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Pharmaceutical package: a short-sighted vision that puts patients' at risk

On December 10th 2008, the European Commission adopted one communication and three legislative proposals concerning medicines (the so-called “pharmaceutical package”)^a.

A thorough analysis of its content reveals that the EU Commission is upholding the competitiveness of Europe’s pharmaceutical industry thus overriding public interests. Our concrete proposals show another way forward (read on page 3).

A short-sighted vision

Globalisation sets the tone. The rationale behind the Commission’s proposals is to support the competitiveness and innovation of European pharmaceutical companies. However, at present, such vision is outdated, as the innovation crisis is of global proportions and the vast majority of pharmaceutical companies are multinational corporations. The global decline in therapeutic innovation should not be used as a red herring to deregulate the European medicines market.

A long-term strategy is needed. “Better access to medicines for European patients” cannot be brought about by encouraging over consumption of medicines, i.e. by deregulating “direct-to-consumer advertising” (DTCA) under the guise of “direct-to-consumer information” (DTCI), or by granting accelerated market access through ‘conditional authorisations’ at the costs of a genuine evaluation (read below).

The industry’s defensive standpoint (through stringent enforcement of intellectual property rights and abuse of the patent system) threatens access to medicines for patients who dramatically need them in developing countries, and unacceptably delays both generic competition and innovation from originator companies^b.

Clearly, a qualitative approach is needed: the industry’s future is dependent on its own capacity to meet the real needs of patients^c.

Opaque legislative proposals. The legislative proposals are written using convoluted arguments to ‘soften’ the message. The paramount example is the replacement of “direct-to-consumer advertising” (DTCA) [wording used by the EU Commission in 2001 during the review of the pharmaceutical legislative frame] by “the provision of high-quality information to the general public on prescription-only medicinal products by marketing authorisation holders”^d.

The legislative framework is becoming extremely complex, and thus opaque for most European citizens. The editing of the proposals is intricate, with many articles being cross-referenced, resulting in an unintelligible text. Elementary principles, such as transparency and the protection of public health, are diluted by numerous exemptions to the rules, leading to a legislation that is ultimately a smokescreen (read below “Key issues of concern”).

^a- Available at : http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm.

^b- Remember the Preliminary results of DG Competition pharmaceutical sector enquiry.

^c- It is the documented therapeutic advantages offered by a new drug in comparison with already existing treatments (“gold standard”) that should form the basis not only for marketing authorisation but also for pricing and reimbursement.

^d- The provision of “information” to patients by pharmaceutical companies is promotional by nature, due to the pharmaceutical companies’ inherent conflict of interest.

Key issues of concern

Proposals on “information” to patients. The vast majority of stakeholders are vehemently opposed to direct-to-consumer communication by pharmaceutical companies. During each of the numerous consultations held by the European Commission, the wider public health community has unanimously stated that the pharmaceutical industry cannot be a reliable source of unbiased information due to an obvious and unavoidable conflict of interest. Yet, the new directive opens the door to direct promotion by pharmaceutical companies.

Useful patient information should enable users to analyse their concerns, give them a realistic idea of the evolution of their health status, help them to understand when further investigations are necessary, to know what treatments exist and what they can expect from them, and to make informed choices (or participate in the choice) among the different available options.

As the “information” by pharmaceutical companies can not be reliable or comparative, the whole directive proposal has no added value for European citizens. The only real rationale for the Commission’s proposal to change the current EU legislation is for the commercial benefit of pharmaceutical companies by expanding their marketing reach. This is a useless exercise for both Europeans and Member States, representing additional bureaucracy and increased costs.

Pharmacovigilance proposals. The proposals on pharmacovigilance have been slightly improved, when compared to the proposals released for public consultation in earlier 2008^e. But they are still insufficient to really improve patient safety and, more worrying, could even weaken European pharmacovigilance and marketing authorisation systems.

In fact, instead of tackling the reasons explaining the multiplication of pharmacovigilance tragedies due to medicines which were authorised even if they were therapeutic regressions or had an unfavourable benefit-harm balance^f, the proposals focus on palliative solutions. The proposed ‘risk management’ approach is product-oriented (designed to study and to protect the marketing of the product, but not to protect patients from preventable drugs’ adverse effects).

Even though these pharmacovigilance proposals are being presented as a technical matter, pertaining to the pharmacovigilance system, their scope is much wider, affecting every step of the commercialisation of medicinal products in Europe: from evaluation to marketing authorisation, including monitoring and product information.

Some provisions remain extremely worrying:

- calling an end to the mandatory public funding of pharmacovigilance. This public health activity would then be funded by industry’s fees, to be collected by the regulatory authorities. This procedure is likely to make pharmacovigilance decisions akin to providing a service;

- lack of means to really protect European citizens: the Pharmacovigilance Risk Assessment Advisory Committee (PRAAC) will not have enough power to act; the crucial role of National and Regional Pharmacovigilance Centres is not recognised, and the implementation of the Commission’s proposals would even lead to their destruction;

- introducing post-authorisation safety studies and ‘risk management’ programmes that could lead to premature marketing authorisations becoming the norm rather than the exception;

- maintaining the delegation of tasks that must be the responsibility of public pharmacovigilance systems to pharmaceutical companies, even though they are both judge and defendant (i.e. assessment of the data that determine the harm-benefit balance of their product);

- lack of transparency: public access to all relevant pharmacovigilance data is not guaranteed; good pharmacovigilance practices (GVP) that are determinant for the organisation of the European pharmacovigilance system are planned to be established in conformity with International Conference on Harmonisation (ICH) recommendations, not from a patient-centred perspective.

^e - Read our analysis at: http://www.isdbweb.org/pag/documents/Pharmacovig_Jan08_En.pdf.

