EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Brussels, February 2007

# STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE

## 1. Pharmacovigilance: the issue

Pharmacovigilance is the process of monitoring the safety of medicines and taking action to reduce risks to the public. While fully recognising that medicines can save lives and relieve suffering, there is abundant evidence of the public health burden that adverse drug reactions cause with adverse reactions to medicines being a common cause of death. Based on an independent study[1], a public consultation, and analysis by Commission services, it is clear that the EU system of pharmacovigilance places significant administrative burdens on industry and competent authorities while weaknesses in the system continue. The current EU legal framework is complex and duplicative and there are a lack of clear roles and responsibilities. A lack of harmonisation of pharmacovigilance requirements among the Member States interferes with the functioning of the single market in pharmaceuticals.

## 2. Current legal Framework and its implementation

Pharmacovigilance rules in the EU are included in a directive of the European Parliament and the Council which lays down the rules for manufacture, distribution, authorisation and post-authorisation supervision of nationally authorised products (Directive 2001/83/EC as amended), in a corresponding regulation of the European Parliament and the Council for centrally authorised products (Regulation (EC) No 726/2004), in a Commission Regulation (Regulation (EC) No 540/95) and in Commission guidance (Volume 9A of Eudralex). Although the legislation was reviewed in 2004 (the so-called "2001 Review") the changes to the pharmacovigilance provisions were relatively minor. Importantly there was no thorough review of the pharmacovigilance provisions and as a result the current provisions have become gradually more complex over time and do not reflect the evolution in science and technology that has occurred, including the opportunities for simplification offered by the full use of modern information technology.

Different implementation by Member States has led to complex and diverse reporting requirements for the industry and this clearly interferes with the functioning of the single market for medicinal products.

The public consultation (see annex) has made clear that the current EU system for pharmacovigilance is complex, unclear, duplicative and an impediment to the single market in pharmaceuticals. There is clear evidence of both industry and regulator resources being diverted away from public health protection to meeting duplicative

[1] Both the study report and the consultation documents can be found at : http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BREY 10/118. Telephone: direct line (32-2) 2961268. Fax: (32-2) 2998046.
E-mail: peter.arlett@cec.eu.int

administrative requirements. Furthermore, a lack of clear roles and responsibilities combined with slow and cumbersome EU action in response to drug safety alerts puts patient safety at risk. Stakeholders are calling for the EU system to be rationalised and strengthened.

## 3. Way forward: strengthening and rationalising the EU pharmacovigilance system

To strengthen and rationalise the EU system of pharmacovigilance the Commission services will work with the European Medicines Agency (EMEA), the competent authorities of the Member States and other stakeholders to improve the implementation of the current legal framework, and, furthermore, it is foreseen to propose changes to the legal framework in 2008.

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 identify and resolve implementation issues, including and administrative practices that interfere with the single market.
- Working with the EMEA to strengthen its coordinating role including supporting full compliance and maximum utilisation of the EU pharmacovigilance database 'Eudravigilance'.

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

- Maintain the current split of competences between the Member States and the EMEA, while making clear the respective roles and responsibilities and minimising duplication of effort.
- 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.
- 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.

European Commission
February 2007