**Pharmacovigilance**

**ID:** 22 **Code:** COM (2008) 665 **Type:** Directive **Date of Proposal:** 10.12.2008 **Current Status:** in force since 20/01/2011

**Memo by:** Daniel Rasch **Team:** DE

**Title:** Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code

relating to medicinal products for human use

**Identified Commission Official:** DG Enterprise and Industry, Günter Verheugen shifted to DG Public Health

**Objective:**

The proposal is an integral part of the Commission "Strategy to Better Protect Public Health by

Strengthening and Rationalizing EU Pharmacovigilance" announced in February 2007 and aims at the strengthening and rationalizing the Community pharmacovigilance system of medicinal products for human use through the amendment of the two legal acts governing this field, with the overall objectives of better protecting public health, ensuring proper functioning of the internal market and simplifying the current rules and procedures. The specific objectives are:

* Rationalizing EU decision-making on drug safety issues in order to deliver measures that are equally and fully implemented for all relevant products and across the Community with a view to preventing unnecessary patient exposure to risks;
* Strengthening medicines safety transparency and communication to increase the understanding and trust of patients and health professionals in the safety of medicines and improve the penetration of key warnings;
* Strengthening companies' pharmacovigilance systems, allowing companies to improve their systems constantly while reducing administrative burden;
* Ensuring the proactive and proportionate collection of high quality data relevant to the safety of medicines through risk management and structured data collection in the form of post authorization safety studies, together with rationalized single case and periodic reporting of suspected adverse reactions;
* Involving stakeholders in pharmacovigilance through direct patient reporting of suspected adverse reactions and inclusion of patients and health-care professionals in decision-making;
* Simplification of the current Community pharmacovigilance procedures with consequent efficiency gains for both the pharmaceutical industry and medicines regulators.

**Background:**

The Community has had legislation on medicinal products on pharmacovigilance since 1965 but there has been no systematic review of the Community pharmacovigilance legislation since an independent study in 2004. One directive from 2001 and one regulation from 2004 are simplified and harmonized by this proposal.

**Consultation / Organised Interest Activity:**

In 2004, the Commission services launched an independent study into the functioning of the Community pharmacovigilance system. Two internet-based public consultations, dedicated workshops, questionnaires and bilateral meetings were held.

The Commission consultation received 81 contributions. In summary:

• 5 responses from patient and consumer groups, • 16 from healthcare professional groups and academics, • 26 from regulators including the European Medicines Agency Committees, individual European medicines agencies and regulatory authorities outside the EEA, • 28 from industry including the relevant European Industry Associations, • 6 others, including the European Monitoring Centre for Drugs and Drug, Addiction, the International Network of Safe Medication Practice Centers, the International Society of Drug Bulletins, and European and International health insurance associations. Only two of eighty-two responses were not welcoming the proposals. There was strong support for improving the robustness of EU pharmacovigilance with clear legal provisions and better use of resources i.e. resources used to monitor the safety of medicines and take action to reduce risks to users rather than used to meet duplicative administrative requirements.

**Issues / Frames:**

* Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse effects of medicinal products.
* Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, as the full safety profile of medicinal products can only be known after they have been placed on the market.
* the package of proposals will save the EU industry sector an estimated €145 Million per year representing 17.4% of their current EU spending on pharmacovigilance
* need to rationalize EU decision-making on safety issues. This support included strong endorsement for the establishment of an automatic pharmacovigilance referral procedure with non-discretional referral triggers placed on the Member States.

**Other Information:**

Definition of pharmacovigilance: the monitoring of adverse effects of drugs and herbal remedies as they are used in the population.

<http://moh.gov.jm/administrative/pharmacovigilance>