



Press release
15 February 2012

Pharmacovigilance data: broadening access to *Signal* is a positive step, but access to *VigiBase* is also needed

Public access to *Signal*: a step into the right direction. The *International Society of Drug Bulletins* (ISDB), a worldwide network of independent drug bulletins, welcomes the World Health Organization /Uppsala Monitoring Centre's long-awaited decision to give broader access to *Signal*, its publication which draws upon data from the large WHO Global Individual Case Safety Reports (ICSR) database, also known as *VigiBase* (a).

The ISDB bulletins that deal with pharmacovigilance issues should benefit from *Signal*. But a degree of secrecy might well persist, as the current procedure "gives the opportunity for relevant pharmaceutical companies to read and comment on *SIGNAL* texts, prior to publishing" and since "articles will continue to be circulated to National Pharmacovigilance Centres prior to publishing in the *WHO Pharmaceuticals Newsletter*".

Suspected adverse drug reactions are public scientific data: public access to *VigiBase* is urgently needed. Data about adverse effects suffered by patients cannot be regarded as commercial data that pharmaceutical companies collect as part of their marketing operations. Health professionals and patients report suspected adverse drug reactions in order to help prevent their recurrence and the suffering of other patients.

Public access to all scientific data is needed to allow for independent decision-making. For example, *rofecoxib* (*Vioxx*®), *rosiglitazone* (*Avandia*®), *benfluorex* (*Mediator*®) were finally removed from the market only because of independent researchers' findings, based on analysis of clinical data and suspected adverse drug reactions. And since thorough collection of adverse event reports is a critical step in pharmacovigilance, public access to *VigiBase* will allow researchers and independent teams, such as ISDB editors, to make more comprehensive assessments of drug harms and check at the same time the quality of the data entered into the database.

In several countries around the world, databases of suspected adverse drug reactions have already been publicly accessible for a number of years (b).

The World Health Organization is "responsible for providing leadership on global health matters" (www.who.int). **We therefore request that *VigiBase* be made publicly accessible by the end of 2012.**

The International Society of Drug Bulletins

Notes:

a- Several times during the last 5 years, ISDB had asked for public access to *Signal*, as well as to the content of *VigiBase*, "in order to fully inform their readers about the safe use of drugs". ISDB as a society sent official letters to the Uppsala Monitoring Centre Director. The answer from the Uppsala Monitoring Centre was that access to *Signal* as well as to *VigiBase* database was restricted to National Health Authorities which were paying for the provision of that service (countries participating in the WHO Programme for International Drug Monitoring only). Consequently, ISDB members from many different countries around the world asked their National Health Authorities to give them access at least to *Signal*. And the answers from National Health Authorities were that they had to ask for Uppsala Monitoring Centre's permission... And despite reminders, up to now no ISDB bulletins were permitted access to *Signal*, either by their National Health Authorities or by Uppsala Monitoring Centre.

b- The US Food and Drug Administration (FDA) provides reports about suspected adverse drug reactions that occurred on its territory since 1998 (Adverse Event Reporting System (AERS) database), the Netherlands' national pharmacovigilance centre (Lareb) since 2003, the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK since 2005, and MedEffet in Canada since 2005.

In 2012, the European Medicines Agency (EMA) is very slowly starting to open "certain levels of access" to the Eudravigilance database (to the public, health professionals and independent researchers e.g. as aggregated summary reports or individual case report forms, but no access to signal detection nor analysis tools) (<http://eudravigilance.ema.europa.eu/human/docs/EV%20Access%20Policy%20for%20human%20use%20doc.pdf>).

The European Ombudsman has however repeatedly denounced EMA's maladministration when the agency refused to reply positively to document requests from the public on drug safety.

ISDB. The International Society of Drug Bulletins (ISDB), founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently it has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org.

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