Artificial Intelligence in Pharmacovigilance", and the development of tools (e.g. AI for literature screening, case adjudication, signal detection, and the "listedness" database) has also been a topic of high interest.

Finally, industry stakeholders were updated on relevant fees per Regulation (EU) 2024/568, effective from 1 January 2025.

Table 11. Overview of PhV platform focus groups

Focus group	Group scope and key deliverable
EudraVigilance Expert Working Group (EV_EWG)	• The EV-EWG is an advisory group within the pharmacovigilance governance structure in the EU Regulatory Network. The mandate is aligned with deliverables for the pharmacovigilance governance and Industry stakeholders are included in the group as experts. In 2025 the group supported the update of the Guideline on good pharmacovigilance practices (GVP) Module VI Addendum II (EMA/178902/2025).

Key achievements

- EMA offered 21 EudraVigilance Individual Case Safety Reporting and 7 EudraVigilance sponsor training to stakeholders between 2024 and 2025. These activities aim at supporting stakeholders in meeting their pharmacovigilance obligations in terms of EudraVigilance access and use. These trainings help users understand functionalities and submit high quality safety data.
- Additional regular training on Extended EudraVigilance medicinal product dictionary (XEVMPD).

Meetings with Interested Parties

During the period reported several committees had reoccurring meeting with Interested Parties to discuss scientific and operational topics. The following tables provide an overview of such meetings and points discussed.

Table 12. Overview of Interested parties meetings

Committee	Key discussions and deliverables
Committee for Veterinary Medicinal Products (CVMP)	• In 2024-2025, the CVMP held two meetings with its interested parties, the topics discussed included roadblocks that might hinder innovation, innovation in the use of data to support medicines registration, AMR, benefit risk guideline, Environmental Risk Assessment (ERA) for companion animal parasiticides, protection of technical documentation, translations of the standard SmPC phrases as annexes to CVMP guidelines, validity period of Art. 23.
Co-ordination Group for Mutual Recognition and Decentralised procedures – Human (CMDh)	• In 2024 and 2025, the CMDh held meetings with interested parties twice a year to engage on topics including CMDh Multi-Annual Workplan to 2028 update, predictability, resources, labelling, package leaflet, digitalisation and procedural optimisation, impact of ERA on marketing authorisation procedures. In line with the CMDh Multi-Annual Workplan, topic-focused meetings were organised, such as the meetings of a subgroup of CMDh with Interested Parties dedicated to the publication of outcomes of safety variations, which took place in February and November 2024.

Committee	Key discussions and deliverables
Co-ordination Group for Mutual Recognition and Decentralised procedures – Veterinary (CMDv)	• In 2024-2025, the CMDv held meetings with interested parties three times a year to discuss the veterinary industry experience and how to overcome challenges on important topics such as variations, the quality review documents (QRD) v9 templates implementation, challenges with the Union Product Database (UPD), and the SmPC harmonisation procedure for generic veterinary medicinal products (VMPs). They also had discussions on e-leaflet, additional national requirements, protection of technical documentation, multicountry-multinational clinical trial applications, AMR.
Committee for Advanced Therapies (CAT)	• In October 2024 the CAT hosted a Scientific Symposium on Advanced Therapy Medicinal Products (ATMPs) - 'Contribution, evolution, revolution'. The event highlighted the significant contributions of the CAT to the regulatory framework for ATMPs in Europe. It showed how CAT has evolved and adapted to new challenges from advanced therapies. The event highlighted CAT's dedication to making sure new treatments are safe, effective, and high-quality. Speakers and participants also shared their vision for the future of ATMPs over the next 15 years.

Key achievement

On the 12th of November 2025, a special event to celebrate the 20th anniversary of the official establishment of CMDh and CMDv was held at EMA. The occasion brought together CMDh/CMDv members, former CMDh/CMDv Chairs, Heads of national competent authorities (NCAs), European Commission representatives and industry stakeholders. It was an opportunity to reflect on two decades of achievements, highlight key milestones and discuss challenges and opportunities for the future of the CMDh and CMDv.

Working Parties and working groups

Network experts and members of committees, working parties and working groups engage regularly with industry stakeholders in more sector specific discussions related to five main areas: quality, clinical and non-clinical development, methodology, veterinary medicines. The engagement includes the four medicines authorisation procedures: centralised, national, mutual recognition and decentralised.

During the reporting period, the workplans of several working parties were updated following public consultation with stakeholders and meetings with interested parties were held to discuss scientific and operational topics.

