IP/07/240

Brussels, 26 February 2007

Strengthening medicines safety monitoring

A public consultation shows that the current EU system of medicines safety monitoring (pharmacovigilance) needs rationalisation and strengthening. There are unclear roles and responsibilities, complex reporting rules implemented differently by different Member States, a lack of robust safety studies and complex decision-making at EU-level. Commission Vice-President Günter Verheugen announced today a strengthening of the EU pharmacovigilance system. By making clear the roles and responsibilities for pharmacovigilance, by simplifying reporting rules and by ensuring that robust safety studies are performed to support rapid EU decision-making, the planned reform will better protect public health and support the safe use of new and innovative medicines.

Commission Vice-President Günter Verheugen responsible for enterprise and industry policy said: *"We will improve and strengthen the monitoring of the safety of medicines so that safety issues are rapidly detected, and effectively dealt with based on more robust data. Rationalisation of the EU medicines safety system will free up resources which can then be directed to better protecting the health of EU citizens."*

Prior to a medicine being authorised it has to undergo extensive studies to demonstrate that it is **safe, of high quality and effective**. Although all medicines have some risks (side-effects / adverse reactions) medicines are authorised when they are judged to have benefits that outweigh risks in the population to be treated. However, the safety profile of a medicine cannot be fully known prior to it being authorised because of the established limitations of clinical trials, for example inclusion of a limited number of patients, limited duration and careful control of how the medicine is use and what patients are selected. Therefore new or changing safety issues are detected once a medicine is on the market.

The current EU system of pharmacovigilance has slowly evolved over the past forty-years. There is a need to strengthen and rationalise the system so that it is fit for an enlarged EU with **innovative products** and reflects the needs and expectations of stakeholders and the opportunities brought by modern information technology and study designs.

Today's proposal includes both **better implementation** of the current system and proposals to **change the legal framework** for pharmacovigilance in the EU.

1. Improving **implementation of the current framework** will include but not be limited to:

- working with the Commission's Directorate General for Research on **funding of studies** into the safety of medicines as well as studies into the methodologies used to conduct pharmacovigilance.
- Working with the Member States to resolve implementation issues, including **administrative practices that complicate reporting** rules for industry.

- Working with the EMEA[1] to strengthen its coordinating role including supporting **full compliance and maximum utilisation** of the EU pharmacovigilance database '**Eudravigilance'**.

2. Proposals for **change to the legal framework** will focus on but not be limited to:

- **Strengthen the rules on transparency** relating to pharmacovigilance data, assessment and decision-making and **involve stakeholders** (e.g. patient and healthcare professional groups) in the processes **including reporting** (including patient reporting).
- **Establish clear standards** ('Good Vigilance Practices - GVP') for the conduct of pharmacovigilance by both the industry and regulators.
- Free up resource by rationalising and **simplifying the reporting of suspected adverse drug reactions** (ADRs), both expedited and periodic reporting, making best use of current information technology (including Eudravigilance) and matching the reporting requirements with the level of knowledge about the safety of a specific product.
- Make clear the respective **roles and responsibilities and minimise duplication of effort,** while maintaining the current split of competences between the Member States and the EMEA.
- Stimulate innovation by establishing a **clear legal requirement to conduct post-authorisation safety studies** including those in risk management systems.
- Rationalise EU decision-making on drug safety issues to deliver **fast, robust decisions that are equally and fully implemented** for all relevant products and across all markets.

The Commission services will be working on an impact assessment during the course of 2007 with a view to **a legal proposal in 2008**.

Background

Pharmacovigilance includes patients, healthcare professionals, regulators and the pharmaceutical industry and focuses on collecting information about medicines safety, detecting and assessing problems, taking decisions on action to reduce risk and implementing that action.

For more information on:

- the strategy to strengthen and rationalise the EU system of pharmacovigilance,
- the results of the public consultation,
- the independent study, and
- the current EU pharmacovigilance rules,

see:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance_acs/index.htm

[1] European Medicines Agency

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