



Press release
February 2008, 1

Pharmacovigilance in Europe and patient safety: no to deregulation

A series of public health disasters (from thalidomide in the 1960s to rofecoxib (Vioxx^o) at the beginning of this century) have served to remind us that effective pharmacovigilance is crucial for the protection of citizens. Regrettably, the European Commission's proposed legislative changes, published on 5 December 2007, pose a serious threat to public health (1).

On the pretext of simplifying administrative procedures and "rationalising the system", the Commission's proposals undermine the European pharmacovigilance system and represent a major backward step for the evaluation of medicinal products.

Pre-authorisation evaluations of medicines: helping to boost the pharmaceutical firms' competitiveness while jeopardising patient safety

The European Commission's proposals will expose European citizens to medicines that have been less thoroughly evaluated prior to authorisation.

Cutting corners on marketing authorisations. The Commission's stated aim is to bring new medicines to market faster: "*Earlier product authorisation provides faster return on investment and, by reducing the cost of capital, the total cost of product development is reduced*".

To achieve this, the Commission proposes to undermine the pre-authorisation evaluation by making conditional authorisations the norm rather than awarding them only in exceptional circumstances, when there is an urgent therapeutic need, as is currently the case.

To foster this shift and at the same time reassure the public, the Commission is hiding behind the concept of "risk management systems", set up and piloted by pharmaceutical companies. Unfortunately, these "risk management systems" are not designed with patient safety as the key priority.

Having medicines approved even when "therapeutic efficacy is insufficiently substantiated". The Commission is proposing to delete "*therapeutic efficacy is insufficiently substantiated*" from the list of reasons for refusing a marketing authorisation or withdrawing a drug. However, only proven efficacy can in fact justify exposing patients to adverse effects.

Furthermore, how can the authorities evaluate the risk-benefit balance of a new drug if they do not have robust evidence of its efficacy?

Companies in charge of pharmacovigilance data: at every stage, at the cost of patient safety

Entrusting the pharmaceutical companies with the task of gathering and analysing data, issuing warnings and informing of their products' adverse effects is unacceptable due to in-built conflict of interests. And yet the Commission's proposals provide for the industry's intervention at every level of decision-making, putting them in the position of both judge and defendant.

Gathering risk evaluation data: minimal demands. The Commission is proposing that post-authorisation studies and risk management plans can only be requested by marketing authorisation committees under limited conditions, and that the "risk management" system shall "*be proportionate to the identified and potential risks taking into consideration the information available on the medicinal product*". Unexpected or delayed adverse effects, even when severe, are likely to be excluded from these systems, which are not designed to identify rare long-term adverse effects.

Routine data gathering: centralisation and dilution of responsibilities. The placing of pharmacovigilance responsibilities on the holder of the marketing authorisation, the parent company, threatens to remove the responsibility from those exploiting it at national level. The stipulations for data recording and processing are unclear and do not allow for any external monitoring.

Asking patients to notify directly to the companies adverse effects for intensively monitored drugs is unacceptable.

The companies' pharmacovigilance systems cannot under any circumstances become a substitute for national public pharmacovigilance systems which unequivocally serve public interest.

Subcontracting data monitoring to pharmaceutical companies: danger. The Commission plans to subcontract the monitoring of "*all available relevant data including data on Eudravigilance for signals of new or changing risks (...)*" to the firms, even though they are both judge and defendant. It will also be up to the companies to alert the authorities in the event of new data likely to affect their product's risk-benefit balance.

Data analysis: lack of transparency. According to the Commission's proposal concerning the results of post-authorisation studies, it is up to the firms to: "*consider whether the results of the study impact on the product labelling*" or "*might influence the risk-benefit balance of the medicinal product*". Subcontracting the interpretation of the data will result in the drug regulatory agencies losing their authority and expertise.

The decision-making process: the payer calls the tune... The 2004 Regulation strengthened the resources to be devoted to pharmacovigilance, insisting that it should be publicly funded to guarantee its independence, specifying that: "*Activities relating to pharmacovigilance, (...) shall receive adequate public funding commensurate with the tasks conferred*" (Article 67.4 of Regulation 726/2004 (EC)).

The Commission is planning to abolish this requirement for adequate public funding and to allow pharmacovigilance to be directly funded by the firms through the marketing authorisation fees paid to the agencies.

Information on adverse effects: blurring of roles. It is the authorities' responsibility to process and interpret data, and to communicate the results. At present, pharmaceutical companies are sending out "Dear Doctor" letters, thus speaking on behalf of health agencies, which is likely to result in abuses with companies trying to promote their medicines to health professionals.

Redressing the balance

Medicines in Europe Forum, ISDB and HAI Europe strongly condemn the Commission's proposals and call on it to re-focus its efforts and defend the public interest, in accordance with its remit to protect European citizens (Article 125 of the Treaty establishing the European Community) (2).

The above organisations' concrete proposals to strengthen pharmacovigilance effectively fall into four categories:

- more stringent marketing authorisation criteria to ensure the approval of medicines offering a genuine therapeutic benefit;
- guaranteeing the transparency of pharmacovigilance data, information and decisions;
- granting authorities the means to be financially and morally independent from the pharmaceutical companies;
- ensuring resources are in place for effective pharmacovigilance systems.

These proposals are set out in detail in their joint contribution to the Commission consultation (2).

Contacts:

MiEF: Antoine Vial (europedumedicament@free.fr)

HAI Europe: Teresa Alves (teresa@haiweb.org)

ISDB: Maria Font (maria.font@ulss20.verona.it)

Références :

1- European Commission – Enterprise and industry directorate-general "EU pharmacovigilance: public consultation on legislative proposals" Brussels, 5 December 2007. Site internet : <http://ec.europa.eu/enterprise> : 49 pages.

2- Medicines in Europe Forum, HAI Europe, ISDB "Joint contribution to the public consultation on pharmacovigilance in the EU of 5 December 2007" January 2008. www.prescrire.org and www.isdbweb.org : 8 pages.