Table 13. Overview of interested parties meetings

Area	Working Party/ Working Group	Key discussions and deliverables
Non-Clinical	Non clinical Working Party (NcWP)	• Annual meetings with interested parties (IP) were hosted in 2024 and 2025 in addition to ad hoc topic specific meetings (ERA guideline, non-mutagenic impurities). • The NcWP actively engaged with stakeholders to gather feedback on its workplan and on a range of guidance-related topics (including the EMA reflection paper on non-mutagenic impurities, the revision of the EMA ERA guideline, potential revision of ICH S7A, nitrosamines impurities guidance, early considerations for the development of a guideline on microbiome-based medicinal products, implementation of standards for exchange of non-clinical data (SEND) requirements). • Stakeholders were also involved in supporting the voluntary data submission pilot project; the development of a "safe harbour" framework, as well as the retrospective review of the regulatory efficiency of the weight-of-evidence approach (ICH S11). • In parallel, the NcWP continued to monitor several broader legislative and policy developments for potential implications on the non-clinical domain, including the cumulative impact of the green, chemical, and animal welfare agendas on the healthcare sector and the proposed revision of the pharmaceutical legislation.
	Methodology Working Party (MWP)	• Annual IP meetings were hosted in 2024 and 2025 with focus on topics such as biostatistics, modelling and simulation, pharmacokinetics, pharmacogenomics, data science and artificial

Area	Working Party/ Working Group	Key discussions and deliverables
		intelligence, and real-world evidence which will be incorporated in the updated workplan.
	3Rs Working Party (3RsWP) (joint with veterinary domain)	• Annual IP meetings held in 2024 and 2025 were an opportunity for stakeholders to provide input on EMA reflection paper on the use of non-human primates, the EC roadmap on phasing out of animal testing for chemical safety assessment, the use of virtual control groups in non-clinical studies, revision of the EMA Guideline on the principles of regulatory acceptance of 3Rs testing approaches, weight of evidence approach for monoclonal antibodies, workplan prioritisation, update on 3Rs activities from ECHA, EFSA and OECD, regulatory interactions on 3Rs, the International Medicines Regulators' Working Group on 3Rs, cumulative impact of EU legislation on industry 3Rs activities. • Additionally stakeholders were consulted on the 3RsWP workplan 2025-2027, on the 'Reflection papers on the current regulatory testing requirements for human/veterinary medicinal products and opportunities for implementation of the 3Rs' (EMA/CHMP/CVMP/3Rs/742466/2015 Rev. 1 & EMA/CHMP/CVMP/3Rs/164002/2016 Rev. 1) and 'Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation' (EMA/CHMP/55697/2025).
Clinical	Central Nervous System Working Party (CNSWP)	• CNSWP consulted stakeholders on workplan priorities and released the following guidance documents for stakeholders: Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders; draft Guideline on Clinical investigation of medicinal products in the treatment of bipolar disorder; Guideline on Clinical investigation of medicinal products in the treatment of depression; Concept paper on

Area	Working Party/ Working Group	Key discussions and deliverables
		Alzheimer Disease; Concept Paper on Parkison's Disease is imminent.
	Cardiovascular Working Party (CVSWP)	• Public consultation on CVSWP workplan priorities.
	Oncology Working Party (OncWP)	• Public consultation on OncWP workplan priorities.
	Infectious Disease Working Party (IDWP)	• Public consultation on IDWP workplan priorities.
	Haematology Working Party (HAEMWP)	• Public consultation on HAEMP workplan priorities.
Quality	Quality Working Party (QWP) (joint with veterinary domain)	• Two IP meetings were held in 2024 and 2025 where stakeholders discussed a wide range of topics including biopharmaceutical modelling and environmental sustainability; QWP priorities and workplan; reflection paper on qualification of non-mutagenic impurities; development and manufacture of oligonucleotides; recycled solvents and risk of nitrosamine contamination; new active substance assessment relating to the chemical structure.
	Quality Innovation Group (QIG)	• In addition to the multistakeholder interaction via the LLFG, the QIG provided support to medicines developers with 1:1 meeting to obtain early advice on new technologies and for plans for scientific advice with QIG involvement.

