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2025 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission

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List of abbreviations

ADR	Adverse Drug Reaction
CAP	Centrally Authorised Product
E2B(R3)	ICH Guideline 'Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports', revision 3
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
EEA	European Economic Area
EDPS	European Data Protection Supervisor
EMA	European Medicines Agency
EV-EWG	EudraVigilance Expert Working group
eRMR	electronic Reaction Monitoring Report
EU	European Union
EVCTM	EudraVigilance Clinical Trials Module
EVDAS	EudraVigilance Data Analysis System
EVPM	EudraVigilance Post-authorisation Module
FDA	Food and Drug Administration (United States)
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
ISO	International Standards Organisation
LMS	Lead Member State
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
MHLW	Ministry of Health, Labor and Welfare (Japan)
MLM	EMA's Medical Literature Review service
MS	Member State
NAP	Nationally Authorised Product
NCA	National Competent Authority
PASS	Post-Authorisation Safety Study
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMS	Product Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Single Assessment
QPPV	Qualified Person responsible for Pharmacovigilance
RMP	Risk Management Plan
SUSAR	Suspected Unexpected Serious Adverse Reaction
WHO	World Health Organization
WHO-UMC	World Health Organisation - Uppsala Monitoring Centre
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

1. Executive summary

Collecting and analysing reports of medical events and problems that occur following the use of a medicine is one of the pillars of the European Union (EU) safety monitoring system. Healthcare professionals and patients play a critical role and are encouraged to continue to report suspected adverse reactions experienced following the use of a medicine.

EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network. Timely detection and assessment of safety signals from sources such as EudraVigilance complements the routine benefit-risk re-evaluation of authorised medicines performed by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) through the assessment of periodic safety update reports (PSURs) and risk management plans (RMPs). EudraVigilance is therefore one of the cornerstones of the EU pharmacovigilance system (See Figure 1).

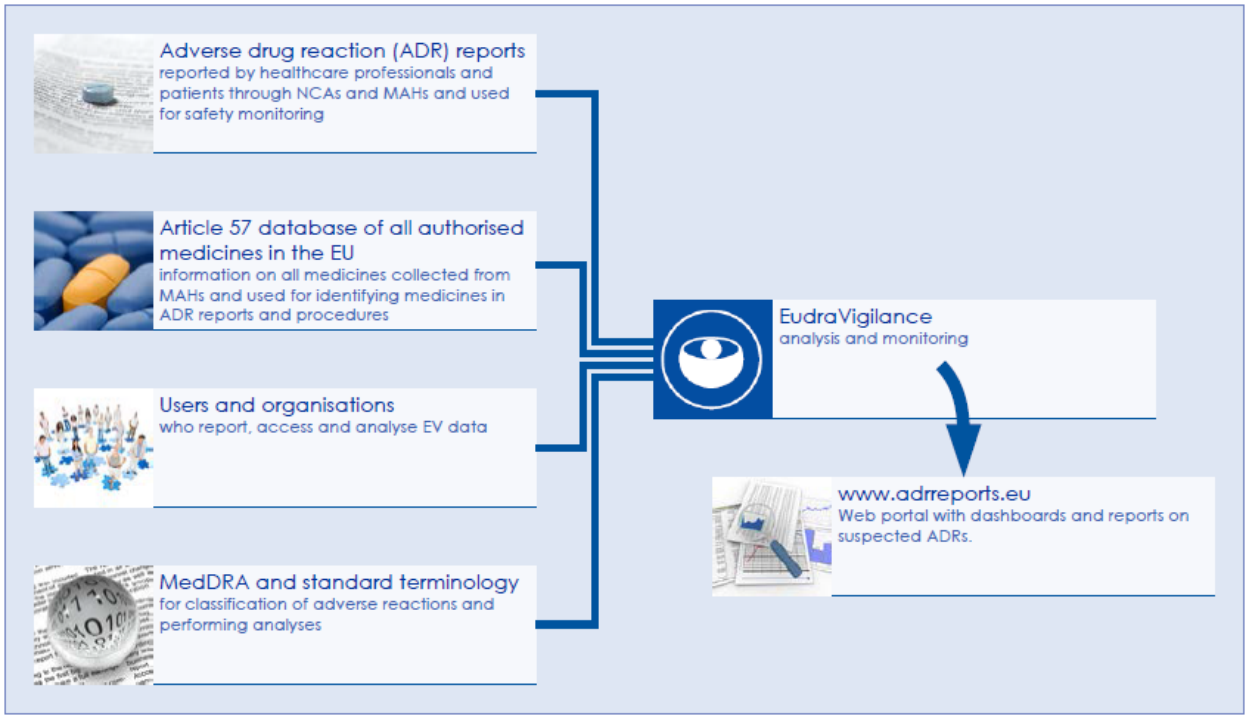

Figure 1. EudraVigilance users, data sources and data use.

The EudraVigilance database is one of the largest pharmacovigilance databases in the world. It currently holds over 31.2 million individual case safety reports (ICSRs) relating to nearly 17.9 million unique suspected adverse drug reaction (ADR) case reports[1] related to medicines for human use. Its functionalities are being continuously enhanced to better support pharmacovigilance activities and ultimately enable EU medicines regulators to protect public health.

This annual report is produced in accordance with Regulation (EC) No. 726/2004, Article 24(2) and summarises the EudraVigilance-related activities for medicines for human use performed in 2025, including:

[1] One case report may contain several ICSRs (i.e. including initial and follow-up ICSRs).

- ***Operation of EudraVigilance, including its new functionalities.*** EudraVigilance is maintained by EMA on behalf of the EU medicines regulatory network. Further functional improvements were delivered in data analysis and signal detection capabilities under the contract with an external vendor in the context of the Signal and Safety Analytics project. Following agreement on the EU business requirements and user acceptance testing performed in 2025, the first phase of the project was delivered in December 2025, with the new systems PV Signal and PV Reports going live for the EMA and a limited number of NCAs users. The objective of this project is to review and replace some of the current tools and user interfaces in place for the Agency and the EU Network in order to deliver evidence from data-driven interrogation of ADR reports more effectively and efficiently.
- ***Collecting and processing suspected adverse drug reaction reports***. In 2025, nearly 1.8 million ICSRs related to suspected ADRs occurring after authorisation were collected and managed in EudraVigilance (a 0.5% increase compared to 2024). The number of ICSRs originating from the European Economic Area (EEA) increased by 1% and non-serious reports decreased by 5%.
- ***Screening for, and review of, potential safety signals***. In 2025, EMA's signal management team undertook a detailed review of 1,201 potential safety signals[2] related to 995 active substances contained in CAPs (an overall decrease of 4% compared to 2024). These potential safety signals were identified following routine screening of the EudraVigilance database and other sources, such as the scientific literature.
- For active substances contained in nationally authorised products (NAPs), the monitoring of ADR reports is shared between NCAs in the EEA. Lead Member States (LMSs) have been appointed to monitor the current list of 1,695 active substances. NCAs also monitor all medicines authorised nationally in their country for which no LMS is appointed.
- ***Supporting the central role of the PRAC in assessing and monitoring the safety of human vaccines and medicines in the EU***. All detected and validated safety signals which are confirmed by a PRAC Rapporteur or LMS are escalated to the PRAC for initial analysis, prioritisation and assessment. In 2025, the PRAC prioritised and assessed 60 confirmed signals. About 85% of these included data from EudraVigilance as part of their evidence base. Of the 60 confirmed signals, 33 were validated by EMA and 27 were validated by the Member States (MSs); 34 were for CAPs, 16 for NAPs and 10 for both CAPs and NAPs.
- ***Transparency and public access to aggregated EudraVigilance data***. The public has access to data on all spontaneous reports of suspected adverse reactions recorded in EudraVigilance through the European database of suspected adverse drug reactions reports. By the end of 2025, this database included information on 4,525 active substances, including 1,040 contained in CAPs and 3,458 in NAPs.
- ***Training and support activities***. Extensive e-learning is available online for all stakeholders, while EU network-specific training is available through the EU Network Training Centre.[3]

[2] A safety signal refers to information on one or more observed adverse reactions potentially caused by a medicine and that warrant further investigation.
[3] https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance/eudravigilance-training-support

2. Operation of EudraVigilance, including its further development

EudraVigilance is a central pillar of pharmacovigilance activities in the EEA. By enabling the effective monitoring of suspected adverse reactions and the timely detection of risks, it plays a key role in safeguarding and promoting public health. EudraVigilance also facilitates the reporting of suspected unexpected serious adverse reactions (SUSARs) during clinical trials.

The key activities undertaken in 2025 are summarised here:

During 2024 and 2025, EMA started working with an external vendor on the Signal and Safety Analytics project. The objective of this project is to review the EudraVigilance data analytics platform and tools in order to enable the Agency and the Network to deliver evidence from data driven interrogation of ADR reports in a more effective and efficient manner.

- Following two rounds of user acceptance testing performed in 2025, the first phase of the project was delivered in December 2025, with the new systems components PV Signal and PV Reports going live. This phase delivered a minimum viable product covering the core functionalities for signal detection and validation by the EMA pharmacovigilance office, as well as selected substances monitored by the national competent authorities (NCAs) that participated as Network subject matter experts. These core functionalities include, among other things, the generation of the electronic Reaction Monitoring Report (eRMR), representing a significant step towards an automated and integrated system for signal detection across the EU network.
- The EMA and the EU network will continue with the next phases of the project during 2026. It is expected that the new systems will be updated with enhanced functionalities and that the new systems will be rolled out to all NCAs.

With regard to the future of the XEVMPD, further analysis and communication activities during 2025 led to agreements within the EU regulatory network concerning the need to replace XEVMPD and to establish central management of medicinal product information. The EMA and the Heads of Medicines Agencies published recommendations for the implementation of human Product Master Data, outlining that PMS (product management system) will be the system replacing XEVMPD. This replacement will not occur before 2028.

