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## **Health Action International Europe's Response to the Directorate of Health and Consumer Protection Consultation on Future Challenges**

### **Health Action International Europe (HAI Europe)**

This response has been prepared on behalf of 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, the poor and the marginalized 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, independent information for prescribers and consumers.

### **Summary**

HAI welcomes the paper and acknowledges the need to assess future challenges within the Directorate of Health & Consumer Protection. Since HAI Europe is primarily concerned with access to essential medicines and their rational use, this response focuses on issues most pertinent to HAI Europe's core mission.

### **Key points**

These are the key points raised by HAI Europe in its response to the DG SANCO consultation on Future Challenges:

- **Overall approach and terminology**
- **Information provision & Public- Private Partnerships**
- **Openness and transparency**
- **Defining responsibilities**
- **Confusing concepts: generic medicines and counterfeit medicines**
- **DG SANCO's position at a global level**

## Overall approach and terminology

Firstly it is essential to clarify the expressions and concepts used throughout the document. Fundamental terms such as consumer, citizen and patient are not interchangeable *per se*, and have different meanings depending on the context in which they are used. Recurrently throughout the document the term ‘consumer’ is used when the word ‘citizen’, and in some cases ‘patient’, would have been better suited.

A specific example is on page 13 - *Critical factor 5: Understanding the consumer’s viewpoint of risk*. In this case, why has the word consumer been employed instead of the term citizen? Shouldn’t risk awareness concern all European citizens, regardless of the fact they are health services users? Not surprisingly, the paragraph thereafter uses the expressions ‘consumers’, ‘general public’ and ‘citizens’ alternately, assuming they are transposable. Another case is in *Critical factor 10: Taking into account additional new influences in consumer’s choice which* is even more unacceptable as it speaks about public health and medicines.

These terms refer to different notions and the paper should make a clear distinction between both terms, briefly stating their meaning and presenting them in a preliminary glossary. DG SANCO should be aware of the political and moral implications of such terminology. Referring in general terms to *consumers* implies the existence of a health market and free choice. And yet, health is a basic human right, and should therefore not be seen as a mere commodity.

Furthermore, the report seems to adopt a deterministic approach to the trends identified. Most notably, phrases such as ‘consumerization of health’, ‘there is a growing view that ‘health’ is a product that can be bought’, ‘everything is becoming more corporate and market driven’, indicate an uncritical perspective on recent developments. By accepting the latter as unavoidable outcomes and so resolutely, the DG is accepting the overriding of public health interests, when it should, in fact, remain critical and question the implications of such developments to the European region. At all times, DG SANCO is expected to defend public health above all other interests, identifying the best strategy and practices accordingly. This is the mission and responsibility of DG SANCO, as no other DG will be inclined to take up public health as a top priority.

## Information provision (Critical Factor 2, 6, 7, 9)

*Delivering “real” results*. On page 12 of the document, a reference is made to new forms of regulation and innovative policy-making, including self-regulatory procedures and public-private partnerships.

In May 2007, the World Health Assembly adopted a resolution on ‘Progress on the Rational Use of Medicines’<sup>i</sup>. Paradoxically, at a moment when the international health community is keen to recognize the conflict of interest inherent in the provision of information on medicines by the pharmaceutical industry and drug promotion as a key driver in the irrational use of medicines<sup>ii iii</sup><sup>iv v</sup>, **the European Commission is proposing public-private partnerships as a solution to the “information desert” that it assumes Europe has become. Private-public partnerships in information provision, involving either the pharmaceutical or medical device industry, represent clear conflicts of interest and very likely will lead to irrational use of medicines and increased costs<sup>vi vii</sup>.**

HAI Europe’s position is that in order to make an informed choice among available options and services, treatment and non-treatment, patients should have access to **independent, unbiased**

**and comparative information**<sup>viii</sup>. Newly diagnosed patients can be extremely vulnerable. They do not require information that has been designed to meet the pharmaceutical industry's need for a competitive advantage. **Patients and the public need information that is independent of any need to promote product sales. The health industries cannot meet this need as no company can be expected to present its own product in an unfavourable light, to promote competitors' products over its own, or to explain how best to avoid the use of its products.** There is a fundamental conflict of interest in such an approach.

Bearing in mind the above points, HAI applauds the clear distinction the paper makes between knowledge and information. Nevertheless, DG SANCO should go beyond the simple recognition of a possible information overload and identify its own role and responsibilities more clearly, for instance, by taking a more active role in health literacy and ensuring unbiased and accurate health information.