Area	Working Party/ Working Group	Key discussions and deliverables
	Biologics Working Party (BWP)	• Two IP meetings were held in 2024 and 2025 to discuss BWP priorities and workplan and a wide range of topics including chemistry manufacturing controls data package for 'sister' bio-manufacturing sites; Guideline on epidemiological data on blood transmissible infections[25]; assessing facility functional equivalency; enabling global implementation of changes to pyrogenicity and endotoxin testing; reconsidering sub-visible particle limits for drug products in siliconized containers; green deal cumulative impact assessment.
	Biosimilar Medicines Working Party (BMWP)	• Two IP meetings were held in 2024 and 2025 to discuss BMWP priorities and workplan and a wide range of topics including the proposed revised pharmaceutical legislation; guideline revision and tailored clinical approach for comparative efficacy studies; reflection paper on a tailored clinical approach.
Veterinary	Antimicrobials Working Party (AWP)	• During 2024 and 2025, AWP actively engaged with stakeholders to gather feedback and provide training on a range of guidance-related topics, such as: – Public consultation of the concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species[26]. – Webinar on the final guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in

[25] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-epidemiological-data-blood-transmissible-infections-revision-1_en.pdf
[26] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-assessment-risk-public-health-antimicrobial-resistance-due-use-antimicrobial-veterinary-medicinal-product-non-food-producing-animal-species_en.pdf

Area	Working Party/ Working Group	Key discussions and deliverables
		food-producing animal species (EMA/CVMP/AWP/706442/2013), held in September 2025. – Survey on diagnostic tests for identifying or excluding the presence of bacterial diseases in animals. The survey was launched to gather information for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals. – AWP also provided advice to EFSA upon request for information about aminoglycosides, in the context of its assessments of renewal applications of genetically modified cotton containing antimicrobial marker resistance genes. – Finally, in October 2024, AWP contributed to the event 'Instrument for Pre-accession Assistance (IPA) EMA training on veterinary aspects of AMR and the One Health approach', to prepare the integration of current candidate and potential candidate countries to the EU.
	Efficacy Working Party (EWP-V)	• During 2024 and 2025, the following guidance documents were released for public consultation: – Revised guideline on data requirements for veterinary medicinal products for zootechnical purposes[27]; – Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances[28];

[27] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-requirements-veterinary-medicinal-products-zootechnical-purposes_en.pdf

[28] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-demonstration-efficacy-veterinary-medicinal-products-containing-antimicrobial-substances-revision-1_en.pdf

Area	Working Party/ Working Group	Key discussions and deliverables
		– Revised guideline on the conduct of efficacy studies for intramammary products for use in cattle[29]; – Revised guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances[30]; – Concept paper for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products[31]; – Concept paper for the revision of the guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees[32]; – Concept paper for the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats[33]. • In March 2024, in the frame of the EMA Veterinary Medicines Info Day, an update from the EWP-V was presented to stakeholders, together with an overview on available guidance for antiparasitic veterinary medicines.
	Environmental Risk Assessment Working Party (ERAWP)	• Public consultation of the concept paper for the development of a reflection paper on the assessment of public health risks related to

[29] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-conduct-efficacy-studies-intramammary-products-use-cattle-revision-3_en.pdf

[30] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-demonstration-efficacy-veterinary-medicinal-products-containing-anticoccidial-substances-revision-1_en.pdf

[31] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-conduct-bioequivalence-studies-veterinary-medicinal-products-ema-cvmp-016-2000-rev4_en.pdf

[32] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-veterinary-medicinal-products-controlling-varroa-destructor-parasitosis-bees-revision-1_en.pdf

[33] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-dossier-requirements-anticancer-medicinal-products-dogs-and-cats-revision-1_en.pdf

Area	Working Party/ Working Group	Key discussions and deliverables
		antimicrobial resistance acquired via the environment, resulting from the use of a VMP[34]. • Public consultation of the concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs[35].
	Immunologicals Working Party (IWP)	• Two IP meetings were held in 2024 and 2025 to discuss the IWP priorities, the IWP workplan, and a wide range of topics relevant to veterinary vaccine availability. These included, among others, vaccine platform technologies master files, vaccine antigen master files, authorisation under exceptional circumstances, multi-strain dossiers, limited markets and association of vaccines.
	Novel Therapies and Technologies Working Party (NTWP)	• Over the past two years, the NTWP has engaged with stakeholders on guidance-related topics, including a public consultation held in July 2024 on the EMA concept paper on the safety data requirements of nanomedicines. • In 2024 a survey on innovative products in development targeted to industry was also launched. • In March 2025, in the frame of the EMA Veterinary Innovation Day, an overview of the guidance developed by the Novel Therapies and Technologies Working Party was given to the veterinary pharmaceutical industry and smaller innovators.