On 22 July 2025 the European Commission published the Commission Implementing Regulation (EU) 2025/1466. This amended Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council. Amongst other updates, this regulation modifies the requirements for Marketing Authorisation Holders (MAHs) regarding the monitoring of the EudraVigilance database and eliminates the requirement for MAHs to submit validated signals to the EMA and the NCAs as standalone signal notifications.

- As a result of the amendments to the Implementing Regulation 520/2012, the pilot initiated in February 2018 for MAHs to monitor EudraVigilance for selected active has concluded. The EMA issued a communication and an announcement to indicate the termination of the pilot.
- A dedicated Questions and Answers document has been published to help MAHs adapt to these updated obligations by providing practical guidance. In 2026, GVP Module IX on Signal Management will be updated to ensure alignment with the new legal framework.

In December 2025, EMA launched new EudraVigilance compliance notifications on the adherence of individual case safety reports (ICSRs) to reporting timelines. These compliance reports are intended to support the legislative requirements established in Article 24(3) of Regulation (EC) No 726/2004 and Articles 11 and 15 of Commission Implementing Regulation (EU) No 520/2012, which set out collaboration between the EMA, NCAs, and MAHs to ensure EudraVigilance data quality and compliance with reporting timelines.

- These compliance reports are based on serious and non-serious cases submitted to the EudraVigilance post-marketing module and the EudraVigilance clinical trials module, and are delivered automatically to all senders of ICSRs, including MAHs, NCAs, and sponsors of clinical trials.

A new version of the EudraVigilance access policy (version 5) was published on 16 April 2025. This update was triggered by the audit conducted by the European Data Protection Supervisor (EDPS) on the EudraVigilance system. The updated access policy introduces Stakeholder Group VII, which defines access rights for clinical trial sponsors to the ICSRs they submit. Level 2C access has also been updated to clarify access for medicines regulatory authorities in third countries and international organisations, in accordance with the European Union Data Protection Regulation (EUDPR) (Regulation (EU) 2018/1725).

- Additional updates relate to access policy defined in annexes C and D (Data Protection and Confidentiality Undertakings for MAHs and Academia) to ensure compliance with the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679).

In line with the actions agreed following the EDPS audit, EMA published Module VI Addendum II – Masking of Personal Data in Individual Case Safety Reports Submitted to EudraVigilance. This addendum to Good Pharmacovigilance Practices (GVP) Module VI was developed in collaboration with the EU Network and the EudraVigilance Expert Working Group.

- The addendum provides supplementary guidance to Section VI.C.6.2.2.10 on data protection legislation in GVP Module VI. It outlines the specific data elements that must be masked or omitted when submitting ICSRs to the EudraVigilance database. In addition, it considers the data elements necessary to fulfil pharmacovigilance and safety-monitoring obligations as defined in the EU pharmaceutical legislation.
- All ICSR senders were expected to implement the instructions outlined in this document within a reasonable timeframe. This addendum is considered an integral part of the existing GVP Module VI guidance and represents a crucial step towards the harmonisation of personal data submitted in ICSRs.

The year 2025 marked an important milestone for the Medical Literature Monitoring (MLM) service, with the achievement of 10 years since its implementation in July 2015. During these 10 years, the MLM service created over 58,000 individual cases and transmitted more than 101,000 ICSRs to EudraVigilance.

- The work performed by the MLM service on behalf of MAHs avoids duplication of effort, prevents the same reports from being entered into databases by multiple MAHs, and enhances the quality and consistency of the data reported.

Following the adoption of the first revision of the ICH-E2D Guideline on *post-approval safety data: Definitions and Standards for the Management and Reporting of Individual Case Safety Reports*, EMA initiated preparatory work required for the implementation of the revised definitions of patient support programmes (PSPs) and non-PSP programmes, as well as the new documentation requirements for organised data collection systems (ODCSs) not conducted according to a protocol.

- This update to the ICH E2D guideline will also trigger the implementation of three new values in ICH E2B(R3) for data element C.1.3, 'Study type where reaction(s)/event(s) were observed'. During 2026, work will start on the revision of GVP Module VI and the EU ICSR Implementation Guide to reflect the changes introduced by ICH E2D(R1).

Following the publication of the Data Quality Framework for EU medicine regulation, and the multi-stakeholder workshop for Adverse Drug Reaction reporting that occurred in 2024, the EMA and the EU network have prepared the draft of the ADR chapter which is expected to be released for public consultation during 2026.

The 6-monthly systematic reviews of the list of EudraVigilance users and the verification of their access role were performed in March and September 2025 through the EMA account management system. The review was performed by the QPPV/Responsible Person (RP) user (or trusted deputy) without major incidents; any roles that were not assessed within one month of the initiation of the review process were revoked. This process, first implemented in 2023, is now well-established and suitable to ensure that the data held in EudraVigilance is protected.

Data management activities were carried out as described in the guide on EudraVigilance data management activities by the European Medicines Agency.

EMA continued providing the monthly publication of spreadsheets with information on nullified ICSRs to facilitate case reconciliation by NCAs and MAHs.

The EudraVigilance Expert Working group (EV-EWG) met twice in 2025, on 16 April and 16 October. The new EV-EWG work programme for 2025-2026 was published in 2025. The EMA-MSs Pharmacovigilance Business Team met quarterly in 2025 to discuss, agree on, and issue guidance for the different EudraVigilance operations.

On 5 November 2025, EMA and the Heads of Medicines Agencies (HMA) hosted the first EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection.

- The forum's main objectives were to inform stakeholders about ongoing and forthcoming developments in international guidance, adverse drug reaction case processing, signal management, and data analysis in EudraVigilance related updates, and to foster stakeholder engagement and collaboration.
- The forum was attended in person by 25 NCA experts and online by almost 600 people, with several hundred more joining via the online broadcast.

The EudraVigilance training page was updated to launch a training course on the enhanced EudraVigilance system and a course for clinical trial sponsors, which will be available in 2026.

3. Data collection and data quality

Medicinal product information

In the database of all medicines authorised in the EU (the so-called "Article 57 database"), the total number of medicinal product entries provided by MAHs in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) was 1,434,187 (as of 31 December 2025), regardless of authorisation status (e.g. valid, withdrawn etc.). These entries relate to both CAPs and NAPs. These data are a very important public health resource, as they allow for better identification of medicines in reports of suspected ADRs, enhanced coordination of safety monitoring, faster implementation of new safety

warnings and improved communication with stakeholders. The dataset also includes information on the location of the Pharmacovigilance System Master File (PSMF). Full details on these items are presented in Annex III.

Reporting of ADRs

Every report of a suspected ADR by a patient or healthcare professional contributes to safety monitoring and thus to the safe and effective use of medicines. Additionally, robust research[4] has demonstrated that collating reports into big datasets and using statistical analyses of the data allows for the timely detection and management of safety issues to be detected. In this context, the reporting of suspected ADRs into EudraVigilance underpins the operation of the EU pharmacovigilance system.

In 2025, 1,765,581 ICSRs were collected and managed in EudraVigilance. This figure represents a 0.5% increase compared to the numbers recorded for 2024 and is characterised by an increase in EEA reports (+1%) and a decrease in non-serious reporting (-5%).

The number of reports submitted directly by patients and consumers through the NCAs and MAHs (113,300) saw a 11% decrease compared to the previous year. Detailed information relating to these figures is provided in Annex II.

EudraVigilance also continued to support the reporting of SUSARs that occurred during clinical trials, in accordance with the Clinical Trials Regulation[5] (see Annex II).

Data quality

Data quality assurance is vital to support pharmacovigilance, providing the basis for robust data analysis, scientific assessment and decision-making aimed to protect public health. This is a shared responsibility between EMA, NCAs and MAHs. In accordance with the pharmacovigilance legislation, EMA has an operational role and undertakes procedures which ensures the quality and integrity of data collected in EudraVigilance. These include providing guidance and training, defining business rules for data entry, ensuring correct identification of medicinal products associated with reported suspected adverse reactions, removing duplicate reports, ensuring timely submission of suspected adverse reactions, adhering to coding practices and standards, and adequately documenting cases.

In addition to the above-mentioned provisions, the Agency’s efforts to improve data quality include providing feedback to individual reporting organisations concerning ICSRs, performing data quality reviews of XEVMPD submissions and conducting a classification of adverse reaction reports using the medicinal product data of the XEVMPD. These activities are summarised in Annex IV.

4. Data analysis

The EU pharmacovigilance system has been efficient in detecting safety issues and ensuring they are appropriately managed. Few examples: in 2025 PRAC evaluated a signal of adverse events requiring hospitalisation in elderly patients with Chikungunya vaccine (live) which subsequently led to a referral triggered by the European Commission. EudraVigilance analysis played a central role in the assessment of this signal. The committee also evaluated the signal of a new aspect of the known risk of neutropenia/ agranulocytosis with potential impact on the risk minimisation measures in association

[4] Alvarez Y et al. Validation of statistical signal detection procedures in EudraVigilance post-authorization data: a retrospective evaluation of the potential for earlier signalling. Drug Saf. 2010; 33(6):475-487.
[5] On 31 January 2022, the Regulation repealed the Clinical Trials Directive (EC) No. 2001/20/EC and national implementing legislation in the EU Member States, which regulated clinical trials in the EU until the Regulation's entry into application.

with clozapine. The signal resulted in a DHPC and PI updates. For the full list of safety issues assessed see table 8.

Monitoring of EudraVigilance data is a shared responsibility undertaken collaboratively by NCAs and EMA. The safety information contained in EudraVigilance is continuously screened; this process is facilitated by the use of eRMRs. In 2025, 14,555 eRMRs were generated for NCAs and EMA's signal management team, for a total of 2,799 substances. These were produced on either a monthly, three-monthly, or six-monthly basis.