#### **Embedding openness and transparency (Critical factor 4)**

'Embedding openness and transparency' should not just be identified as an important objective but recognised as an actual need to change both structure and operations. Admittedly, DG SANCO has been engaging in several initiatives promoting increased transparency. Yet democratic illegitimacy remains one of the greatest shortcomings of the EU bodies and great efforts have to be undertaken to unravel this scenario.

An important item to be addressed within this section is the 'Stakeholder dialogue' initiative. DG SANCO should not only define clear criteria for interaction with stakeholders, but also openly disclose participants' names and their potential conflicts of interest. For instance, DG SANCO is heading the Pharmaceutical Forum, a high-level group which has operated obscurely since its inception, without disclosing criteria for participation or distributing minutes and proceedings in a timely manner. Consequently, the legitimacy of such a group, and its outcomes, remains open to question.

#### **Defining responsibilities**

The document is voided of a sense of strong ownership. The overall theme '*DG SANCO as a credible partner*' reiterates this interpretation. DG SANCO could and should be more than just a credible partner and should take the lead to proactively defend public health within the European Union. The influence of the EU is remarkable and widely recognised: DG SANCO should acknowledge this fact by acting upon it, and taking up its responsibilities.

A flagrant example of such a lack of ownership is the undermined role played by DG SANCO within the European medicines' policy. DG SANCO could and should have more prominence in the pharmaceuticals portfolio which is currently dominated by DG Enterprise & Industry. Pharmaceuticals are not average products or commodities. They should involve at all times an informed choice between the overall benefits to be accrued and the harms incurred from treatment, and such a decision should be voided of commercial interests. By recognizing the human right to health, the European Union will have to reconsider medicines policy also in a human rights approach, rather than as a tool to increase overall competitiveness of the European pharmaceutical industry. Thus, DG SANCO ought to take a stand from a public health perspective and assertively demand and/or build up its position a key-player role in the field of pharmaceuticals.

## **Confusing concepts: generic medicines and counterfeit medicines (Critical factor 10)**

The draft as it stands confuses the notion of counterfeit medicines with the notion of generic medicines. Counterfeit medicines are a major concern to public health. However this is mainly a problem outside Europe, although there are reports of growing numbers of counterfeit medicines being seized within the E.U..

The paragraph referring to ‘other factors may influence the increase of counterfeited medicines and other medicinal products and devices’ .... ‘This will raise issues for DG SANCO as to whether it should become involved in intellectual property right and/or quality standards rather than safety’ is extremely vague and insinuating. Counterfeit medicines are not directly related to intellectual property issues. As the UN bodies have recognized, counterfeits are the result of criminal activity. They are illegal.

Generic medicines, however, are indeed related to intellectual property matters. They do not represent a risk for European patients or consumers, but rather an opportunity to achieve equitable access to essential treatments.

## **DG SANCO’s position at a global level**

HAI applauds the fact that DG SANCO is willing to reinforce its position at a global level. Globally DG SANCO should also take up the responsibility to ensure health to all in the progressively deregulated and competitive EU environment. Concerns have been raised that Free Trade Agreements negotiated by the EU with developing countries tend to undermine the access to health of the poor, through liberalisation and privatization of public health systems. At a recent meeting on EU bilateral and regional free trade agreements, representatives from both Central America (Central America Association Agreement) and Asia (ASEAN Free Trade Agreement) voiced their criticism on FTAs and their implications to public health in their respective regions<sup>ix</sup>.

Finally, we appreciate the chance to comment and hope that the above points will be taken duly in account.

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<sup>i</sup> Progress in the Rational Use of Medicines, WHA60.16. *WHO Website*: [http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R16-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R16-en.pdf)

<sup>ii</sup> Prosser, Almond and Walley *Family Practice* 2003; 20:61-68

<sup>iii</sup> Mintzes B et al. “How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA” *CMAJ* 2003; 169 (5): 405-412.

<sup>iv</sup> Kravitz et al. “Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial” *JAMA* 2005; 293: 1995-2002.

<sup>v</sup> Mansfield P “There’s a better way than DTCA”. In: “What are the public health effects of direct-to-consumer drug advertising?” *Plos Medicine* 2006; 3 (3): 777-778.

<sup>vi</sup> Lazarou et al. *JAMA*, 1998;279:1200-1205

<sup>vii</sup> Lasser et al. *JAMA*, 2002;287:2215-2220

<sup>viii</sup> HAI Europe, ISDB, BEUC, AIM, Medicines in Europe Forum "Relevant information for empowered citizens" 3 October 2006: 9 pages. Website: <http://www.haiweb.org/01102006/PatientInformationDeclaration.pdf>

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ix «EU bilateral and regional free trade agreements. *Bringing women to the centre of the debate*», organised by the WIDE network in Brussels on 22 November 2007. For more information see [www.wide-network.org](http://www.wide-network.org).