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- WORKSHOP 3 DECEMBER 2004 -

Recommendations in the area of pharmacovigilance

"Lack of Vigilance, Lack of Trust"[1]

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1 - Phil B. Fontanarosa, MD; Drummond Rennie, MD; Catherine D. DeAngelis, MD, MPH JAMA. 2004;292:(DOI 10.1001/jama.292.21.2647).

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Pharmacovigilance under scrutiny

By the time it was withdrawn, an estimated 80 million people worldwide had taken Vioxx (rofecoxib). A memo posted by the US Food and Drug Administration (FDA) on its website on 2 November 2004 suggests that Vioxx may have contributed to almost 28,000 heart attacks in the US between 1999 and 2003. By the time it was withdrawn, an estimated 80 million people worldwide had taken Vioxx (rofecoxib).

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Introduction to our propositions

- Pharmacovigilance encompasses surveillance and investigation of adverse drug reactions (ADRs) after short-term and long-term use of medicines in order to promote the appropriate and safer use of available medicinal products including risk minimisation.
- When medicinal products enter the market, clinical experience is limited. After marketing authorisation, further knowledge on their characteristics and toxicity **safety and risk profile** is gained continuously and previously unknown ADRs and interactions may be identified at any time.
- One major tool in pharmacovigilance today is spontaneous reporting by healthcare professionals, a method of passive surveillance. Throughout Europe, the level of spontaneous reporting of ADRs is low (so-called underreporting).

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Introduction to our propositions

- Due to underreporting and missing data in case reports (incomplete or low-quality information) of ADRs, spontaneous reporting systems have their limitations but have nevertheless identified previously unknown ADRs in many cases. However, one cannot be sure to efficiently identify all ADRs by means of spontaneous reporting.
- Spontaneous reporting by patients to healthcare professionals will be encouraged by competent authorities in accordance with revised EU legislation on medicinal products.
- Given the limitations of spontaneous reporting, epidemiological studies and other methods of active surveillance may be used to investigate and quantify the risks of medicinal products.

Introduction to our propositions

- There is lack of adequate awareness among the public about pharmacovigilance as an issue of public health.
- To effectively distribute new information to prescribers and patients remains a major challenge. This is in particular true for delivering information that balances the benefits and risks for individual patients appropriately. Safety information should not jeopardise therapeutic adherence.
- The success of any pharmacovigilance system depends on the capacity to communicate safety information effectively to the users of medicinal products.

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Comments received and discussed by the subgroup

Comments received by: CPME, EGA, MSD, Ministry of Health – Germany, EFPIA, PGEU, EPFA, Finnish National Agency, MEB

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Well accepted document

- comments were supportive
- most of them lead to "light" modifications (phrasing, etc.)
- only 3 were rejected

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A work in progress

- audit
- transparency and communication
- improvement of reporting (development of active pharmacovigilance methods)

Urgent mobilisation needed

- public scrutiny
- need to address the issue beyond pharmacovigilance (evaluation for example)

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Back up slides

- back up slides