Screening of these outputs is one of the principal sources of validated safety signals, i.e. information on observed ADRs potentially caused by a medicine that warrant further investigation. For CAPs, EMA is responsible for the monitoring: 1,201 potential safety signals were reviewed by the Agency in 2025 (see Annex V for further breakdown). For active substances contained in NAPs, the monitoring of ADR reports in EudraVigilance and in national databases is shared between the NCAs, in line with the 'List of substances and products subject to worksharing for signal management' which defines a LMS for each active substance. It currently includes 1,695 active substances. NCAs also monitor all medicines authorised nationally in their country for which no LMS has been appointed. Substances and combinations of substances that were no longer eligible for work-sharing, or were no longer authorised in Member States, were removed from the eRMR monitoring work-sharing.

All detected and validated signals that are confirmed by the Rapporteur or LMS are escalated to the PRAC for initial analysis, prioritisation and assessment. In 2025, the PRAC assessed 60 confirmed signals (see Figure 2).

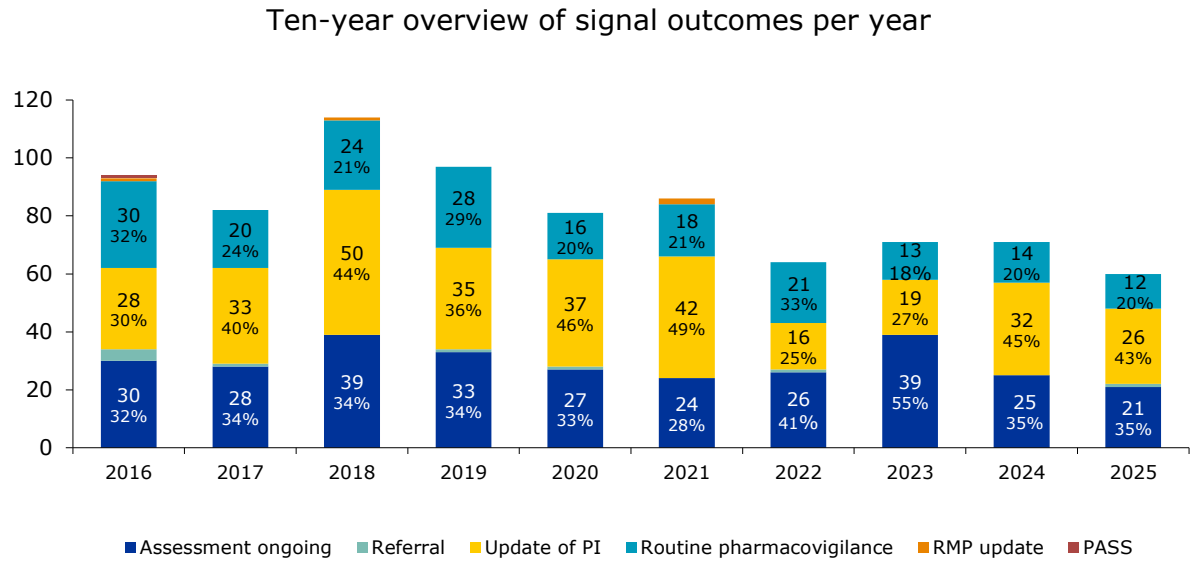

Figure 2. Overview of signals assessed by the PRAC

Of the 60 signals assessed by the PRAC, (85%) included data from EudraVigilance. Twenty-six (43%) resulted in a recommendation for an update of the product information for patients and healthcare professionals, thus providing updated guidance on the safe and effective use of the affected medicines (45% in 2024). Maintaining routine safety monitoring was considered sufficient for 12 signals (20%). The evaluation of 21 signals (35%) was ongoing at the end of 2025, including 13 via a follow-up signal procedure and 8 as part of upcoming PSURs/PSUSAs. One signal led to a referral procedure and 1 resulted in a DHPC (as the outcome concerned an update of the product information and a and a DHPC, this signal is merged with "update of PI" in Figure 2 above).

EudraVigilance monitoring therefore facilitated detection and assessment of new ADRs, as well as new aspects of already known ADRs such as changes in their frequency or severity. This, in turn, resulted in prompt warnings and advice to prescribers and patients. Further details on all signals assessed by the PRAC in 2025 can be found in Annex V. The progress of process improvements and simplifications in signal management is detailed in Annex VI.

From February 2018 to December 2025, the network received 61 standalone signal notifications from MAHs. Of these, 13 signals were considered valid and processed accordingly, ultimately leading to 1 signal being confirmed and subsequently evaluated by PRAC in 2023 (no new signals were confirmed in 2024 nor 2025). The pilot programme on signal detection by MAHs in EudraVigilance was terminated given the Implementing Regulation (EU) No 520/2012 as amended (Implementing Regulation (EU) 2025/1466), came into force.

5. Transparency, communication and training

PRAC agendas, minutes, and signal recommendations, continue to be published monthly on the EMA website, including PRAC recommendations for product information updates following signal assessments translated into all official EU languages.

Aggregated EudraVigilance data has been publicly accessibly since 2012 via aggregated reports available in the European database of suspect adverse drug reactions reports

(https://www.adrreports.eu/). This information was enhanced in November 2017 through the provision of additional outputs, including line listings and ICSR forms. By the end of 2025, the website provided information on a total of 4,525 active substances, of which 1,040 were contained in CAPs and 3,485 in NAPs.

In line with the EudraVigilance access policy, EMA continued responding to requests for information related to EudraVigilance and access to EudraVigilance documents. The Agency responded to a total of 25 of these requests in 2025 (1 more than in 2024). These consisted of requests from the EU regulatory network as well as external requests requiring tailored EudraVigilance searches given that these requests could not be addressed with the information provided via www.adrreports.eu. More details are provided in Annex VII.

The Agency organised several training courses, operational and technical support activities, many of which were open to all stakeholders:

- 9 training sessions on EudraVigilance ICSR submissions, with 175 users trained in total;
- 3 training sessions on EudraVigilance ICSR submissions for clinical trial sponsors, with 45 users trained in total;
- the EMA/HMA Multi-Stakeholder Forum on EudraVigilance and Signal Detection.

6. Conclusion

EudraVigilance continued to play a crucial role in 2025, and it remains a central pillar for pharmacovigilance activities in the EEA.

EudraVigilance currently contains over 31.2 million ICSRs, corresponding to nearly 17.9 million unique suspected ADR case reports. In 2025, around 1.77 million ICSRs were collected and managed in EudraVigilance, a 0.5% increase compared to the previous year. Approximately 6% of the ICSRs received in 2025 were submitted directly by patients and consumers through NCAs and MAHs.

Based on these reports, over 14,500 statistical outputs were produced to facilitate the continuous monitoring of the safety of medicines by the Agency and NCAs and the detection of signals which were subsequently assessed by the PRAC.

Some important changes were implemented in 2025, such as the termination of the signal detection by MAHs in EudraVigilance pilot, as a result of the adoption of Commission Implementing Regulation (EU) 2025/1466. EMA began disseminating EudraVigilance compliance reports, assessing compliance to reporting timelines by MAHs, NCAs and sponsors of clinical trials. Finally, an important milestone was reached in the development of the new data analytics platform and tools (i.e. the Signal and Safety Analytics project): a minimum viable product covering the core functionalities for signal detection and validation was deployed at EMA in December 2025. Further enhancements for EMA and the EU network are expected in 2026.

The operation of EudraVigilance thus continues to contribute significantly to the protection of public health and the reduction of risks associated with the use of medicines.

Annex I – Summary of EudraVigilance related activities

Implementation activities	Status
Operation and maintenance of EudraVigilance by EMA in collaboration with Member States. [*Legal basis:* Regulation (EC) 726/2004, Article 24]	New system operational since 22 November 2017. Maintenance continued.
Initiation of pilot for safety signals validated and notified by MAHs based on EudraVigilance monitoring. [*Legal basis:* Commission Implementing Regulation (EU) 520/212, Article 18 and 21]	Started 22 February 2018. Ended in 2025.
Data quality review and duplicate management of suspected adverse reaction reports in EudraVigilance. [*Legal basis:* Regulation (EC) 726/2004, Article 24(3)]	Continued during 2025.
Collection of core data set for all medicinal products authorised in the EU in EudraVigilance. [*Legal basis:* Regulation (EC) 726/2004 Article 57(2), second subparagraph]	Continued during 2025.
Provision of all suspected adverse reaction reports occurring in the Union to the World Health Organization Uppsala Monitoring Centre (WHO-UMC) directly from EudraVigilance. [*Legal basis:* Regulation (EC) 726/2004 Article 28c(1), second subparagraph]	Continued during 2025.
Operation of the signal management processes based on EudraVigilance data, including the monthly provision of eRMRs to LMSs for non-CAPs and provision of eRMRs to MAHs, as well as the production and review of eRMRs for CAPs by EMA. [*Legal basis:* Regulation (EC) 726/2004, Article 28a Directive 2001/83/EC, Article 107h. Commission Implementing Regulation (EU) 520/212, Article 18(2), 18(3), 21 and 23].	Continued during 2025.
Access to adverse reaction data held in EudraVigilance for CAPs and certain substances included in NAPs http://www.adrreports.eu/ [*Legal basis:* Regulation (EC) 726/2004, Article 24]	Continued during 2025.
Operation of the medical literature monitoring service. [*Legal basis:* Regulation (EC) 726/2004, Article 27]	Continued during 2025.

Annex II – EudraVigilance data-processing network and number of suspected adverse reaction reports processed by the EudraVigilance database

EudraVigilance data-processing network (EudraVigilance gateway)

The EudraVigilance data-processing network, as referred to in Article 24 of Regulation (EC) No. 726/2004, facilitates the electronic exchange of suspected ADR reports between the Agency, NCAs and MAHs for all medicines authorised in the EEA. This network, known as the EudraVigilance gateway, has been in continuous operation since December 2001.

