Press release

EudraVigilance signal detection methods help detect drug safety issues earlier
Adding EudraVigilance statistical signal detection methods to routine drug safety monitoring methods leads to earlier detection of safety issues

An evaluation of the use of the European Medicines Agency’s statistical signal detection method in the adverse drug reaction data collected in the EudraVigilance database has shown a significantly earlier detection of drug safety issues in about 54% of cases where a clinically important adverse drug reaction report was found (compared to ‘routine’ pharmacovigilance).

The study which was published in Drug Safety, the journal of the International Society of Pharmacovigilance, was carried out by the European Medicines Agency and was conducted in relation to centrally authorised medicines. It provides direct evidence for a strong additive role of EudraVigilance signal detection methods. The study also underlines the importance of established pharmacovigilance systems, such as active surveillance, clinical trials or periodic safety update reporting, and concludes that a combination of routine pharmacovigilance and statistical signal detection provides the optimal safety monitoring with earlier detection and better management of safety issues, thereby improving the protection of public health.

EudraVigilance is the European Union database for adverse drug reaction reports. It provides a single repository for all spontaneous reports of suspected serious adverse reactions concerning medicines that are authorised in the European Union received via the national competent authorities for medicines regulation and the pharmaceutical industry.

While the study looked at statistical signal detection retrospectively, the European Medicines Agency is now routinely using the statistical signal detection method to strengthen signal detection for centrally authorised medicines. By detecting new or changing safety issues with medicines earlier, action can be taken more quickly to reduce the risk to the public. This is one important way in which EudraVigilance makes a contribution to the health of EU citizens through reducing the suffering caused by adverse reactions.

The development of EudraVigilance and the use of statistical signal detection methods is an essential part of the European Risk Management Strategy (ERMS), a multi-annual programme aiming to provide
for a more proactive conduct of pharmacovigilance by putting in place measures that allow for the early detection, assessment, minimisation and communication of risks of medicines in Europe throughout their lifecycle.

The Agency’s commitment to the continuous improvement of the safety monitoring of medicines is also underlined by its central coordinating role in PROTECT, a project of the Innovative Medicines Initiative (IMI), which is aimed at strengthening the monitoring of the benefits and risks of medicines in Europe by developing innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions.

**Notes**


3. More information on the PROTECT initiative can be found here: http://www.imi-protect.eu/index.html

4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency’s website: www.ema.europa.eu

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