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Press release

EU collaboration strengthens safety monitoring of medicines

European Commission publishes three-year report on implementation of pharmacovigilance legislation

Closer collaboration between the European Medicines Agency (EMA), the European Commissionand the EU Member States,enabled by the new European pharmacovigilance legislation, has enhanced the monitoring of the safety of human medicines throughout their life cycle, for the benefit of patients. This is highlighted in the European Commission report on the pharmacovigilance activities of the European medicines regulatory network published today.

The reportdescribes the activities of the EU system for monitoring and managingthe safety of human medicinesfrom the timethe new Pharmacovigilance legislation came into effect in July2012, until July2015.

The creation of a dedicated scientific committee for the safety management of medicines, the Pharmacovigilance Risk Assessment Committee (PRAC), and the regulatory tools made available under the revised legislation,allow for a more proactive approach to ensuring medicine safety. For all medicines, pharmacovigilance activities are planned early on in the medicine development so that each medicine comes to the market with a comprehensive plan to gather more information on its benefits and risks.The analysis shows that the new system has been successful atdetecting safety issues more quickly, thus enabling regulators to take rapid action whenneededand provide advice and warnings to users of medicines.This system effectively engagespatients and healthcare professionals, who report suspected side effects, contribute to the decision-making process in case of safety concerns and add the invaluable perspective of the people most affected by diseases and their treatment.

Some of the concrete achievements during the past threeyearsinclude:

- **Risk management plans,** which identify the studies and risk minimisation measures required to manageimportant known or potential risks, are now an integral part of proactive safety management. The PRAC assesses around 600 risk management plans each year for centrally authorised medicines, while over the reporting period some 20,000 risk management plans have been submitted to the Member States for nationally authorised medicines.

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- **Reporting of side-effects**has improved; in particular direct reports from patients have increased by 50%. Reporting of side effects by all stakeholders is an essential element for gathering more information on the benefits and risks of medicines in real life;
- Nearly 200 **safety signals**(information about new or changing safety issues potentially caused by a medicine) were investigated by the PRAC up to the end of 2014. Half of the confirmed signals led to updates of the product information, and a further quarter to other regulatory measures. Through rapid detection and management of safety signals, the EU pharmacovigilance system is delivering advice on the safe and effective use of medicines more quickly to patients and healthcare professionals;
- Regular re-assessment of the benefit-risk balance of marketed medicines is being carried out via submission of **periodic safety update reports** (PSURs) for assessment by regulators. Member States evaluated over 12,000 PSURs for purely nationally authorised medicines. In addition, PRAC reviewed and finalised over 900 assessments for centrally authorised medicines, or for active substances found in both centrally and nationally authorised medicines. Because PSURs can lead to directly-binding changes to product information this delivers faster safety warnings to patients;
- The PRAC led 31 safety-related **referrals**. This type of review procedure allows assessment of the safety or benefit-risk balance of a medicine or a class of medicines by the PRACleading to a recommendation for a harmonised position across the EU;
- Around 200 pharmacovigilance **inspections** have been carried out every year;
- A clearer focus was put on **medication errors**through the provision of new guidance.Side-effect reports related to medication errors increased from around 4,500 in 2012 to over 7,000 in 2014, in part because of increased awareness and a clearer legal basis for reporting.

The report and an accompanying, more detailed working document are now published on the website of the European Commission.