Commission Pharmacovigilance Strategy: Public consultation on draft legislative proposals (5 December 2007 – 1 February 2008)

Proposal by the European Pharmaceutical Law Group
www.eupharlaw.com

One of the reasons for the changes to EU legislation on medicines made in 2004 (the so-called "2001 Review") was the awareness of cases of damage caused to the health of a large number of people owing to the adverse effects of "super" drugs such as Vioxx, Agreal, Lipobay, etc. Such situation highlighted the fact that it was necessary to greatly improve the management of global pharmacovigilance, and that this in turn also required changes to legislation.

In Spain, by means of Royal Legislative Decree 1/2007, of 16 of November[1], the Restated Text of the General Consumer and User Protection Act and other related provisions, has recently been approved, which is based on the provisions of Directive 85/374/EEC[2] (defective products) and Directive 98/27/EC[3] (consumer protection). The text is of enormous significance for the pharmaceutical sector, despite the fact that it is not specific to the sector, but provides for the general protection of consumer interests. It includes provisions on liability for any damages caused by products, including "medicines and foodstuffs".

The approval of the aforementioned law concerns us all (evidently as consumers, but also, more importantly, as citizens), since it perpetuates the system of strict liability of manufacturers for any damages caused by their products. Such system of liability is upheld with the apparent purpose of promoting the right of consumers to information and safeguarding their right to take legal action to claim compensation for the damages caused by the products.

However, for citizens of the 21st century it is incredible, and indeed, unacceptable, that legal liability for the damages caused by erroneous information provided on medicines is confined to the exclusive scope of the laws governing consumer and user

[1] REAL DECRETO LEGISLATIVO 1/2007, de 16 de noviembre, por el que se aprueba el texto refundido de la Ley General para la Defensa de los Consumidores y Usuarios y otras leyes complementarias. BOE núm. 287 de 30 de noviembre.

[2] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

[3] Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests.

protection and defective products. Such system is not as favourable to the interests of citizens as we are led to believe[4].

As regards pharmacovigilance, the situation is much worse, since we lack any law in Europe allowing citizens to bring legal action for the damages caused by the action or omission of the Medicines Regulatory Authorities –of either a national or European level (EMA) – or by the personal actions of their officials, which could seriously damage our health.

Given this situation of legal vulnerability encountered by citizens, new effective legal mechanisms must be negotiated and created in order to ensure that they may exercise their rights if they find themselves in such situation.

Likewise, better mechanisms must be established so that citizens may be quickly warned of the serious adverse effects of medicines, once such effects are known by the regulatory authorities.

It is also essential that the procedures for the registration of medicines are also made much more stringent and efficient, and that the post-sale vigilance and inspection of medicines and health products is tightened.

In short, although we are aware that the trade of medicines within the European Union must be strengthened, nevertheless, it is not only necessary to protect the economic interests of the European Union and its companies, but also to protect the health of all of us, not just as consumers but as citizens.

A clear and robust legal framework must be created allowing for a new approach to health, whereby citizens may take centre stage in the decisions concerning their health, and may be accurately informed of the real situation regarding medicines. In this new context, citizens should even be able to take the lead themselves in notifying of the adverse effects and reactions of such medicines on their health.

Our European institutions must take an active stand to promote and safeguard the right of citizens to direct therapeutic information (DTIC)[5], but making a distinction at all times between the concept of information provided directly to the citizen, and the advertising of medicines "Direct to the Consumer". The latter is permitted in the United States, and it has been proven not only that it does not help us as citizens, but that in fact it has damaging effects on us, especially the advertising of medicines that must be used with a medical prescription. Advertising must therefore be restricted to those products without possible serious adverse effects for our health.

In any event, both information and advertising must be adapted to take into account the current state of science, and the patient information leaflet and product characteristics must be constantly updated, especially if new adverse effects are discovered. Both pharmaceutical laboratories and the Health Authorities must work together to achieve such objective.

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[4] See Eupharlaw's proposal to the Public Consultation (19 July – 12 October 2007) on the future of the Single Market in Pharmaceuticals
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacommunication/pubconsult.htm (doc 88)

[5] Amarilla, Manuel, La información terapéutica directa al ciudadano™, Eupharlaw, 2005.

In conclusion, we make a call for the laws that apparently seek to protect us - but which fail to do so-, to stop misleading us, merely benefiting the pharmaceutical companies by limiting their liability[6].

Medical products are not just any "product whatsoever", and must be governed by specific laws outside the scope of application of the laws on consumer protection and defective products.

In our view, "Health Laws" are necessary to effectively safeguard the health rights of citizens[7]. One of the most important of such rights is to receive accurate, adequate and truthful information on all matters concerning their health.

"Health Laws" should contribute to a legal framework that is fairer for all concerned. Specifically, it needs to negotiate new mechanisms that provide for the liability of both the pharmaceutical laboratories for the damages caused by their products, as well as the authorities that assess and authorize such products, if they should omit information or provide incorrect information to citizens.

Manuel Amarilla
President

[6] For further explanation see note 4.

[7] See also Eupharlaw's proposal for the reflection process on EU health policy (October 2004) http://ec.europa.eu/health/ph_overview/strategy/results_reflection_process_en.htm (doc R-099)

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