EudraVigilance database

For medicinal products authorised in the EEA, ADR reports are collected from both within and outside the EEA. Each individual case in EudraVigilance refers to a single patient; an individual case is composed of at least one ICSR (or ADR report), called the initial report, which might be complemented by follow-up reports with updated or additional information on the case. These reports, both the initial and follow-up ICSRs, constitute a unique suspected ADR case report.

By 31 December 2025, the EudraVigilance database held a total of 31,253,245 ICSRs, referring to 17,898,709 individual cases (Figure 3.). The EudraVigilance post-authorisation module (EVPM) contained 29,097,802 ICSRs (originating from 17,347,873 individual cases) and the EudraVigilance clinical trial module (EVCTM) contained 2,155,443 ICSRs (originating from 550,836 individual cases of Suspected Unexpected Serious Adverse Reactions [SUSARs]).

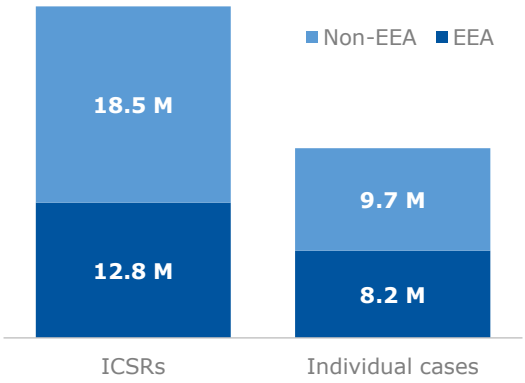

Figure 3. Number of ICSRs versus individual cases received in the EudraVigilance database (EVPM and EVCTM) from its inception in December 2001 until 31 December 2025, split by origin of the report (in or outside the EEA).

Figure 4. presents the number of ICSRs processed per year in EVPM stratified according to cases occurring in and outside of the EEA. Figure 5. presents the total number of ICSRs received in EVPM for 2025, compared to the number of individual cases they are referring to.

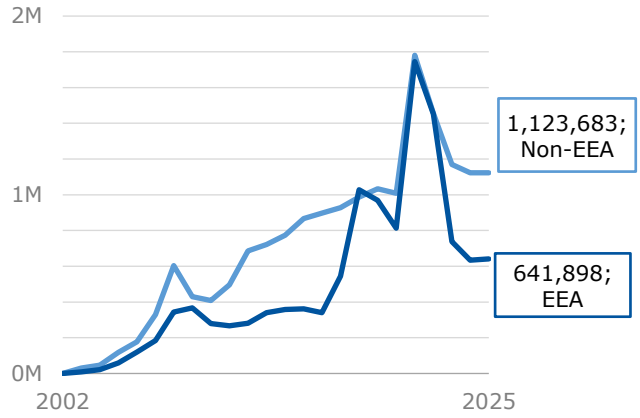

Figure 4. Number of ICSRs processed per year in EVPM split by cases occurred inside and outside the EEA.[6]

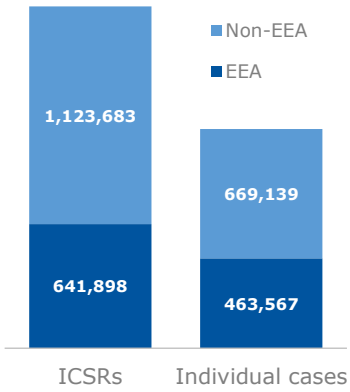

Figure 5. Number of ICSRs versus the number of individual cases in 2025 in EVPM.

The numbers presented in Figure 6. and Figure 7. refer to the ICSRs received in EVPM. A total of 29,097,802 EVPM ICSRs were processed from 2002 to the end of 2025; of these, 1,765,581 EVPM ICSRs were processed in 2025. This represents a 0.5% increase compared to the numbers recorded in 2024; this reflects an increase in reporting in the EEA (i.e. +1%) and a decrease in non-serious reporting (-5%) compared to 2024. ICSRs are subsequently made available by the Agency in EudraVigilance to facilitate signal detection and data analysis by the Agency and NCAs in the Member States.

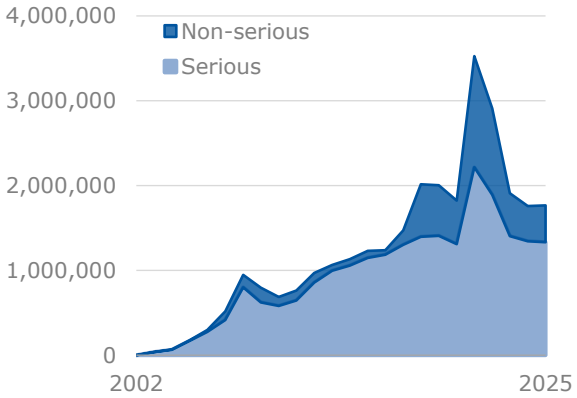

Figure 6. Number of ICSRs processed per year in EVPM.

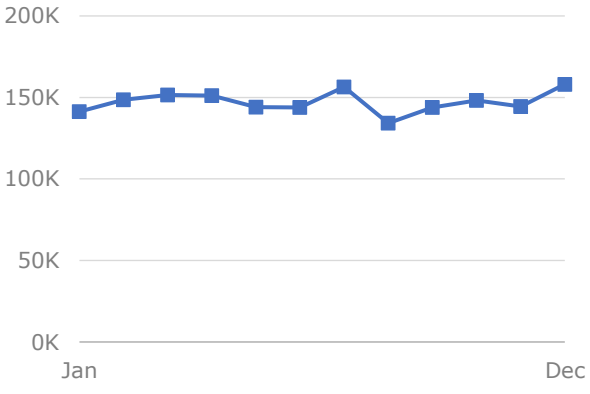

Figure 7. Number of ICSRs processed per month in EVPM in 2025.

[6] Non-serious EEA ADR reports need to be submitted only since November 2017.

In 2025, 113,300 ICSRs were submitted by EEA patients and consumers through the NCAs and MAHs; these concerned to 90,844 individual cases. This represents an 11% decrease compared to 2024 (Figure 8.).

In 2025, 1,322,748 spontaneous ICSRs (EEA and non-EEA) were processed, a slight decrease compared to previous year (-0.6%, Figure 9.).

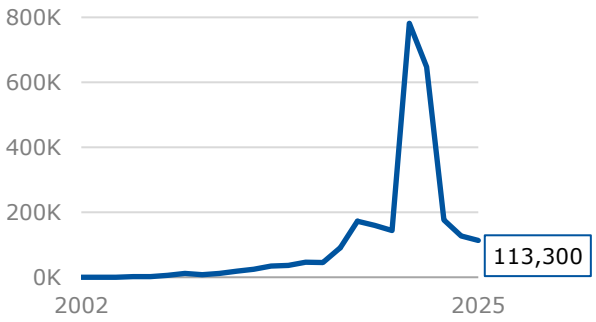

Figure 8. Number of ICSRs reported by EEA patients and consumers through the NCAs and MAHs.

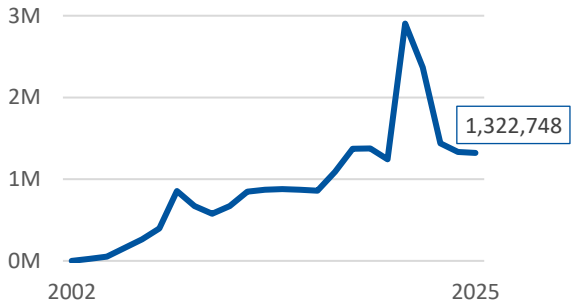

Figure 9. Number of spontaneous ICSRs per year (EEA and non-EEA).

Table 1. Number of EVPM ICSRs transmitted in 2025. Counts for 2024 are provided for comparison.

	2025	2024
	Total count	Total count
ICSRs processed	1,765,581	1,757,524
ICSRs originated in EEA	641,898	633,662
Non-serious ICSRs	435,085	415,462
ICSRs submitted by EEA patients and consumers through the NCAs and MAHs	113,300	127,329

E-reporting status for MAHs and sponsors of clinical trials

- 1,174 MAHs (at headquarter level) sent reports to EVPM in 2025, a 2.9% increase compared to 2024;
- 690 sponsors of clinical trials (at headquarter level) sent reports to EVCTM in 2025, a 6% decrease compared to 2024;
- A total of 20,331 individual MAH users and 9,826 sponsors of clinical trials are registered in EudraVigilance.

Table 2. outlines the total number of individual cases and ICSRs transmitted by MAHs and sponsors to EVPM and EVCTM in 2025; Figure 10. illustrates the 15-day and 90-day reporting compliance of MAHs when reporting to EVPM.

15-day reporting compliance is calculated by subtracting the date the ICSR was received by the EudraVigilance gateway (EV message gateway date) from the date of receipt of the most recent information ('date of most recent information for this report'– ICH E2B(R3) C.1.5). The receipt date is

treated as day 0, giving the MAH 15 days from that day to transmit the reports. Nullification, amendment and error reports are excluded from the compliance calculations.

In 2025, 287,551 ICSRs and 181,894 SUSARs (total 469,445) were rerouted to NCAs following receipt of the reports from MAHs and sponsors in EudraVigilance. A total of 658,743 ICSRs were forwarded to the WHO. A total of 219,318 download requests were made by MAHs, resulting in 6,436,079 ICSRs downloaded from the EudraVigilance database while adhering to the EudraVigilance access policy.

Table 2. Number of ICSRs and unique cases transmitted by MAHs and sponsors to EVPM and EVCTM in 2025.

