AIM

Pharmacovigilance in Europe: overwhelming opposition to the EU Commission's proposals

● ***The European Commission must change its strategy if it is to strengthen pharmacovigilance in Europe.***

Various public health disasters (from thalidomide in the 1960s to rofecoxib (Vioxx) at the start of this decade) are constantly reminders of the need for an effective pharmacovigilance system in order to guarantee patients' safety.

Despite this, in February 2008, the European Commission submitted some very worrying legislative proposals for public consultation. Under the pretext of simplifying administrative procedures to "rationalise the system", the Commission proposes:

- to allow new drugs that have not been sufficiently evaluated to be marketed increasingly prematurely;
- to "delegate" tasks which should be the responsibility of the public pharmacovigilance systems to the pharmaceutical companies, even though they are both judge and defendant (1,2).

Fortunately, numerous stakeholders in the healthcare system have voiced their overwhelming opposition to these proposals which are a major threat to public health, as the Commission's own analysis of the public consultation shows (3).

"Risk management systems" benefit the pharmaceutical companies

In order to allow European pharmaceutical companies to obtain "*a faster return on investment*", the Commission proposes to speed up the marketing of new drugs by granting a greater number of premature marketing authorisations (1).

This step goes hand in hand with "risk management systems" based, significantly, on post-market studies piloted by the pharmaceutical companies. The Commission proposes to make these studies compulsory, otherwise sanctions should be applied. This proposal is a clear demonstration of how the proposed legislation seriously undermines pre-market evaluation.

The proposed legislation is tantamount to using European citizens as guinea pigs once medicinal products have been launched onto the market, relying on post-market studies to identify risks since the products will have not undergone thorough pre-market evaluation.

Civil society respondents to the public consultation expressed their overwhelming opposition to exposing the entire population to unknown risks in the interests of ensuring that the companies obtain a rapid return on investment.

► **First of all, do not jeopardise patients' interests: the most important means of strengthening pharmacovigilance and improving patient safety is to approve only medicinal products that have been thoroughly evaluated and which offer a genuine benefit for patients. Relying on "risk management systems" to compensate for insufficient pre-market evaluation is misguided and dangerous.**

The Commission must rethink its proposals

In order to strengthen pharmacovigilance and improve patient safety, the health authorities need the resources to be financially and intellectually independent from the companies. There must also be genuine transparency concerning data, information and pharmacovigilance decisions.

Strengthening the authorities' independence. The 2004 legislation gave a boost to pharmacovigilance resources by making it compulsory for this activity to be publicly funded, thus guaranteeing its independence (article 67.4 of Regulation (EC) 726/2004). As a number of national agencies and patient and consumer organisations have stressed, it is crucial that this provision be maintained and applied by the Member States (**a**) (3).

A major issue concerning the Pharmacovigilance Directive scheduled for autumn 2008 is the responsibilities that will be handed over to the future European Pharmacovigilance Committee. Many of the responders to the consultation demand that this body should have the power to demand the immediate

withdrawal of medicinal products with an unfavourable risk-benefit balance, without the risk of being vetoed by the European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) (**b**).

Break the companies' stranglehold on pharmacovigilance data, build strong public expertise. The European Commission proposes to entrust the pharmaceutical companies with the task of gathering and interpreting data, warning, analysing and informing the public of their products' adverse effects. This creates a major conflict of interests for the pharmaceutical companies (**c**).

Subcontracting the task of interpreting the data to the companies undermines the authority and expertise of the national drug regulatory agencies and public pharmacovigilance systems.

On the contrary, the European Commission must acknowledge and reinforce the role of the national and regional heath authorities, as many of the responses to the consultation emphasise (locally based, knowledge of the culture which enables them to process the data and make an in-depth analysis, etc.), and boost their independence to enable them to fulfil their public health remit (3).

Increased transparency of pharmacovigilance data. The vast majority of responders stress the need to increase the transparency of pharmacovigilance in Europe (3), apart from the pharmaceutical companies which are opposed to the limited transparency measures envisaged by the European Commission (**d**) (4). In actual fact, the pharmaceutical companies want to have greater influence over the health authorities' decisions: they demand a "right to monitor" – to veto even – each stage of the process, with a total lack of transparency (**e**) (4).

Making public the detailed minutes of meetings of all working parties, committees and sub-committees of the Agencies in charge of pharmacovigilance is a fundamental condition for maintaining the authorities' credibility.

The *Medicines in Europe Forum*, *Health Action International* (HAI) Europe and the *International Society of Drug Bulletins* (ISDB) call on the European Commission to rethink its proposed Pharmacovigilance Directive scheduled for autumn 2008 in the interests of protecting public health.

The European Commission's mission to protect public health (article 152 of the Treaty establishing the European Community) demands that it prioritises the interests of European citizens over the short-term financial interests of the pharmaceutical companies.

Medicines in Europe Forum **HAI Europe** **ISDB** **AIM**

Contacts:
MiEF: Antoine Vial (europedumedicament@free.fr)
HAI Europe: Teresa Alves (teresa@haiweb.org)
ISDB: Maria Font (maria.font@ulss20.verona.it)
AIM: Rita Kessler (rita.kessler@aim-mutual.org)

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Notes :

a- The drug regulatory agencies' chief source of funding being fees paid by the pharmaceutical companies puts them in a situation of dependency and makes them indebted to the pharmaceutical companies.

b- The Marketing Authorisation Committees are faced with an inherent conflict of interests since it is they who approve the marketing of the offending drugs in the first place.

c- Whereas the proposal that patients should report drugs' adverse effects directly was welcomed, the health authorities and many other responders were clearly opposed to the fact that under the Commission's proposals patients would report to the pharmaceutical firms, and demand that they should report to the national health authorities (ref. 3).

d- For example, reluctance for a list of drugs under intensive monitoring to be made public for fear of "*stigmatising those products*"; the refusal to make public the risk management plans, assessment reports and periodic safety update reports (PSUR); the conditions laid down for the formulation of summaries of these documents which, for example must not give an "*unbalanced presentation of safety signals outside the context of potential benefits*" (ref. 4).

e- E.g, requests to be routinely referred, to approve all publications of summaries of study findings, to make certain "experts" be invited to hearings of the future Pharmacovigilance Committee, and to read through and amend all the inspection reports, etc. (ref. 4).

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Références :

1- European Commission – Enterprise and Industry Directorate-General "EU pharmacovigilance: public consultation on legislative proposals" Brussels, 5 December 2007. Website: www.prescrire.org/docus/VigConsultEurope.pdf: 49 pages.

2- Medicines in Europe Forum, HAI Europe, ISDB "Joint contribution to the consultation relative to pharmacovigilance in Europe of the 5th December 2007" January 2008. Website www.prescrire.org/docus/ConsulPharmacovigJan08En.pdf : 8 pages.

3- European Commission – Enterprise and Industry Directorate-General "Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance: analysis of the results of the public consultation" http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/docs/information_april_2008/analysis_consultation_responses_200804.pdf.

4- EFPIA (European Federation of Pharmaceutical Industry Associations) "Submission of comments on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance" http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/docs/information_april_2008/48.pdf : 108 pages.