

European legislative proposal planned for autumn 2007. Full information material on:
<http://www.prescrire.org/cahiers/dossierEuropeMedInfoPatientAccueilEn.php>
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EU Pharmaceutical Forum: public health is not its overriding priority

The current priority for the European Commission is to support the competitiveness of the pharmaceutical industry. Nowhere is this clearer than in the recommendations of the EU Pharmaceutical Forum, an advisory group set up by the Commission (1). European citizens do not see their needs reflected in the recently published Pharmaceutical Forum's report and recommendations.

This report aims to increase competitiveness in three main ways: expansion of direct-to-consumer product promotion under the guise of 'patient information'; weakening comparative evaluation of therapeutic value for new drugs; and continued support for unjustified and arbitrary pricing policies. The position taken by the Commission and the Forum poses grave risks to health and sustainability of health care services. Alternative approaches are needed, as outlined below.

Practically two years' work in total opacity resulted in highly questionable outcomes. The Pharmaceutical Forum's flawed methodology and lack of transparency have already been widely criticised (2,3). By June 2007 there were still no significant improvement, and some members of the Forum even felt morally bound not to endorse a few of the report's findings (4). The Forum's conclusions were based on incomplete lists of information providers, methodologically unsound surveys and hasty observations which open up the way to biased proposals heavily favouring pharmaceutical companies.

Patient information: soon to be entrusted to the pharmaceutical industry? The report on current sources of "patient information" in the European Union drawn up by the Commission, and based on work carried out by the Pharmaceutical Forum, omits many independent providers of relevant information and undermines the role of numerous players who inform patients on a daily basis. The "quality criteria" developed by the Pharmaceutical Forum do not guarantee the requisite impartiality and relevance which enables patients to make informed choices. The "information model" on diabetes is extremely unsatisfactory and its inadequacy has been widely pointed out (4). And yet the Pharmaceutical Forum persists, blithely ignoring the numerous criticisms which have transpired during the external consultation.

In short, the Commission's patient information initiative's sole aim seems to be to support a proposal to deregulate the legislation, which has been in the pipeline for a long time, and allow the pharmaceutical industry to communicate directly with the public.

The evaluation of drugs' therapeutic benefits: postponed. The conclusions of the Pharmaceutical Forum on "relative effectiveness" of treatments fall short of the efforts made in recent years by many Member States to improve methods in the evaluation of the benefits of new medicines. These conclusions amount to a minimalist platform and lead the public to believe that a reliable comparison between new drugs and already available treatments is hardly ever possible. Conversely, all the demands of the pharmaceutical companies are taken into account, namely the rapid consideration of the slightest evidence likely to enhance a drug. The report proposes a Europe-wide "harmonisation" of practices in the comparative evaluation of a medicine's therapeutic benefit, which is likely to lead to a levelling down to the lowest common denominator, curbing the most advanced practices.

In short, the Commission's initiative has resulted in a list of wishful thoughts which will be of no help to Member States attempting to improve their methods when identifying real therapeutic innovations.

The causes for the surge in medicines' prices: ignored. The Pharmaceutical Forum's report on pricing is an opportune reminder of what is needed: a guarantee of equitable access to medication, controlled drug expenditure in Member States, and rewards for innovation. Yet the report does not specify how these objectives are to be met. It does not mention the pharmaceutical industry's artificial and unjustifiable pricing strategies, when an appropriate evaluation of research and development costs would enable setting fairer prices.

Concerning the comparative evaluation of therapeutic benefits (relative effectiveness), another essential criterion for a coherent pricing policy, the report's conclusions refer to the working group in charge of this issue, whereas this group has not produced a single consistent report (see above).

In short, it would seem that the Commission's initiative on pricing and reimbursement is not underpinned by the will to achieve a successful outcome.

The citizens' proposals: deliberately ignored. Various actors in the healthcare sector have already published robust, well-substantiated documents on the three issues which the Commission has delegated to the Pharmaceutical Forum. They define patients and consumers' needs, provide lists of the existing measures which fulfil these needs, and put forward concrete proposals for improvement. The joint Declaration by HAI Europe, the ISDB, BEUC, AIM, and the Medicines in Europe Forum on Health Information of October 2006 (5) and the ISDB Declaration on therapeutic advances of November 2001 (6) are examples of such fundamental documents. Holding these documents into account would have painted a truer picture of patients' needs. Yet, these documents have been virtually ignored by the Commission, primarily concerned with short-term interests of the pharmaceutical industry.

The signatories of this press release call upon the Pharmaceutical Forum to re-focus its work and take up public health as their overriding priority before any changes are to be considered in the legislation governing medicines information.



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Extracts from the press review:

● **The British Medical Journal, the Lancet and the Guardian** covered this issue:

- "Direct to consumer advertising should not come to Europe" by Ray Moynihan *BMJ* 2007; 19 May.
- "Consumers fight to halt move towards direct to consumer advertising in Europe" by Ray Moynihan *BMJ* 2007; 334 : 1025.
- "Sweetening the pill – Can big pharma be trusted to provide independent health information to patients?" by Hannah Brown *BMJ* 2007; 334: 664-666.
- "Pfizer conducts survey of French patients on information provided by industry" by Barbara Mintzes *BMJ* 2007; 334: 1027.
- "The direct-to-consumer advertising genie" *Lancet* 2007 ; **369** : 1.
- "Coming soon: the shopping channel run by drug firms" by Sarah Boseley *The Guardian* May 21, 2007
- "Drug firms and patients groups join in fight to overturn advertising ban" by Sarah Boseley *The Guardian* May 21, 2007.

● The Pharmacists Representative Organisation (**Ordre des Pharmaciens**) and the **Haute Autorité de Santé** expressed concerns:

- "Information des patients : l'Ordre est inquiet" *Bulletin national de l'ordre de l'Ordre des Pharmaciens (LNP)* (Pharmacists Representative Organisation - France) 2007, May 31.
- "Informations des patients : la législation en danger" *Bulletin national de l'ordre de l'Ordre des Pharmaciens (LNP)* 2007 ; (343) : 1.
- Laurent Degos et François Romaneix "Lettre au Collectif Europe et Médicament" le 7 juin 2007 : 1 page.

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References:

- 1- Pharmaceutical Forum "Second progress report". 26 June 2007. Website <http://ec.europa.eu/enterprise>: 17 pages.
- 2- Joint Position of Medicines in Europe Forum, International Society of Drug Bulletins, Health Action International Europe "Health Information - a clear division of roles is needed to protect public health" March 2007: 4 pages. Websites www.prescrire.org or www.isdbweb.org.
- 3- "Patient-information in Europe: many concerns" press review and extracts from contributions to the consultation organised by the "patient information" group (May 2007). Website www.prescrire.org/cahiers/dossierEuropeMedInfoPatientAccueilEn.php (full information material).
- 4- ESIP and AIM "Joint Position Statement on Information to Patients on Diseases and Treatment Options". Website ec.europa.eu/enterprise: 1 page.
- 5- Joint declaration by HAI Europe, the ISDB, BEUC, the AIM and the Medicines in Europe Forum "Relevant Information for Empowered Citizens" 3 October 2006. Website www.prescrire.org ou www.isdbweb.org: 8 pages.
- 6- ISDB "Declaration on Therapeutic Advance in the Use of Medicines" Paris 15-16 November 2001. Website www.isdbweb.org: 12 pages.