Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

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The Commission presented a report on pharmacovigilance related activities of Member States and the European Medicines Agency (EMA) concerning medicinal products for human use (2012 – 2014).

The EU legal framework of pharmacovigilance for medicinal products for human use is provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC. The legislation was amended in 2010 and 2012.

Pharmacovigilance, as defined by the World Health Organisation (WHO), is 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem'.

This report and the accompanying Staff Working Document describe the **activities of the EU's networked and collaborative system for monitoring and controlling the safety of human medicines** and is focused on activities since the start of operation of new legislation in 2012 until the end of 2014, but also includes information on some tasks and processes initiated up to July 2015.

The main conclusions of the report are as follows:

Strong collaboration between the European regulatory authorities: the medicines regulatory authorities in 31 European Economic Area (EEA) countries, the EMA and the European Commission closely **collaborate and work in partnership as a network** to discuss and deal swiftly with any emerging problem in the interest of patients' access to safe and efficacious medicines. The ability to take quick and robust regulatory action was **enhanced through the legislation by**:

- the creation of the Pharmacovigilance Risk Assessment Committee;
- strengthening of the Co-ordination group for Mutual recognition and Decentralised procedures – human;
- the introduction of new procedures to fast-track decision-making when public health is at risk.

Continuing and future development of the network: over the period of the report and beyond, the pharmacovigilance network is focusing on training to develop understanding of pharmacovigilance and regulatory science to enable sharing of best practice, improving the efficiency and effectiveness of the processes, and building capacity.

The European pharmacovigilance network represents an example of successful co-operation at the European level, to the benefit of EU citizens. The networked system allows participants to share in the best available expertise and evidence and co-ordinate the regulatory actions, producing more efficient and consistent outcomes for everybody.

The regulatory tools made available under the revised legislation represent an increasingly proactive approach to medicines safety. These tools comprise the following:

- **risk management planning**: Pharmacovigilance Risk Assessment Committee (PRAC) reviewed 48 risk management plans (RMPs) in July–December 2012, 637 in 2013 and 597 in 2014. The Member

States, collectively, received around 3 500 (2012), 7 500 (2013), and 9 000 (2014) RMPs for nationally authorised medicines;

- **post-authorisation studies**: between July 2012 and December 2014, PRAC reviewed protocols for 38 imposed non-interventional post authorisation safety studies (PASSs);
- **signal detection and management at EU level**: analysing reports of suspected side effects to identify signals. Some 193 unique signals were evaluated by PRAC between September 2012 and December 2014;
- **periodic safety update reports**: routine benefit-risk monitoring of medicines via periodic safety update reports (PSURs) and maintaining the list (EURD list) of schedules for submitting PSURs;
- **inspections**: carrying out inspections to ensure company pharmacovigilance systems comply with good pharmacovigilance practice.

The regulatory tools are complemented by improvements in regulatory action and communication when safety concerns are identified.

Increased transparency: mechanisms have been put in place to ensure that accurate safety information reaches the EU public in a timely manner. Engagement of key stakeholders such as patients and healthcare professionals is embedded in the system including through patient reporting of suspected side effects.

For the future, **deepening involvement** is foreseen, including the holding of public hearings for critical safety issues.

Improving service systems: work is proceeding on the infrastructure needed to support further development of the system, and to **simplify and streamline existing processes** where possible so that the regulatory burden is minimised for all stakeholders. Work concerns:

- delivery of the medical literature monitoring service of the **new EudraVigilance system**, of the PSUR repository;
- full use of **EU product database** (provided for by Article 57) of all authorised medicines (both centrally and nationally authorised) in the EU with information on over 580 000 medicines from nearly 4 300 marketing authorisation holders.

Work continues to complete the development and implementation of other systems such as centralised ADR reporting through the EudraVigilance database. Ongoing research in the field of regulatory science, such as the research supported through the EU Research Framework Programmes, will also support future improvements.