



## Time to act for Patient Safety in Europe

Answer to the open consultation "Patient safety" (1);  
deadline : May 2008, 20

### Joint open letter

to interested parties:

- DG Sanco Stakeholder Group
- Health Policy Forum members
- Members of European Parliament
- Media

Commissioner Androulla Vassiliou  
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Paris, May 2008, 19

Dear Commissioner Vassiliou,

The *Medicines in Europe Forum*, *Health Action International (HAI) Europe* and the *International Society of Drug Bulletins (ISDB)* take notice of the European Commission's intention to strengthen patient safety, notably through the launch of a public consultation in March 2008 by the Health and Consumer Protection Directorate (1). The protection of European citizens is, as a matter of fact, one of the European Commission's remits (article 125 of the European Treaty).

### Patient safety: beyond reinforced pharmacovigilance

Various public health disasters have stressed the need for adequate assessment of medicines before marketing and for effective pharmacovigilance, i.e. the two mainstays of patient safety. Under the guise of simplifying administrative procedures and "rationalizing the system", the Commission's proposals made public in February 2008 undermine European pharmacovigilance and represent a major step backwards in the evaluation of medicinal products (2).

On this occasion, the *Medicines in Europe Forum*, the *International Society of Drug Bulletins (ISDB)* and *Health Action International (HAI) Europe* submitted several proposals to reinforce European pharmacovigilance (and thus improve patient safety):

- to reinforce marketing authorisation criteria so that new medicines being approved offer genuine therapeutic benefit;
- to guarantee that all data, information and decisions in the field of pharmacovigilance are transparent;
- to grant authorities the means to be financially and morally independent from pharmaceutical companies;
- to provide resources for effective pharmacovigilance systems, notably by encouraging adverse effect reporting by patients directly to health authorities, and by promoting exchanges between the authorities and networks specialized in medication error management and adverse events reporting (2).

► **The *Medicines in Europe Forum*, *HAI Europe* and *ISDB* invite the European Commission to overhaul its proposals regarding pharmacovigilance for the benefit of patient safety.**

### Consultation on patient safety: yet another survey, when European citizens' have already expressed their views

The framework of the present consultation on patient safety, which consists of a simple survey, does not allow an effective contribution towards the improvement of patient safety in Europe (1). It is surprising that

such survey was deemed necessary, as recently in 2006 the European Commission published the results of a “Special Eurobarometer” survey on the European citizens’ perception of medical errors (3). The latter revealed that Europeans regard medical errors to be a major issue.

► **The Medicines in Europe Forum, HAI Europe and ISDB encourage the European Commission to revisit the results of the 2006 Eurobarometer survey, and to focus on existing European recommendations.**

### Other European and international initiatives on patient safety must be taken into account

The preface of the 2008 survey does not mention the efforts already made by the European Commission in the field of patient safety, such as:

- the High Level Group on Health Care (2004-2006) created by the Directorate-General Health and Consumer Protection;
- the Luxemburg conference entitled "Patient safety – making it happen!" that led to the publication of the Luxemburg declaration in April 2005;
- the 2005-2007 SIMPATIE program (Safety Improvement for Patients In Europe);
- and the European Network for Patient Safety (EUNetPaS) launched in February 2008.

**The Council of Europe recommendation as a stepping-stone.** Long committed to patient protection, the Council of Europe adopted in 2006 a recommendation on the management of patient safety and adverse event prevention in health care (4). The European Commission should not hesitate to use this as the basis for its work, especially as the SIMPATIE program was conducted in collaboration with the Council of Europe.

**Patient safety is a global issue, at an international scale.** Following the famous report of the US Institute of Medicine, the “Quality of care: patient safety” resolution was adopted in May 2002 at the 55<sup>th</sup> World Health Assembly (5,6). Since then, the World Health Organization (WHO) proposed, among other aspects, increased patient and consumer participation, an international taxonomy, and further research and implementation of "solutions" to improve patient safety. Guidelines for consumer adverse event reporting and learning systems are also available. The "Patients for Patient Safety" program enables patient participation through adverse events reporting and to recommend improvements, was launched in 2005.

► **The Medicines in Europe Forum, HAI Europe and ISDB encourage the European Commission not to limit its work to the current “open consultation”, as this could delay the implementation of important measures previously established by the Council of Europe and by the World Health Organization. This could also give the impression of inconsistency.**

### Patient safety cannot wait: immediate action is required

The consultation launched in March 2008 by the European Commission is likely to delay the implementation of existing practical proposals, thus unnecessarily exposing patients to otherwise preventable adverse events.

► **The time has come to act and to implement the proposals developed by the World Health Organization and the Council of Europe (4), and by opposing the February 2008 proposal of the Directorate general Enterprise to undermine the European pharmacovigilance system (2).**

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#### References:

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- 2- Medicine in Europe Forum, HAI Europe ISDB “Joint contribution to the public consultation on pharmacovigilance in the European Union of 5 December 2007” January 2008. <http://www.prescrire.org/docus/ConsulPharmacovigJan08En.pdf> and [www.isdbweb.org](http://www.isdbweb.org): 8 pages.
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- 4- Council of Europe “Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care” 24 May 2006.
- 5- Kohn LT et al. “To err is human. Building a safer health system” National Academy Press, Washington 2000: 239 pages.
- 6- World Health Organization “Quality of care: patient safety” Fifty-Fifth World Health Assembly, WHA55.18 18 May 2002.