4-year overview of pharmacovigilance activities in the EU shows robust and effective medicines safety system

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A report on the activities ensuring the safety of medicines carried out by EMA and the [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority) of the European Union (EU) Member States, Norway and Iceland from 2015 to 2018 shows that the EU [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) system is strong and adaptable and has had a positive impact on public health.

The report measures the longer-term impact of the [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance" \t "_blank" \o "Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.   More information can be found under 'Pharmacovigilance -  Overview'.)legislation, which came into effect in July 2012, in terms of simplification of [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) processes, improved transparency and stakeholder engagement and protection of patient health. The measurement of impact is based on a [strategy and action plan for measuring the impact of pharmacovigilance activities](https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview#measuring-the-impact-of-pharmacovigilance-activities-section), adopted by EMA’s [safety committee (PRAC)](https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac) in 2017.

**Some key outcomes 2015-2018**

* More than 500 new or updated [risk management plans](https://www.ema.europa.eu/en/glossary/risk-management-plan) were assessed by the [PRAC](https://www.ema.europa.eu/en/glossary/prac) each year, ensuring the safety monitoring and risk minimisation is proportionate and planned. In addition, nearly 7,000 [risk management plans](https://www.ema.europa.eu/en/glossary/risk-management-plan) were assessed by the Member States for nationally authorised medicines during the reporting period.
* Enhanced [EudraVigilance](https://www.ema.europa.eu/en/glossary/eudravigilance" \t "_blank" \o "A centralised European database of suspected adverse reactions to medicines that are authorised or being studied in clinical trials in the European Economic Area (EEA).   More information can be found under 'EudraVigilance'. ) database of suspected side effects, resulting in improved reporting and greater analytical power;
* Evaluation of nearly 9,000 potential signals (information about new or changing safety issues potentially caused by a medicine) by EMA’s [signal management](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management) team over the period covered by the report, and a similar number of potential signals assessed by Member States;
* Radical simplification and improvement of the way [periodic safety update reports](https://www.ema.europa.eu/en/glossary/periodic-safety-update-report) are handled, by establishing a common repository with a single portal for access;
* Development of criteria to determine when a [public hearing](https://www.ema.europa.eu/en/about-us/how-we-work/public-hearings) on issues of medicines’ safety would be of value, and the successful holding of the first such hearings, for [valproate-containing medicines](https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances-0) in 2017 and for [quinolone and fluoroquinolone antibiotics](https://www.ema.europa.eu/en/medicines/human/referrals/quinolone-fluoroquinolone-containing-medicinal-products) in 2018;
* Continued development of the ‘[Article 57 database](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/public-data-article-57-database)’, which now contains information on more than 800,000 [medicinal products](https://www.ema.europa.eu/en/glossary/medicinal-product) authorised through central, decentralised, [mutual recognition](https://www.ema.europa.eu/en/glossary/mutual-recognition) and national procedures across the European Economic Area.

The report on the impact of [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) measures was prepared by EMA in collaboration with the [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority) and aims to meet the European Commission’s ongoing obligation to publish information on [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) activities carried out by the Agency and the competent authorities of the EU Member States, Norway and Iceland. It includes quantitative data covering the period 01/01/2015 to 31/12/2018 and shows that the [European regulatory network for medicines](https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network) is held accountable for the [implementation of the pharmacovigilance legislation](https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/legal-framework/implementation-pharmacovigilance-legislation).