EV Module	Transmission type	Count
EVPM	ICSRs	1,526,106
	Individual cases	883,993
EVCTM	ICSRs	169,724
	Individual cases	49,167

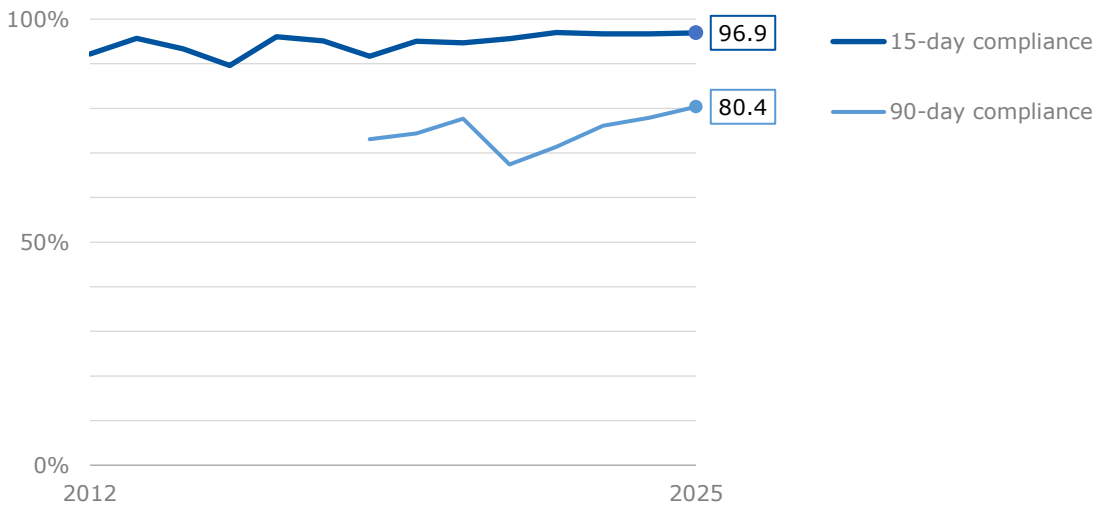

Figure 10. Compliance rate for serious (15-day) and non-serious (90-day) ICSRs to EVPM for all MAHs and sponsors by year. Non-serious ICSRs need to be submitted since November 2017.

EudraVigilance database and support of signal management process

In 2025, a total of 14,555 eRMRs were generated for2,799 active substances, to facilitate the continuous monitoring of the safety of medicines by both EMA and NCAs in the EEA. Of these:

- 7,731 were generated on a monthly basis;
- 5,169 were generated on a 3-monthly basis, and;
- 1,655 were generated on a 6-monthly basis.

E-reporting status for NCAs

- All NCAs in the EEA are authorised to transmit safety reports to EudraVigilance;
- All NCAs report ICSRs to EVPM, except for Liechtenstein; all ICSRs occurring in Liechtenstein are transmitted to EudraVigilance by MAHs.
- A total of 1,356 individual NCA users are registered in EudraVigilance.

Error! Reference source not found.outlines the total number of individual cases and ICSRs transmitted by NCAs to EVPM and EVCTM in 2025. Figure 11. illustrates 15-day reporting compliance of NCAs when reporting serious cases to EVPM and 90-day reporting compliance for non-serious cases.

15-day reporting compliance is calculated by subtracting the date the ICSR was received by the EudraVigilance gateway (EV message gateway date) from the date of receipt of the most recent information ('date of most recent information for this report'– ICH E2B(R3) C.1.5). The receipt date is treated as day 0, giving the NCA 15 days following that date to transmit the reports. Nullification, amendment and error reports are excluded from the compliance calculations.

Table 3. Number of ICSRs and unique cases transmitted by NCAs to EVPM and EVCTM during 2025.

EV Module	Transmission type	Count
EVPM	ICSRs	239,475
	Individual cases	201,959
EVCTM	ICSRs	93
	Individual cases	12

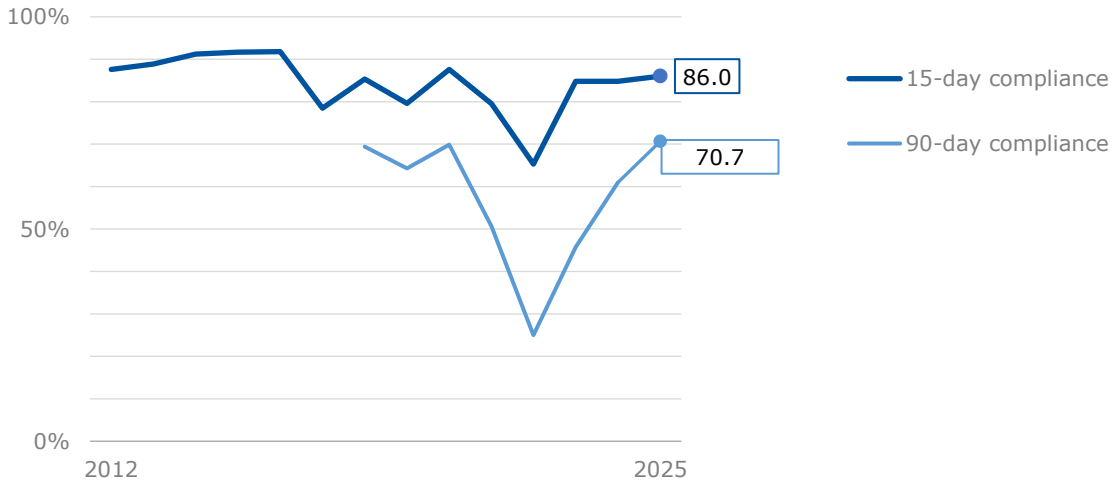

Figure 11. Compliance rate for serious (15-day) and non-serious (90-day) ICSRs to EVPM for all NCAs by year. Non-serious ICSRs need to be submitted since November 2017.

During 2025, the following two NCAs transmitted SUSARs to EVCTM (SUSARs from other countries were received directly from sponsors of clinical trials):

- Germany (Federal Institute for Drugs and Medical Devices);
- Netherlands (Central Committee on Research Involving Human Subjects).

Annex III - Total number of medicinal product submissions by MAHs

In 2014, the Agency published an updated format for medicinal product information and updated the XEVMPD, in order to ensure that the database could meet the following objectives:

- facilitating data analysis and signal detection to better support safety monitoring for patients;
- providing access to EudraVigilance data:
    - reactively in accordance with the revised EudraVigilance Access Policy;
    - proactively:
        - to MAHs to enable the performance of signal detection activities,
        - to healthcare professionals and the public via the www.adrreports.eu website.
- reliably identifying medicinal products that fall within the scope of the PSUR submissions and referral procedures;
- supporting literature monitoring activities;
- facilitating NCAs' inspections (e.g. sharing information on Pharmacovigilance Master File location);
- computing pharmacovigilance fees.

These data are validated by the Agency (see Annex IV for a summary of the validations performed in 2025). Table 4. and Figure 12. provide a summary of the data submitted.

Table 4. Summary of medicinal product submissions to the XEVMPD.

Total number of medicinal product submissions by MAHs by 31 December 2025 in accordance with Article 57(2), second subparagraph of Regulation (EC) 726/2004	
Total number of medicinal product submissions (counted on the basis of EudraVigilance codes).	1,434,187
Total number of MAHs (legal entities) established in the EU (corresponding to EudraVigilance codes).	6,503

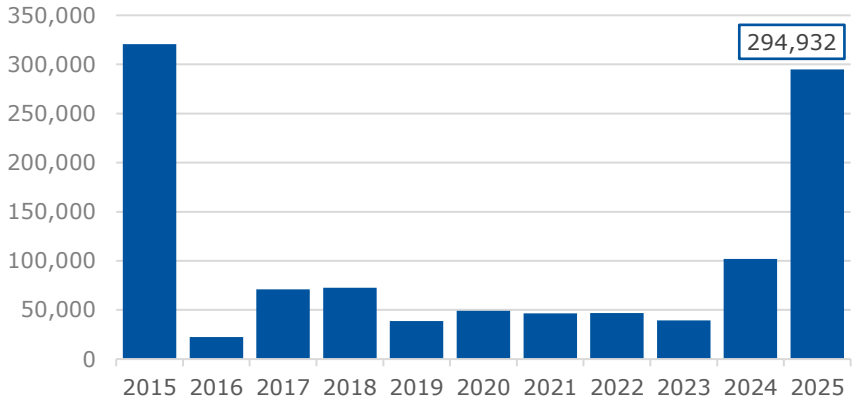

Figure 12. Yearly number of medicinal product submissions (counted on the basis of EudraVigilance codes) since 2015.

A surge in medicinal product submissions was observed in 2025 due to continued pack size submission from xEVMPD to product management service (PMS). Since the second half of 2024, each new product record must make reference to one pack size. This will support the European Shortages Monitoring Platform (ESMP).

The EudraVigilance code is the level to which a product is defined in the context of the XEVMPD. It encompasses the following parameters:

- Name of the medicinal product;
- MAH;
- Authorising national competent authority;
- Authorisation Country;
- Active ingredient(s);
- Strength(s);
- Pharmaceutical form;
- Authorisation number;
- Authorisation procedure;
- Pack size (only if Competent Authority assigns unique marketing authorisation number at package level).

Annex IV - EudraVigilance data quality activities

In accordance with Regulation (EC) No 726/2004, Article 24(3), the Agency operates procedures to ensure the quality and integrity of the information collected in EudraVigilance in collaboration with the EU medicines regulatory network. This includes identifying duplicate individual cases, performing the coding of reported medicinal products and active substances, and providing feedback on the quality of both ADR reports and medicinal product information sent by NCAs, MAHs and sponsors. Table 5. includes metrics for the data quality activities performed by the Agency from 2023 to 2025. Master reports generated from duplicated data more than doubled in 2025 compared to 2024; this trend is partially attributable to a change in the weighing algorithm (leading to more precision in identifying duplicates) and clearing smaller sized clusters of duplicate cases originating from Health Canada data. Additionally, a 52% increase was observed in 2025 for quality reviewed medicinal products in xEVMPD compared to 2024. This can be attributed to the requirement for MAHs to provide pack size submissions. By 31 May 2025, this was obligatory for products on the critical medicines list.

