

Amsterdam, 18th May 2009

Response to the Committee of the Regions' Draft Opinion on Pharmaceutical Package

This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, growing, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI Europe promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

Summary

HAI Europe welcomes the opportunity to comment on the draft working document from the Committee of the Regions. We would like to highlight particular worrying elements of the so-called pharmaceutical policy package.

(Text from the Working Document on which HAI-Europe wishes to directly comment on is below in *italics*. HAI-Europe's comments, corresponding to selected numbers in the Working Document, are below in text.)

1. *“There is a need for harmonization of legislation on information provided to patients on medicinal products subject to medical prescription.”*

The current legislation (Directive 2001/83/EC amended by Directive 2004/27/EC) does not preclude the dissemination of information about prescription medicines to patients. That is, information can currently be given through many facets, with the exception of dissemination by the pharmaceutical industry. HAI strongly supports upholding the current Directive. In order to enhance information provided to patients, there is no need to change the present legislation. Instead, national information dissemination systems can be strengthened (i.e. national agencies, health professionals, etc.) without changing EU legislation.

2. HAI Europe reminds the Committee of the Regions that the World Health Organization (WHO) emphasizes that independence of medicines information is [a crucial element of the rational use of medicines](#)

4. HAI Europe recognizes that the European-based pharmaceutical industry is primarily accountable to stakeholders and it motivated to continuously advance their market share for financial gain. These economic interests often supersede the pharmaceutical industry's public health role.

6. HAI Europe recommends the strict application of competition policy in the area of pharmaceuticals. Patent rules should be applied more rigorously and the granting of patents should be more stringent. Patents were developed as tools to foster innovation by providing a temporary exemption from open market competition that can only work if it is, indeed, temporal. The high premium for patented brand name products is tolerated for the simple reason that it should stimulate research and development into new pharmaceutical products. Patent lengths should thus reflect the innovation life cycle of an industry. The longer the patent life, the more the monopolistic dangers of patents increase and the less their innovation benefits are manifested. ([See HAI Europe's Response to DG Competition Consultation, January 2009](#))

8. *“Pharmaceutical companies must only be allowed to provide information on medicinal products subject to medical prescription in accordance with the established criteria and via pre-specified information channels. TV and radio advertising must not be permitted.”*

HAI believes that any involvement of pharmaceutical companies, beyond that which is currently established in Directive 2001/83/EC amended by Directive 2004/27/EC, in the delivery of information on prescription medicines to patients is inappropriate. Informational channels besides TV and radio, such as the internet, can be equally problematic and need to be avoided. The internet, for example, offers many facets through which an audience can be captured and brand loyalty developed. (i.e. elaborate “informational” animated clips about the advantages of the medicine, flashy images coaxing continued website viewing, discrete links to further “information” or related medicines, e-mail alert prompting routine exposure to medicines “information”, etc.)

Certain information channels, such as e-mailed or posted documents, could require the collection of private patient information (i.e. patient contact details, type of condition, duration, medical history, etc.) by pharmaceutical companies. In these situations, there is the potential for the invasion of patient privacy. This threat further substantiates the need to limit the pharmaceutical companies' role in providing information on prescription medicines to that on the package and leaflet.

The provision of information on prescription medicines by pharmaceutical companies is another promotional facet to build patient trust in the product and/or brand, thereby developing brand loyalty and expanding the companies' market share. Greater promotion of branded medicines hampers generic competition, as generic producers can not afford to deliver “information” of promotional nature through the same means as originator companies. Brand loyalty can overburden healthcare professionals with patient requests for specific medicines, including the newest, and likely most expensive products, with limited benefit-risk balance.

9. *“believes that information provided by the pharmaceutical industry must comply with quality standards and preferably be approved in advance, either by the member State where the medicinal product is authorized or at the EU level in the case of centrally authorized medicinal products. Each Member State would decide itself on a monitoring system for*

ensuring compliance with the rules applicable to medicinal products authorized under the mutual recognition framework in accordance with directive /83/EC.”

In granting the industry an expanded “informational” role, this proposal would bring about additional bureaucracy and increased costs for the approval and monitoring of “informational” messages. This proposal would risk the financial sustainability of Member State’s public health systems. This leads us to ask: should public authorities use their limited resources to act as law enforcers and control the pharmaceutical industry, or that be proactive and invest in validated processes towards the provision of independent and comparative information to the general public?

11. *“Information provided by pharmaceutical companies should complement that provided by healthcare services.”*

HAI believes that pharmaceutical industry’s role to provide accurate information to patients through medicines packaging and the patient information leaflet, as prescribed by the Directive currently in place, is sufficient. The pharmaceutical industry’s “informational” role should not be extended past this responsibility; further information can be provided to the patient by the medicines’ authorities, independent bodies, as well as the healthcare services within the context of an honest and trusting relationship; all these without changing the current legislation.

