Brussels, 31 December 2010

# Questions & Answers: Pharmacovigilance

## What is pharmacovigilance?

Pharmacovigilance is the science of the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) and the related activities. An ADR is a response to a medicine which is noxious and unintended. The limitations of clinical trials in terms of their size, duration and controlled conditions means that some ADRs will only be detected after a medicine has been authorised and has entered the market. The aim of pharmacovigilance is to identify new information about hazards associated with medicines and to prevent harm to patients.

## Why did existing EU legislation need to be updated?

The Commission's Impact Assessment Report [1] estimates that 5% of all hospital admissions are due to an ADR, 5% of all hospital patients experience an ADR and they are the 5th most common cause of hospital death. The report also estimates that through the measures laid out in the new Pharmacovigilance legislation, up to 5910 lives can be saved per year across the EU.

ADRs are a major health and societal burden and any weakness in the system of pharmacovigilance will have a major impact on patients. Some areas for improvement in the existing legislation were identified - for example, unclear and overlapping responsibilities between the various players, lack of clear standards for the authorities and industry and absence of a legal basis for certain requirements.

## How will the new Pharmacovigilance legislation ensure greater patient safety?

The Regulation and Directive on Pharmacovigilance, published today, address these issues by:

- Setting out clear tasks and responsibilities for all parties involved (Member States, marketing authorisation holders and the European Medicines Agency).
- Improving decision-making procedures and using resources more efficiently.
- Managing risk proactively and proportionately, avoiding unnecessary administrative burden and providing for a stronger link between safety assessments and regulatory action.
- Involving stakeholders in pharmacovigilance, including through direct patient reporting of suspected ADRs.
- Strengthening communication and transparency on medicine safety.
- Strengthening companies' pharmacovigilance systems.
- Ensuring the proactive and proportionate collection of high quality data.

## How will this legislation ensure greater transparency and patient involvement?

[1] Commission Staff Working Document dated 10 December 2008. Link: http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol2_en.pdf

Once this legislation comes into effect in the Member States, patients, in addition to healthcare providers will be able to reports ADRs directly to the competent authorities. This can be done through the web-portals that the National authorities are required to set up and through at least one other reporting means of the Member State's choice. The Member States are responsible for gathering and verifying national data. They will then submit regular reports to "Eudravigilance", the central computer database for reporting and evaluating ADRs, maintained by the European Medicines Agency.

The legislation also allows for public hearings on medicines to be held, when justified. This is primarily to obtain information from all parties, including the public. The hearings will be announced on the European web portal.

These new rules will improve transparency and provide the opportunity notably for patients to express themselves, allowing them to become more active participants in their health and to play a role in identifying patterns of ADRs.

The web portals set up by the National authorities and which are linked to the European medicines web-portal, will also ensure greater transparency by allowing patients and healthcare professionals to access the latest information on medicines.

## What is the Committee on Pharmacovigilance that will be set up under this legislation?

The Pharmacovigilance legislation foresees the creation of a new scientific committee at the European Medicines Agency. This Committee will be called the ”Pharmacovigilance Risk Assessment Committee (PRAC)”. Its aim will be to ensure access to the best scientific and medicinal expertise for the evaluation of the safety of medicines and risk minimisation measures, with the ultimate goal of reducing ADRs. Appointments will be based on relevant experience in pharmacovigilance and risk assessment. The committee will be composed of:

- 1 member and 1 alternate appointed by each Member State;
- 6 members appointed by the Commission to ensure availability of relevant expertise in the committee, on the basis of a public call for expression of interest;
- 1 member and 1 alternate appointed by the Commission on the basis of a public call for expression of interest in order to represent healthcare professionals and 1 member and 1 alternate in order to represent patients.

## When will this legislation come into effect?

The legislation will become applicable in July 2012.