Table 5. Summary of EudraVigilance data quality activities in 2025.

Data quality area	Activities performed	2025	2024	2023
Identifying and managing duplicate individual cases	Duplicate couples assessed	202,820	205,187	190,689
	Master reports generated based on duplicated data	106,666	52,661	105,033
Coding of reported medicines and active substances	Reported medicinal products and active substance terms recoded	84,358	137,335	77,598
	ADR reports recoded (ICSRs)	66,150	109,037	66,461
Providing feedback on data quality	Organisations subject to ICSR data quality review	191	186	160
	Medicinal products in XEVMPD quality reviewed (and corrected if necessary)	284,340	187,381	163,013

Annex V – Signal detection

Signal detection by EMA

A signal refers to information on one or more observed suspected adverse reactions potentially caused by a medicine and that warrant further investigation. In 2025, EMA's signal management team undertook a detailed review of 1,201 potential safety signals (i.e., drug-event pairs from screening of the EudraVigilance database, medical literature or information received from other regulatory authorities). This represents a 4% decrease in the total number of reviewed signals compared to the previous year (see **Table 6**).

Table 6. Potential signals reviewed

Potential signals reviewed	2025	2024	2023	2022	2021	2020
Total	1201	1254	1364	1605	1829	1888
Change from previous year	-53	-110	-241	-224	-59	+82
% change from previous year	- 4%	- 8%	-14%	-12%	-3%	+4%

EudraVigilance screening continues to be the major source of EMA's potential signals, with 68% of reviewed potential signals in 2025 originating from EudraVigilance screening (compared to 76% in 2024). Scientific literature screening accounted for 27% of potential signals in 2023 (22% in 2024). Additionally, cooperation with other regulatory authorities worldwide accounted for 4% of potential signals (only 1% in 2024), including notifications from the World Health Organisation - Uppsala Monitoring Centre (WHO-UMC), the United States' Food and Drug Administration (FDA), Japan Pharmaceuticals and Medical Devices Agency (PMDA)/Ministry of Health, Labor and Welfare (MHLW), and Health Canada. The breakdown of actions taken by potential signals opened by EMA has been relatively stable over time, with approximately 3% of reviewed signals being validated for further PRAC assessment (see **Table 7**).

Table 7. Overview of potential signals by action taken is shown below

Action taken	Number of potential signals - 2025	% of total	Number of potential signals - 2024	% of total
Not validated (closed)	894	74.4%	953	76.0%
Monitored	99	8.2%	83	6.6%
Ongoing	175	14.6%	179	14.3%
Prioritised and assessed by PRAC	33	2.7%	39	3.1%
Total	**1,201**	100.0%	**1,254**	100.0%

Overview of signals prioritised and assessed by the PRAC

All detected validated signals that are confirmed by the Rapporteur or LMS are brought to the attention of the PRAC for initial analysis and prioritisation, and assessment. The number of confirmed signals prioritised and assessed by the PRAC in 2025 was 60. Of these 60, 33 were validated by EMA and 27 by the NCAs during ongoing safety monitoring through screening of reaction monitoring reports, ADR reports, medical literature and other safety data.

Twenty-six of the assessed signals (43%) resulted in a recommendation for an update of the product information for patients and healthcare professionals, thus providing updated guidance on the safe and effective use of the affected medicines. For 12 signals (20%), continuing with routine safety monitoring of the medicine was considered sufficient. The evaluation of 21 signals (35%) was ongoing at the end of 2025, including 13 via a follow-up signal procedure and 8 as part of upcoming PSURs/PSUSAs. One signal led to a referral procedure and 1 signal resulted in a DHPC (as the outcome was update of PI and DHPC, this signal is merged with "update of PI" in Figure 13 below).

See Figure 13 for a summary of signal outcomes and table 8 listing all the signals noting the latest status or outcome as of 31 December 2025.

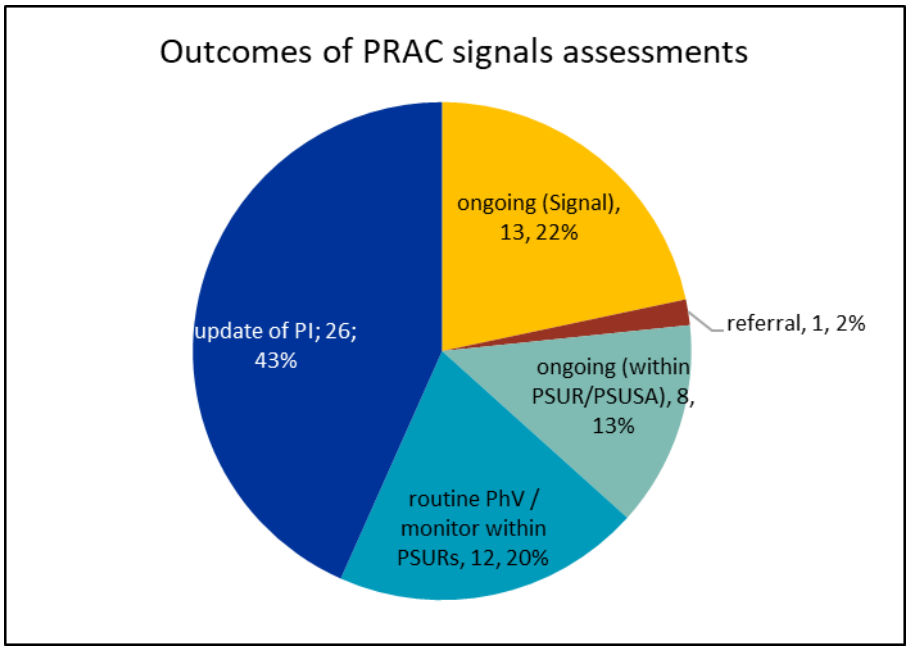

Figure 13. Outcomes of PRAC signal assessments (2025). PI: product information, PSUR: Periodic Safety Update Report, PSUSA: Periodic Safety Update Single Assessment, PhV: pharmacovigilance.

Table 8. A list of signals prioritised and assessed by the PRAC in 2025 is provided below, in alphabetical order, noting the status or outcome as of 31 December 2025.

Medicine	Issue	Status or outcome
Adagrasib	Thrombocytopenia	Routine pharmacovigilance / monitor within PSURs
Adalimumab	Morphoea	Routine pharmacovigilance / monitor within PSURs
Adalimumab	Paradoxical hidradenitis	Ongoing (within PSUR/PSUSA)
Afatinib	Growth of eyelashes	Update of PI
Amlodipine	Subacute cutaneous lupus erythematosus	Ongoing (within PSUR/PSUSA)
Atezolizumab; avelumab; cemiplimab; dostarlimab; durvalumab; ipilimumab; nivolumab; nivolumab, relatlimab; pembrolizumab; retifanlimab; tislelizumab; toripalimab; tremelimumab	Scleroderma, systemic scleroderma, morphea	Routine pharmacovigilance / monitor within PSURs
Atezolizumab; avelumab; cemiplimab; dostarlimab; durvalumab; ipilimumab; nivolumab; nivolumab, relatlimab; pembrolizumab; retifanlimab; tislelizumab; toripalimab; tremelimumab	Thrombotic microangiopathy	Routine pharmacovigilance / monitor within PSURs
Axicabtagene ciloleucel; brexucabtagene autoleucel; ciltacabtagene autoleucel; idecabtagene vicleucel; lisocabtagene maraleucel; tisagenlecleucel	Immune-mediated enterocolitis / Immune effector cell-associated enteritis with CAR T-cell products	Update of PI
Axicabtagene ciloleucel; lisocabtagene maraleucel	Increased risk of brain oedema in primary mediastinal large B-cell lymphoma (PMBCL) patients	Ongoing (signal)
Binimetinib; cobimetinib; dabrafenib; encorafenib; trametinib; vemurafenib	Tattoo associated skin reaction	Update of PI and monitor within PSURs
Bosutinib	Cutaneous vasculitis	Update of PI
Brodalumab	Pyoderma gangrenosum	Update of PI
Cana-, dapa-, empa- and ertugliflozin-containing	Sarcopenia	Routine pharmacovigilance / monitor within PSURs

Medicine	Issue	Status or outcome
mono products and their combinations		
Cefazolin; cefazolin, lidocaine hydrochloride	Kounis syndrome	Ongoing (signal)
Chikungunya vaccine (live)	Adverse events requiring hospitalisation in elderly patients	Referral
Ciltacabtagene autoleucel; idecabtagene vicleucel; tisagenlecleucel	Progressive multifocal leukoencephalopathy	Update of PI
Clozapine	Appendicitis	Update of PI
Clozapine	Haematological malignant tumours	Update of PI
Clozapine	New aspect of the known risk of neutropenia/agranulocytosis with potential impact on the risk minimisation measures	Update of PI and DHPC
Dabigatran	Splenic rupture	Routine pharmacovigilance / monitor within PSURs
Datopotamab deruxtecan	Anaphylactic reaction	Update of PI
Desogestrel; etonogestrel	Meningioma	Ongoing (signal)
Diazoxide	Necrotising enterocolitis neonatal	Update of PI
Dinutuximab beta	Atypical haemolytic uraemic syndrome	Update of PI
Emtricitabine, tenofovir disoproxil	Trigeminal neuralgia	Routine pharmacovigilance / monitor within PSURs
Enzalutamide digoxin	Laboratory test interference leading to falsely elevated digoxin plasma levels with enzalutamide	Update of PI
Epcoritamab	Hypogammaglobulinaemia	Update of PI
Erdafitinib	Growth accelerated	Ongoing (signal)
Folic acid	Increased risk of cancer with high-dose folic acid (≥1mg)	Routine pharmacovigilance / monitor within PSURs
Galantamine	Nightmares	Ongoing (signal)
Ibrutinib	Cough	Ongoing (within PSUR/PSUSA)
Idecabtagene vicleucel	Sarcoidosis	Ongoing (within PSUR/PSUSA)
Ixekizumab	Demyelinating disorders	Routine pharmacovigilance / monitor within PSURs

