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Press release

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

A report on the activities ensuring the safety of medicines carried out by EMA and the national competent authorities of the European Union (EU) Member States, Norway and Iceland from 2015 to 2018 shows that the EU 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 legislation, which came into effect in July 2012, in terms of simplification of 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, adopted by EMA's safety committee (PRAC) in 2017.

Some key outcomes 2015-2018

- More than 500 new or updated risk management plans were assessed by the PRAC each year, ensuring the safety monitoring and risk minimisation is proportionate and planned. In addition, nearly 7,000 risk management plans were assessed by the Member States for nationally authorised medicines during the reporting period.
- Enhanced 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 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 are handled, by establishing a common repository with a single portal for access;
- Development of criteria to determine when a public hearing on issues of medicines' safety would be of value, and the successful holding of the first such hearings, for valproate-containing medicines in 2017 and for quinolone and fluoroquinolone antibiotics in 2018;

- Continued development of the 'Article 57 database', which now contains information on more than 800,000 medicinal products authorised through central, decentralised, mutual recognition and national procedures across the European Economic Area (EEA).

The report on the impact of pharmacovigilance measures was prepared by EMA in collaboration with the national competent authorities and aims to meet the European Commission's ongoing obligation to publish information on 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 is held accountable for the implementation of the pharmacovigilance legislation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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