Six-year review shows success of the EU signal management system in improving safe use of medicines

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In the first six years since the implementation of the 2012 EU [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) legislation, the EU network has demonstrated its ability to reliably detect, assess and manage [safety signals](https://www.ema.europa.eu/en/glossary/safety-signal) for medicines, opening a new era for patient protection and transparency in medicines safety, highlights an article published in Clinical Pharmacology & Therapeutics. A [safety signal](https://www.ema.europa.eu/en/glossary/safety-signal) is information on a new or known [adverse event](https://www.ema.europa.eu/en/glossary/adverse-event) that is potentially caused by a medicine and that warrants further investigation.

[Pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) systems ensure proactive monitoring of all authorised medicines throughout their lifecycle in clinical use. Signal detection and management are core activities in [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance), rapidly delivering new information on the safety of medicines in real-world use which helps to fill knowledge gaps.  At the heart of this process is a strong collaboration based on expertise from the [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority) and EMA, with the contribution of the [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) systems of marketing-authorisation holders, combined with a culture of continuous improvement.

In the first six years of the implementation of the [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) legislation, over 26,000 potential signals were reviewed, resulting in 453 signals assessed by EMA’s safety committee ([PRAC](https://www.ema.europa.eu/en/glossary/prac)). More than half of the [PRAC](https://www.ema.europa.eu/en/glossary/prac) recommendations resulted in changes to medicine [product information](https://www.ema.europa.eu/en/glossary/product-information) supporting the safe and effective use of medicines. The system proved responsive with recommendations for risk minimisation measures made in as few as five days of a signal being confirmed (with a median of five months).

The article describes the signal management process in place in the EU, underpinned by transparency, with specific actions to rapidly communicate reliable information on the safety of medicines to patients and healthcare professionals.