Medicine	Issue	Status or outcome
Leflunomide	Pulmonary nodule	Update of PI
Lenvatinib	Tumour lysis syndrome	Update of PI
Mepolizumab	Alopecia	Ongoing (within PSUR/PSUSA)
Mogamulizumab	Colitis	Update of PI
Nemolizumab	Erythema multiforme	Ongoing (within PSUR/PSUSA)
Omalizumab	Hearing losses	Routine pharmacovigilance / monitor within PSURs
Osimertinib	Hepatitis B reactivation	Update of PI
Oxytetracycline hydrochloride / hydrocortisone acetate / polymyxin B sulfate (ear/eye drops/suspension/ointment)	Hearing and vestibular disorders	Update of PI
Pancreatin	Infection due to viral transmission	Ongoing (signal)
Pegylated liposomal doxorubicin	Renal-limited thrombotic microangiopathy	Ongoing (signal)
Pemetrexed	Lupus erythematosus	Ongoing (signal)
Polatuzumab vedotin	Infusion site extravasation	Ongoing (within PSUR/PSUSA)
Ponatinib	Congenital megacolon, maternal exposure during pregnancy	Ongoing (signal)
Regorafenib	Hyperammonaemia, hyperammonaemic encephalopathy	Update of PI
Regorafenib	Nephrotic syndrome	Routine pharmacovigilance / monitor within PSURs
Risankizumab	Pemphigoid	Ongoing (signal)
Selumetinib	Photosensitivity reaction	Ongoing (within PSUR/PSUSA)
Sertraline	Multiple acyl-coenzyme A dehydrogenase deficiency (MADD)	Update of PI
Somatrogon	Lipoatrophy	Update of PI
Sulfamethoxazole, trimethoprim (cotrimoxazole)	Circulatory shock	Update of PI
Sulfasalazine	Idiopathic intracranial hypertension (Pseudotumor cerebri)	Routine pharmacovigilance / monitor within PSURs
Tegafur, gimeracil, oteracil	Hyperammonaemia	Update of PI

Medicine	Issue	Status or outcome
Tirzepatide	Drug interaction with warfarin and other coumarin derivatives leading to international normalised ratio decreased	Ongoing (signal)
Valproate and related substances	Neurodevelopmental disorders with paternal exposure	Ongoing (signal)
Varicella vaccine (live); measles, mumps, rubella and varicella vaccine (live)	New aspect of the known risk of encephalitis	Update of PI
Venlafaxine	Cardiotoxicity	Ongoing (signal)
Vortioxetine	Hallucinations, not related to serotoninergic syndrome	Update of PI

Annex VI - Signal management process and methods

The Signal Management Review Technical Working Group (SMART) is a joint collaboration between Member States and EMA with the objective to strengthen and simplify the signal management process in the EU. Its two work streams are focused on signal management tools and processes (SMART processes) and methodological guidance and signal detection methods (SMART methods). SMART reports to PRAC. The progress achieved in 2025 is summarised below.

The SMART process group continued to support the signal management process by providing internal guidance aimed at enhancing the clarity on roles and responsibilities between EMA and Rapporteurs, as well as the predictability of the various steps involved in the handling of class signals.

The SMART process group also discussed the importance of a coordinated approach to safety communications across the Network following PRAC recommendations resulting from safety signals assessments.

The SMART methods group successfully delivered on all priorities outlined in the 2022 – 2025 workplan. This milestone reflects steady progress and effective execution across a broad spectrum of pharmacovigilance research areas reinforcing the network's commitment to innovation and collaboration. Key achievements include:

1. implementation of the pregnancy algorithm to enhance case retrieval in spontaneous reporting databases;
2. lessons learned for rapid evidence generation and contextualisation using observed to expected analyses;
3. impact assessment for COVID-19 masking effect in spontaneous databases;
4. renew focus on drug interaction using EMA historical data analysis to describe signals assessed by PRAC (poster presented at ISoP Cairo 2025);
5. AI and Digital Transformation remained a central theme, with pilots on automatic literature review, the reference dataset for ADRs and the automatic case adjudication.

The third meeting of 2025 was held in a hybrid format providing an opportunity to review past achievements and discuss future strategic initiatives:

- The role of SMART Methods was recognised as a platform for piloting and implementing novel tools for the pharmacovigilance toolkit, beyond ideation.
- NCAs expressed strong interest in structured knowledge exchange, learning on new tools available for the network as well as in opportunities for cross-NCA collaboration.
- The introduction of focus groups as an adaptable, targeted collaboration model, proved effective for the exploration of complex topics.
- The increasing volume and complexity of pharmacovigilance data has underscored the need to strengthen knowledge contextualisation using robust methods for automated, descriptive analyses and data visualisations and diverse sources to support causality assessment and preparedness, with integration of RWD into signal management unanimously prioritised for future work.
- The need to enhance collaboration between EMA, NCAs, and MAHs, particularly during the signal validation window, was a topic of recurring discussion. Members advocated for working

in parallel with MAHs to generate additional evidence, which can be supported by emerging AI tools and DARWIN EU.

- In the context of innovation using AI tools, modular and interoperable systems were seen as the preferred option to address privacy concerns and diverse stakeholder needs. A stepwise approach of innovate, validate, implement was proposed, with industry involvement through initiatives such as the Innovative Health Initiative (IHI) seen as beneficial.

Information on SMART working groups can be found at www.ema.europa.eu under Committees > Working parties and other groups.

Annex VII - Requests for information and documents

In 2025, EMA responded to 25 requests for EudraVigilance data for which requests for information (aggregated data) and/or documents (line listings/cases) were provided. This corresponds to requests for which a detailed, tailored EudraVigilance search was required. This represents a small increase in the number of requests compared to 2024 (24 requests).

EMA continues to receive significantly fewer EudraVigilance data requests than before 2018, owing to the adverse reaction data provided through the publicly available www.adrreports.eu website. The portal continues to address the majority of request for information without the need for further intervention. In 2025, EMA supplied an additional 36 responses to requests for clarifications concerning this website or general aspects of EudraVigilance data (19 responses in 2024).

Of the 25 requests for EudraVigilance data, 16 (64%) were requests for documents (line listings or cases), 8 (32%) were requests for information (aggregated data), whilst 1 (4%) involved a mix of both types. As for the type of medicinal products concerned, most requests were related to either CAPs (44%) or a mix of CAPs and NAPs (36%); NAPs accounted for the remaining 20% (see **Figure 14**).

The 25 requests include queries for data from the EU regulatory network or EU institutions (8), academia (8), the general public including patients (5), a non-EU regulatory authority (1), an EU national competent authority outside the EMA network (1), a consultancy company (1) and the pharmaceutical industry (1) (see **Figure 15**).

As regards the geographic origin of the queries, 24 (96%) originated from the EU, while only 1 (4%) originated from outside of the EU (see **Figure 16**).

In 2025, a small proportion of requests for EudraVigilance data continued to relate to one or more of the centrally authorised COVID-19 vaccines (4 out of 25 requests, accounting for 16% of the requests). This trend is similar to the previous year (3 requests in 2024, accounting for 12% of the requests).

For further details on the 2025 requests for EudraVigilance data responded, please refer to **Table 9**.

Figures 14, **15** and **16** below provide an overview by authorisation type of concerned products, type of request, requester type and geographic origin.