12. HAI Europe recognizes the compromised capacity of the pharmaceutical industry to objectively present the risks and assess the benefits of medicines, due to their inherent financial interest(s) in the product at hand. The information” from pharmaceutical companies can be neither reliable nor comparative. Therefore this aspect of the Commission’s proposal has no added value for European citizens. A change to the current EU legislation upholding a ban on direct-to-consumer-advertising (or communication, in this case) would only serve the commercial benefit of the pharmaceutical companies by expanding their market reach.

18. *“requests the Commission to also take steps to address the problem of falsified medicinal products traded outside the legal supply chain”*

Identification systems that ensure the trade of safe and quality medicines should not impair access to medicines. HAI Europe cautions against the adoption of “high tech” identification methods (i.e. use of radiofrequency identification or bar coding) in the chain of supply, which can inadvertently increase medicines prices, therefore reducing access to medicines and significantly hampering the fair competition of generics that are unable to afford such extravagant identification systems.

20. *“asks the Commission to monitor price developments with a view to ensuring that the proposed authorization procedure does not lead to higher medicine prices and notes that the measures taken must be devised so as to strike a balance between increased safety and growing costs”*

In the interests of increased safety and cost effectiveness, HAI proposes that a fourth criteria, that of real therapeutic advantage, be added to the current evaluation criteria of efficacy, safety and quality when granting market authorization. The therapeutic advantage would be compared with existing treatments, and demonstrated by relevant clinical data collected from well-designed comparative clinical trials. This would protect patients from the needless exposure to adverse effects, and it is an efficient way of halting the present waste where Member States’ health budgets are funding, at high prices, too often new drugs of little therapeutic value. In addition, this would encourage the pharmaceutical industry to refocus its efforts in its core public health role, which is to develop new medicines to meets patients’ needs.

21. “endorses the proposal to rationalize the Community pharmacovigilance system for medicinal products for human use with a view to improving patient safety”

HAI asks that the national and regional pharmacovigilance centres be maintained and recognized as an authority with expert knowledge of the local population. Their services are accessible to patients, particularly in their own language, and, as a local agency, these pharmacovigilance centres can provide a rapid response to reports of adverse effects. (The elimination of national and regional centres in favour of a single European pharmacovigilance centre gives a diluted, macro view of medicines on the market. Such a far removed agency will experience delayed responses to patient reports, which leaves the patients exposed for too long to the harms of drugs.)

Moreover, pharmacovigilance centers at all levels (inc. European, national, regional) should continue to be publicly funded so as to provide objective monitoring and impartial analysis of medicines on the local market. The alternative proposed by the Commission is to have pharmacovigilance agencies funded by industry’s fees, to be collected by the regulatory authorities. This procedure reduces these “watchdog” groups to the rank of service providers to industry.

The creation of a Pharmacovigilance Risk Assessment Advisory Committee (PRAAC) can be a positive measure to protect European citizens IF the Committee is granted increased authority to withdraw or amend a marketing authorization without further recommendation by the marketing authorization committee (Committee for Medicinal Products for Human Use at the EU level). Otherwise it will remain an Advisory Committee without teeth, which will only have the means to produce recommendations.

22. HAI supports the creation of a direct reporting system used by patients and healthcare services; but is, however, cautious about which party will be designated to process and have access to these reports, particularly if pharmaceutical industry, with a clear conflict of interest, processes this information. HAI asks that direct patient reporting of adverse effects is collected, accessible and researched by independent authorities.

23. HAI endorses public access to all relevant pharmacovigilance data including the European database on adverse effects. Moreover, HAI proposes full and immediate public access to Periodic Safety Update Reports (PSURs), including consumption data. Increased transparency on the known effects of medicines will support healthcare services and enhance patient safety.

24. “believes that the proposed amendments with respect to package leaflet – in particular those concerning the close monitoring of adverse reactions – will help to speed up changes to the contents of package leaflets. This may lead to a situation where patients receive out of date package leaflets, possibly containing misleading or false information. The long-term aim must be that when a medicinal product is dispensed it is always accompanied by an up to date package leaflet.”

The improved regulations relating to the medicines authorities’ transparency introduced in the pharmaceutical review in 2004 should be applied more rigorously and strengthened. HAI supports several measures that would be relatively simple to implement:

– to enable easy identification of adverse events and recent pharmacovigilance decisions, by highlighting key points and printing them on the patient leaflet in bold type;

– help identify medicines that have been authorised despite insufficient evaluation, by including the statement "This medicinal product is under intensive monitoring. All suspected adverse reactions should be reported to <name and web-address of the national competent authority>"

Other relevant comments

Under the proposed changes, Risk Management Systems (RMS) are being proposed to mitigate public concern (about drug safety) when medicines with ambiguous risk-benefit balance have been granted (premature) market authorisation.

A clear opinion on Risk Management Systems is absent from the Committee of the Regions' Working Document.

- HAI Europe believes RMS are inept at justifying “conditional” marketing authorisation. First, RMS needlessly risk patient and consumer safety. Medicines that would require RMS are in this category because the benefit-risk balance can not be clearly demonstrated, thus the need for a “conditional” market authorisation. Second, RMS could potentially jeopardize patient privacy. RMS require patient monitoring during and after the course of drug administration, which elicits concerns about the use of the medicine and the overall security of the patient.



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