[34] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-assessment-risk-public-health-antimicrobial-resistance-due-use-antimicrobial-veterinary-medicinal-product-non-food-producing-animal-species_en.pdf

[35] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-methodology-environmental-risk-assessment-ectoparasiticidal-vmps-cats-dogs_en.pdf

Area	Working Party/ Working Group	Key discussions and deliverables
	European sales and use of antimicrobials for veterinary medicines Working Group (ESUAvetWG)	• Contribution to the Instrument for Pre-accession Assistance (IPA) EMA training on veterinary aspects of AMR and the One Health approach in October 2024. • Jointly organised an info session with FVE in May 2025 for veterinary practitioners introducing the first ESUAvet report.
	Pharmacovigilance Working Party (PhVWP-V)	• Annual IP meetings were held in 2024 and 2025, the latter in conjunction with the PhV IWG. Topics included the following in 2024: Union pharmacovigilance database and data quality issues; experience with targeted signal management and direct animal healthcare professional communication; veterinary pharmacovigilance promotional material; 2025: signal management- improvements to the signal assessment report template for marketing authorisation holders; experiences with pharmacovigilance inspections; and utilising the ADR website for enhancing veterinary pharmacovigilance communication. • Three PhVWP-V industry stakeholder meetings were held in 2024 and two in 2025 to discuss practical implementation of Regulation (EU) 2019/6 with particular focus on the Union pharmacovigilance database, adverse event reporting and signal management. • The annual VeDDRA review meetings were in 2024 and 2025 for revision of the standard list for reporting suspected adverse events in animals and humans to veterinary medicinal products.

Area	Working Party/ Working Group	Key discussions and deliverables
	Safety Working Party (SWP)	• Public consultation on concept paper for revision of the guideline on user safety for pharmaceutical veterinary medicinal products[36]. • Public consultation on concept paper for development of a guideline on consumer safety of active substances of immunological veterinary medicinal products acting against endogenous targets[37].

During the reporting period, Inspectors working groups had reoccurring with interested parties were held to discuss scientific and operational topics.

Table 14. Overview of interested parties meetings

Working groups	Key discussions/ outputs
Good Clinical Practices Inspectors Working Group (GCP IWG)	• One IP meeting was held in 2025 with focus on ICH E6 R3 related topics such as quality by design, essential records, use of computerised systems and AI in clinical trials.
Good Manufacturing and Distribution Practices Inspectors Working Group (GMDP IWG)	• Two IP meetings were held in 2024 and 2025 focussing on: Annex 1 Implementation and drafting work on Annexes 11, 22 and Chapter 4; GMP for medicinal products for veterinary use and revisions to Annexes 4 and 5; as well as inspection practices and reliance; revision to Chapter I and Annex 15 following ICH Q9(R1); planned revisions for GMP for ATMPs and Annex 14, decentralised manufacturing and GDP.
Pharmacovigilance Inspectors Working Group (PhV IWG)	• Two IP meetings were held in 2024 and 2025 focussing on: inspection findings (harmonisation and information sharing, pre-inspection requests guidance / simplification); Pharmacovigilance System Master File(PSMF) -

[36] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-concept-paper-guideline-user-safety-topically-administered-products_en.pdf

[37] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-consumer-safety-active-substances-immunological-veterinary-medicinal-products-acting-against-endogenous-targets_en.pdf

Working groups	Key discussions/ outputs
	expectations and harmonisation; AI pharmacovigilance inspections.

Engagement with micro, small and medium-sized enterprises

Throughout 2024 and 2025, the EMA's SME Office continued to strengthen its engagement with stakeholders and partners to support small and medium-sized enterprises (SMEs).

Key initiatives included:

- **Enhanced Communication Tools**

  EMA launched a redesigned newsletter to more effectively highlight new and updated regulatory and scientific guidance documents, as well as activities relevant to SMEs across the EU regulatory environment.

- **Training and Education**

  In-person SME Info Days were relaunched, offering tailored sessions on regulatory topics, including training on the new HTA regulation, EMA's fee regulations and medical devices. These events provided opportunities for SMEs to engage with regulatory experts and receive practical guidance.

- **Strategic Collaboration**

  EMA strengthened its collaboration with the European Innovation Council (EIC) and SMEs Executive Agency (EISMEA), supporting EIC beneficiaries through joint training activities and participating at EIC Annual Summits.