^f - I.e. recently: the Vioxx^o affair (an anti-inflammatory drug which caused fatal cardiac accidents and was finally withdrawn from the market), the Zyprexa^o affair (an anti-psychotic drug that was found to cause diabetes and metabolic disorders), Accomplia^o (an anti-obesity drug that carries an increased risk of suicide and was withdrawn from EU market in 2008), Avandia^o (an antidiabetic drug that can cause fatal cardiac disorders), Seroxat^o (an antidepressant that carries an increased risk of suicide).

“Fake medicines” proposals. Counterfeiting is a public health matter which requires appropriate action, particularly outside Europe^g. The EU Commission opted to refer to “fake medicines”, rather than to “counterfeit medicines”, as defined by the World Health Organisation^h. The terminology, as adopted by EU, encompasses not only the notion of “counterfeits”, but also of intellectual property violations, creating confusion. Tackling counterfeits should not be used to discredit generics in order to boost brand loyalty. Safety-features used to trace medicines should not curtail individual freedom nor reduce access to treatment (i.e. RFID technology raises privacy issues as well as cost concerns). Some provisions are welcomed, i.e. audits of supplying wholesale distributors of medicinal products and provisions aimed at improving pharmaceutical qualityⁱ.

Another way forward

Concrete proposals on Patient-‘information’ include:

- make the officially approved leaflet more useful and accessible for patients by ensuring that pharmaceutical companies consistently abide by their **obligations relative to drug packaging and patient leaflets** (i.e. consultations with target patient groups) (enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE);
- optimise **communication between patients and health professionals**: informing patients and fulfilling their needs implies a relationship of trust and interpersonal dialogue, which are the core responsibilities of the healthcare professions;
- encourage **national agencies to become proactive and more transparent providers of information** so as to guarantee full public access to data on the efficacy and safety of medicines and other healthcare products both before and after a product is marketed;
- **develop and reinforce existing sources of comparative, unbiased information on treatment choices**;
- put a **rapid and permanent end to the confusion of roles between the pharmaceutical companies and other stakeholders** in the healthcare sector: full implementation and enforcement of the European regulation on pharmaceutical promotion, including measures to ensure that article 88 of Directive 2001/83/EC, is not weakened or undermined.

Concrete proposals on Pharmacovigilance include:

- **more stringent marketing authorisation criteria** - a fourth criteria, that of real therapeutic advantage, should be added to the current evaluation criteria of efficacy, safety and quality when granting a marketing authorisation. The therapeutic advance would be compared with existing treatments, and demonstrated by relevant clinical data collected from well-designed comparative clinical trials^j;
- full and adequate **public funding for European, National and Regional pharmacovigilance centres**;
- grant **increased authority to the Pharmacovigilance Risk Assessment Advisory Committee (PRAAC)**;
- collect **direct patient reporting of adverse effects** and exploit this information efficiently;
- increase **transparency**: label recently approved medicines, particularly if a “conditional authorisation” was granted, with special symbol to raise awareness^k; grant public access to Periodic Safety Update Reports (PSURs), including consumption data, and to extended PSUR assessment reports; grant access to the minutes of the Pharmacovigilance Committee and related working groups meetings^l;
- **impose dissuasive penalties** on firms that do not fulfil their obligations, including license withdrawal.

^g- According to the World Health Organisation, there is less than 1% of counterfeit in Europe.

^h- WHO IMPACT definition of a Counterfeit Medicine states: “Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting”. Full definition available at: www.egagenerics.com/pr-2008-12-08.htm.

ⁱ- Apart from the “counterfeits” issue, some proposals are welcomed in order to improve pharmaceutical quality of medicines:

- strengthening inspections in emergent, developing countries as well as European countries in order to improve compliance to good manufacturing practices and increase transparency of their results;

- reinforce controls of active pharmaceutical ingredients (API) imported from third countries.

^j- 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 useless new drugs.

^k- i.e. using a black triangle pointing downwards as a pictogram, which is already used widely in Europe.

^l- Effective enforcement of article 126b of Directive 2001/83/EC modified by Directive 2004/27/EC.

The priorities for “Fake medicines” are:

- **mandatory notice** of counterfeit reports by pharmaceutical companies to health authorities in order to carefully monitor the market and alert both health professionals and patients;
- **improve patients’ access to the medicines they really need**, avoiding purchases of unknown quality from questionable or illegal sources;
- careful **monitoring of commercial websites** that sell medicines online;
- **discourage aggressive promotion of brand-name pharmaceuticals**, in order to inhibit the lucrative counterfeits market.

To conclude

One of the EU Commissions’ key responsibilities is the protection of European citizens’ health (article 152 of the European Treaty). Initiatives supporting industrial competitiveness must not be allowed to override public health interests.

More than ever before, we see how placing medicines within the Enterprise Directorate’s sphere of activity has led to a fundamental imbalance in the Commission’s proposals.

The organisations endorsing this document call upon the European Parliament and the European Council to require that the Commission reviews its priorities, which should, first and foremost, protect patients’ and consumers’ interests.

Association Internationale de la Mutualité (AIM)
International Society of Drug Bulletins (ISDB)
Medicines in Europe Forum (MiEF)
Health Action International (HAI) Europe



AIM. The *Association Internationale de la Mutualité* (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM’s membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org. Contact: rita.kessler@aim-mutual.org.



ISDB. *International Society of Drug Bulletins* (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 79 members in 40 countries around the world. More info: www.isdbweb.org. Contacts: jschaaber@bukopharma.de; fvandeveld@prescrire.org.



Medicines in Europe Forum (MiEF), launched in March 2002, covers most European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Contacts: pierrechirac@aol.com; europedumedicament@free.fr.



HAI Europe. Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org. Contact: teresa@haiweb.org.