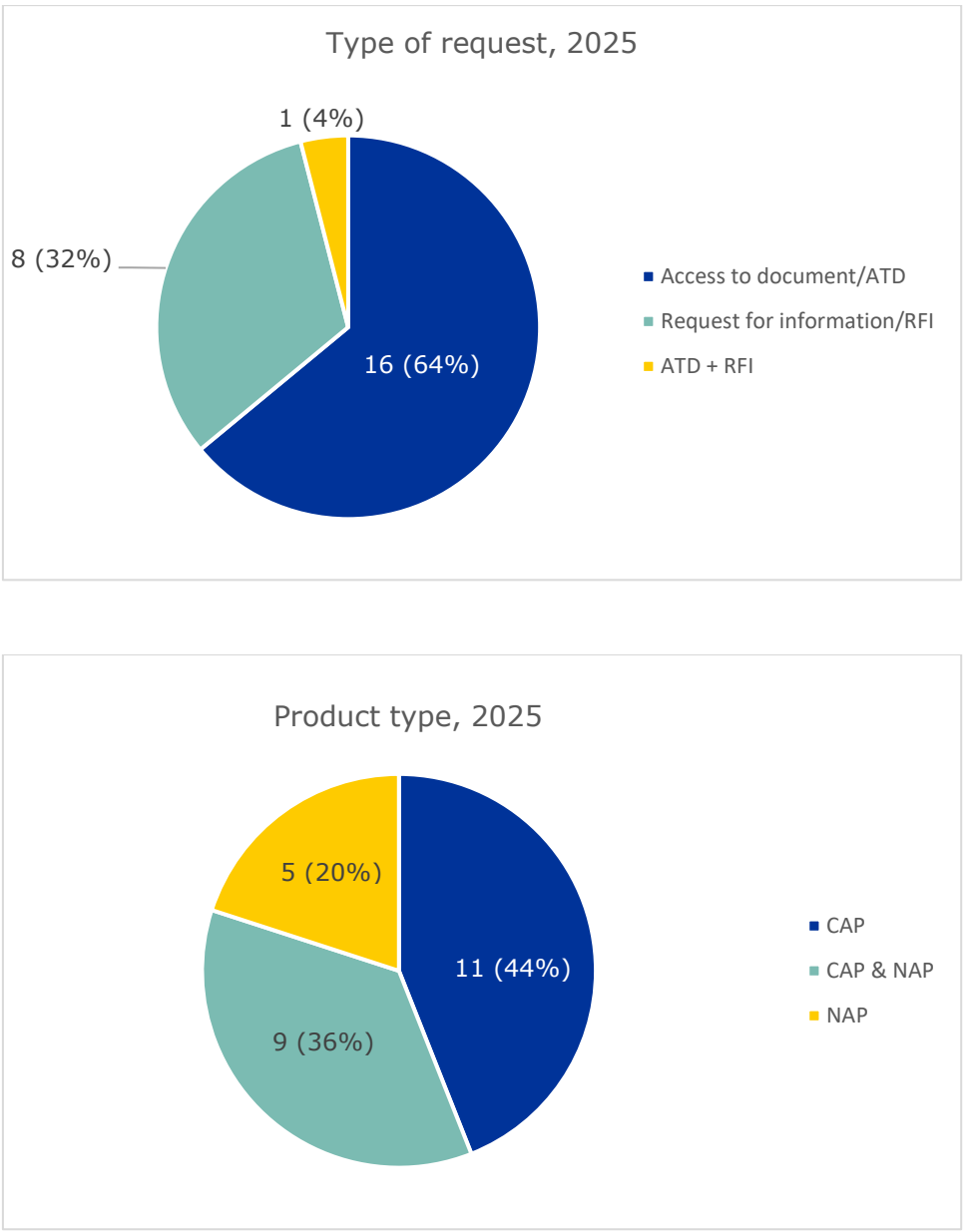

Figure 14. Overview of requests for EudraVigilance data in 2025 by type of request (top) and product type (down).

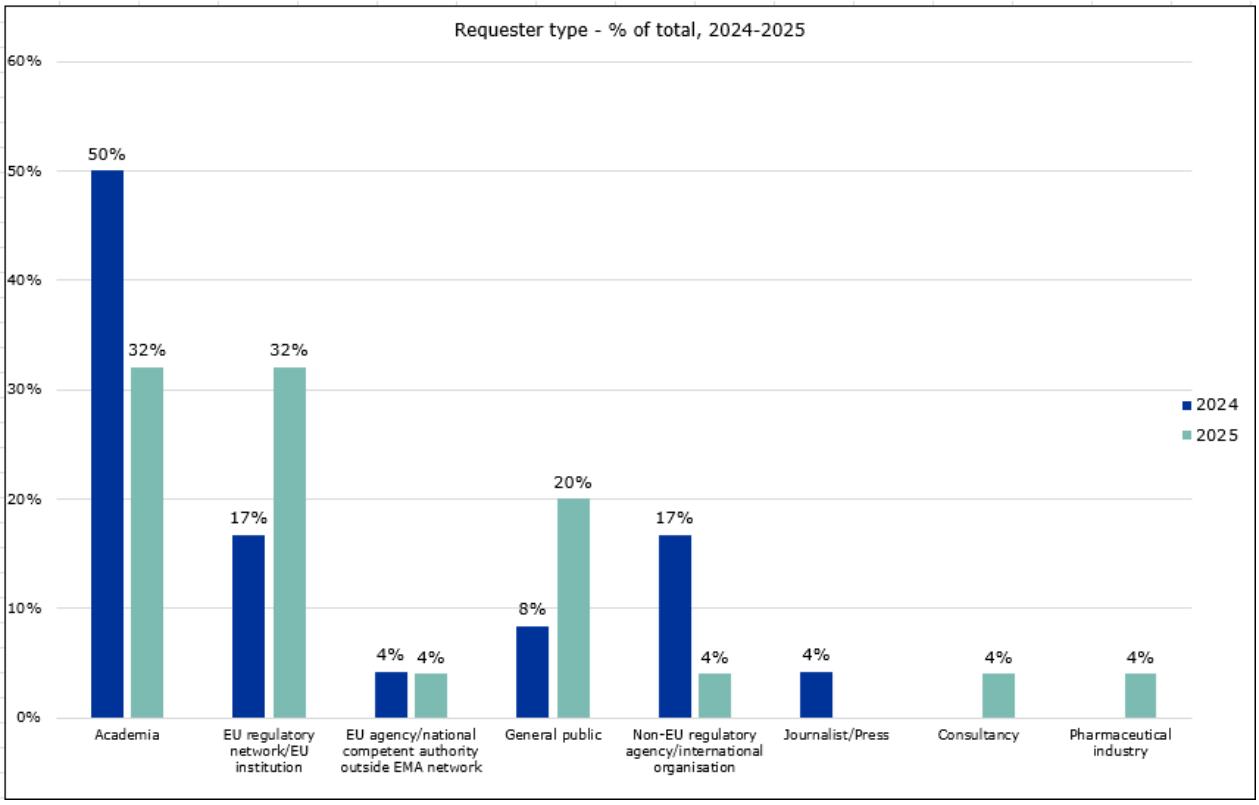

Figure 15. Overview of requests for EV data in 2024 and 2025 by requester type.

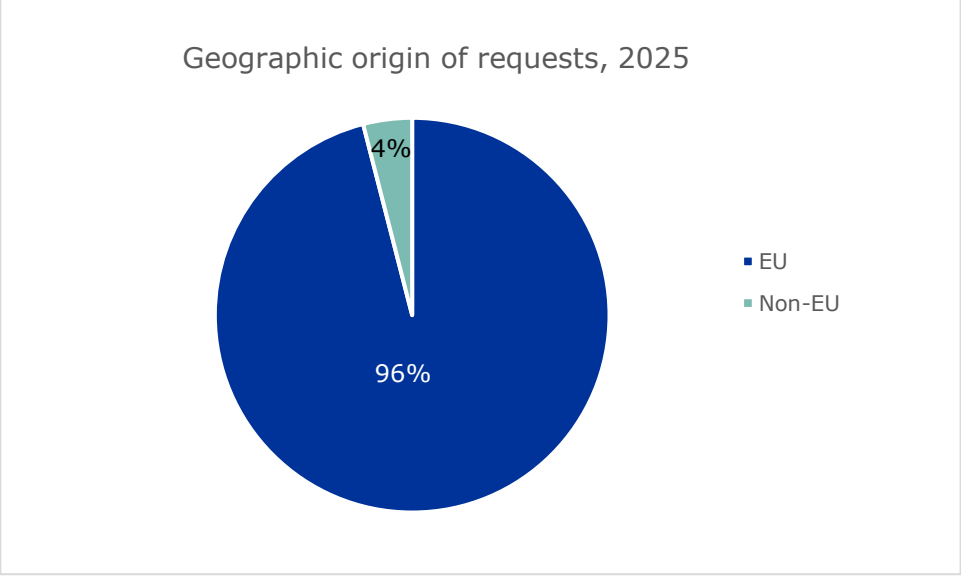

Figure 16. Overview of requests for EV data in 2025 by geographic origin.

Table 9. Overview of requests responded to in 2025.

Type of requester	Substance/ product	Issue	Type of request
EU regulatory network/EU institution	Abrysvo (respiratory syncytial virus vaccine [bivalent, recombinant])	Selected cases	Request for information/RFI
EU regulatory network/EU institution	Abrysvo (respiratory syncytial virus vaccine [bivalent, recombinant]), Arexvy (respiratory syncytial virus vaccine [recombinant, adjuvanted]), Vabysmo (faricimab)	Medication errors	Request for information/RFI
EU regulatory network/EU institution	Acetylsalicylic acid	Kounis syndrome	Access to document/ATD
Academia	All medicinal products	Withdrawal events	Access to document/ATD
Academia	All medicinal products	Follow-up query on withdrawal events	Request for information/RFI
Academia	All medicinal products	Second follow-up query on withdrawal events	Access to document/ATD
Patient or consumer	BCG vaccine	Selected cases	Access to document/ATD
EU regulatory network/EU institution	Beyfortus (nirsevumab)	Selected cases	Request for information/RFI
Patient or consumer	COVID-19 vaccine	Specific case	Access to document/ATD
Patient or consumer	COVID-19 vaccine	Specific case	Access to document/ATD
Law firm	COVID-19 vaccine	Specific case	Access to document/ATD
Patient or consumer	COVID-19 vaccine	Specific case	Access to document/ATD
EU regulatory network/EU institution	GLP-1 receptor agonists	Non-arteritic anterior ischemic optic neuropathy	Access to document/ATD
EU regulatory network/EU institution	GnRH-agonists	Selected cases	Request for information/RFI
Non-EU regulatory agency/international organisation	Ixchiq (Chikungunya vaccine [live])	Selected cases	Access to document/ATD
Academia	Leuprorelin	Medication errors	Access to document/ATD
Academia	Methotrexate	Medication errors	Access to document/ATD
EU regulatory network/EU institution	Methotrexate	Medication errors	Access to document/ATD

Type of requester	Substance/ product	Issue	Type of request
Academia	Methylphenidate; dexamfetamine; lisdexamfetamine; atomoxetine; guanfacine	All ADRs for requested period	Access to document/ATD
EU regulatory network/EU institution	Paracetamol	Overdose	Request for information/RFI
Academia	Pregabalin, gabapentin, diazepam, carbamazepine, amitriptyline	Selected cases	Access to document/ATD
EU agency/national competent authority outside the EMA network	Resorcinol	Information on specific case	Request for information/RFI
Patient or consumer	Revolade (eltrombopag)	Selected cases for requested period	Request for information/RFI
Pharmaceutical industry	Stivarga (regorafenib)	Specific case	Access to document/ATD
Academia	Various	Fatal ADRs for requested period	Request for information/RFI + Access to document/ATD