- **Stakeholder Feedback and Consultation**

  In 2024, the SME Office conducted a comprehensive survey to gather feedback on the implementation of the SME Regulation. Survey results confirmed the relevance and effectiveness of the regulation and provided valuable insights into the challenges faced by SMEs which will help shape future support activities.

These activities underscore EMA's continued commitment to supporting SMEs as key drivers of pharmaceutical innovation and to ensuring their effective engagement within the EU regulatory framework.

Industry engagement in Agile transformation and Network portfolio governance

During 2024 and 2025, the Agile way of working has become business as usual for the delivery of EMA's digital products. By design, the Scaled Agile Framework (SAFe) adopted by EMA, places users at the centre and involves them throughout both, the design phase and continuous development. Industry stakeholders have continued to participate in strategic portfolio review meetings twice a year; including, for the first time in September 2025, an in-person meeting. Quarterly system demos continued to draw in a high number of industry

stakeholders who actively interact with the agile product development teams by giving feedback and asking questions during the demos.

Industry representatives have contributed directly as subject matter experts to the development of electronic product information (ePI), electronic Common Technical Document version 4 (eCTD v4.0), European Shortages Monitoring Platform (ESMP), Clinical Trials Information System (CTIS), Product Management Service (PMS), Union Product Database (UPD) and Regulatory Procedure Management for Product Lifecycle Management.

The Agency has given regular updates about the agile transformation and the Network Portfolio during ISG meetings, and organised regular webinars on specific topics such as PMS, SPOR, CTIS, as well as one-day meetings, such as PMS info day in May 2025. The changes resulting from the New Fee Regulation were communicated widely to industry stakeholders, before and after the regulation entered into force on 1 January 2025.

Product Lifecycle Management Value Stream launched a quarterly PLM Insights newsletter in April 2024, giving industry and other stakeholders a comprehensive overview of system changes and upcoming events.

Conclusion and next steps

This report provides a comprehensive overview of the key activities carried out during 2024-2025 and highlights the many areas where patients, healthcare professionals, academia and industry (including SMEs) were involved. Throughout this period, EMA's engagement strategy continued to place a strong emphasis on fostering a meaningful multistakeholder dialogue complemented by targeted bilateral exchanges.

This dual approach enabled an enhanced, transparent and inclusive exchange of information and ensured that diverse perspectives were heard and taken into account when developing strategies, workplans and guidance documents and other regulatory outputs. This model of engagement is now firmly embedded in the Agency's operating practice and will remain the foundation for strengthened engagement with key stakeholders in the years ahead.

The coming years will be characterised by the implementation of the new pharmaceutical legislation. EMA's established dialogue platforms such as PCWP, HCPWP and ISG will be instrumental to implementation, ensuring that the views of stakeholder groups continue to inform regulatory activities.

The Agency is planning to pilot a framework for stakeholder ecosystem management and to implement its updated strategic framework for external communication and engagement in 2026-2028. Continued engagement with the extended network of eligible organisations will remain a priority. This engagement will support the European regulatory network in accessing expertise, gathering important information on views and opportunities for joint collaboration, and amplifying important messages aimed at supporting science-based communication about medicines and regulatory decision-making.

A series of upcoming multistakeholder workshops, on innovation in cardiovascular treatments (planned for 2026), patient experience data (planned for 2026), and on vaccines hesitance (planned for 2027), will offer further opportunities to discuss and identify priority actions for future work in these key areas.

More specifically, EMA will further anticipate expertise needs linked to patient, consumer and healthcare professional involvement in its activities, and will continue to promote the open call for remuneration of these experts.

The regulatory support and training for academia will continue through established channels. In addition, continued dialogue with the research community will help ensure that scientific findings are effectively translated into practical applications through the newly established European platform for Regulatory Science Research.

Regarding engagement with industry stakeholders, including SMEs, EMA will maintain its collaboration through the ISG and other established platforms, alongside ongoing support for developers. Furthermore, in light of the rapid pace of technological, scientific, and geopolitical developments, the Agency intends to strengthen its direct engagement with senior leadership within the pharmaceutical sector. This initiative will provide an opportunity will foster deeper strategic dialogue and provide valuable insights from key players involved in the development of medicines. valuable insights from key players in the development of medicines.

