OPINION OF HUNGARY

in respect of the public consultation document

LEGAL PROPOSAL ON INFORMATION TO PATIENTS

Hungary welcomes the Communication from the Commission to the European Parliament and the Council concerning the report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use (hereinafter referred to as the Communication) and recognizes the need to improve provision of information to patients in respect of the whole range of pharmaceuticals. We note that Patients tend to play a more and more active role in taking decisions relating to their treatment, which can be further ensured if they are enabled to take informed decisions. There is therefore a good opportunity to balance the information asymmetry experienced in the healthcare sector.

The legal proposal, which is not yet an official Commission position, tackles the issue of non promotional information about prescription medicines without the intention of affecting the existing ban on advertisement applied in this field.

Before the Commission decides on submitting a legislative proposal to the European Parliament and the Council, we would like to express our expectations as regards such a proposal.

Need for clear distinction between advertisement and non promotional information – Hungary strongly supports the current regime prohibiting advertising of prescription medicines. It is therefore of utmost importance to find a methodology enabling all the stakeholders to provide information without commercial interests. Hungary can accept only a mechanism which guarantees that information provided on prescription medicines will remain unbiased and objective and free of commercial motivations.

Enhancing active patient participation in information mechanisms (focus on pull approach) – In our view, an eventual legislative proposal should build on the patients' active search for information. This could contribute to excluding promotional elements. Unsolicited provision of information on prescription medicines always risks to constitute *de facto* advertisement, while information if provided when patients seek for it can be free of advertisement elements (provided that other quality criteria defined by Pharmaceutical Forum are also met). It should be examined whether existing mechanisms already ensures effective information to patients.

Content of information strictly based on summary of product characteristics (SPC) and product information leaflets (PIL) – SPC and PIL contain information which is already validated by authorities and their modification is subject to the

respective variation rules, so the reliability is sufficiently ensured. Hungary would have serious concerns if information on medicines contained "*other medicine related information*" going beyond the SPC and PIL or any implications on possible off label use.

Efficient monitoring with clearly defined roles - If the eventual legislative proposal contains rules on monitoring of information in line with the mechanisms described in the public consultation document, particular attention should be paid to exclude conflicts of interests within self regulatory bodies. The role of public authorities at different levels of the monitoring system is not clear. In the majority of cases, public authorities to be participating in national co-regulatory bodies are medicines authorities, while the competent authority supervising these bodies will also be a medicines authority (since other public authorities have no sufficient competence in monitoring information on pharmaceuticals). We can not see how it is possible to delimit responsibilities of these authorities on the different levels.

Another contradictory point of the proposal is to extend systematic monitoring of all information, which can result in increased task for authorities, while the other objective is to reduce administrative burdens.

Main elements of code of conducts should be clearly defined at Community level in order to ensure equal standards of monitoring all over the Union. It should also be taken into account that cooperation relating to patient information can have cross border elements in certain regions, which makes harmonized rules particularly important.

The health professional and public authorities as the primary source of information – While the communication underlines new emerging sources of information (such as internet), the new legislatives proposal should build on the principle that the main source of information should remain health professionals and public authorities.

Conclusions – Hungary is fully aware of the need for efficient information to patients about the whole range of medicines. All the same, the current regime concerning the ban on advertisement of prescription medicines must not be changed. Careful distinction should be elaborated between advertising and non-promotional information, which can be better ensured by enabling patients to search for information. The principal sources of information should remain healthcare professionals and public authorities, and information coming from other sources should be subject to careful validation.

Budapest, 7 April 2008