Glossary

3RWP	3Rs Working Party
ACT EU	Accelerating Clinical Trials in the EU
ACT EU MSP	Accelerating Clinical Trials in the EU Multi-Stakeholder Platform
AESGP	Association of the European Self-Medication Industry
AHEG	Ad Hoc Expert Groups
AI	Artificial Intelligence
ATMP	Advanced Therapy Medicinal Products
AVC	Association of Veterinary Consultants
BDSG	Big Data Steering Group
BEUC	European Consumer Organisation
BMPWP	Biosimilar Medicinal Products Working Party
BWP	Biologics Working Party
CAT	Committee for Advanced Therapies
CECP	Clinical Evaluation Consultation procedure
CHMP	Committee for Medicinal Products for Human Use
CIOMS	Council for International Organizations of Medical Sciences
CMDh	Co-ordination Group for Mutual Recognition and Decentralised procedures - Human
CMDS	Critical Medical Device Shortages
CMDv	Co-ordination Group for Mutual Recognition and Decentralised procedures -Veterinary
CNSWP	Central Nervous System Working Party
CP	Centralised Procedure
CRO	Contract Research Organisation
CTCG	Clinical Trials Coordination Group
CTD	Common Technical Document
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation
CTTI	Clinical Trials Transformation Initiative
CVMP	Committee for Medicinal Products for Veterinary Use
CVSWP	Cardiovascular Working Party

DHPC	Direct Healthcare Professional Communications
eAF	electronic Application Form
EAP	European Academy of Paediatrics
EAU	European Association of Urology
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EFPC	European Forum for Primary Care
EHN	European Heart Network
EIC	European Innovation Council
ELPA	European Liver Patient Association
EMA	European Medicines Agency
EMNR	European Medicines Regulatory Network
ENPR	European Network of Paediatric Research
EPAR	European Public Assessment Report
ePI	Electronic Product Information
ERA	Environmental Risk Assessment
ESMP	European Shortages Monitoring Platform
ETF	Emergency Task Force
EU	European Union
EUCOPE	European Confederation of Pharmaceutical Entrepreneurs
EU-IN	EU Innovation Network
EUnetHTA	EMA/European Network for Health Technology Assessment
FDA	Food and Drug Administration
FWG	Formulation Working Group
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
GVP	Good Pharmacovigilance Practices
HAEMWP	Haematology Working Party
HCPWP	Healthcare Professionals Working Party
HCP POG	Healthcare Professionals Policy Officers' Group

HERA	Health Emergency Preparedness Authority
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
ICMRA	International Coalition of Medicines Regulatory Authorities
IDWP	Infectious Disease Working Party
IMI	Innovative Medicines Initiative
ISG	Industry Standing Group
ISPOR	The Professional Society for Health Economics and Outcomes Research
IT	Information Technology
ITF	Innovation Task Force
IWG	Inspectors Working Group
JICF	Joint Industrial Cooperation Forum
MAA	Marketing Authorisation Applications
MSP AG	Multi-stakeholder Platform Advisory Group
MDSSG	Joint Industrial Cooperation Forum
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MWP	Methodology Working Party
NCA	National Competent Authority
NcWP	Non-clinical Working Party
NIOG	Nitrosamines Implementation Oversight Group
NIRS	Near Infrared Spectroscopy
NSOEG	Nitrosamines Safety Operational Expert Group
NRG	Name Review Group
OEG	Operational Expert Group
OncWP	Oncology Working Party
OPEN	Opening procedures at EMA to non-EU authorities
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PEC	Patient Engagement Collective
PED	Patient Experience Data
PECP	Performance Evaluation Consultation Procedure

PFAS	Per-, poly- Fluorinated Alkyl Substances
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance Working Party - Veterinary
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	Priority Medicines
QIG	Quality Innovation Group
QoNM	Qualification of Novel Methodologies
QRD	Quality Review of Documents
QWP	Quality Working Party
R&D	Research & Development
RIWP	Rheumatology/Immunology Working Party
RMM	Risk Minimisation Measures
RWD	Real World Data
RWE	Real World Evidence
SAFe	Scaled Agile Framework
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SEND	Standard for exchange if non-clinical data
SMEs	Micro, Small and Medium-sized Enterprises
SPOR	Substance, Product, Organisation and Referential
TIF	Thalassaemia International Federation
UEMO	European Union of General Practitioners
UPD	Union Product Database
UPhD	Union Pharmacovigilance Database
VeDDRA	Veterinary Dictionary for Drug Related Affairs
WONCA Europe	World Organization of Family Doctors

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

+31 (0)88 781 6000

www.ema.europa.eu