

Editorial

Challenges for the pharmaceuticals Policy in the EU

1. Introduction

At the beginning of the 21st century, Europe was facing challenges such as pharmaceutical innovation, the increasing globalization of the sector and scientific breakthroughs. A more competitive and innovative industry will generate more growth and sustainable jobs and also foster the development of new medicines for unmet medical needs.

The EU has been losing ground in pharmaceutical innovation. To address these challenges, the Commission had tabled different proposals. In the Communication, in 2008, about a *Renewed Vision for the Pharmaceutical Sector* lays down objectives relating to the future of the pharmaceutical sector.

The objective was contributed to reinforcing the safety of pharmaceuticals, encouraging innovation, making medicines more accessible for European patients and affront challenges of globalisation. Options have been envisaged to identify, by 2010, ways to optimize the functioning of the network of European Union medicines authorities and better regulation for a more competitive industry. The safety of medicines should be reinforced by new legislative proposal on pharmacovigilance and to provide the patients with reliable and objective information. In the other hands to combat the circulation of illegal medicines and in the area of pandemics, bilateral and multilateral relations should be strengthened. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level.

2. Global cooperation and harmonization

Inspection mechanisms with the United States, Japan and Canada should be established. In addition, bilateral cooperation with Russia, India and China should be extended.

International harmonization is advocated, particularly by means of the International Conference on Harmonisation (ICH). It is also recommended that the areas of the Transatlantic Economic Council (TEC) be used for the simplification and convergence of rules between the United States and the European Union.

Finally, for the European Union to be internationally competitive, the Communication encourages it to implement and enforce the framework of the World Trade

Organisation (WTO), as well as the Free Trade Agreements (FTAs) in particular as regards the protection of intellectual property rights.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), launched 20 years ago, is the more ambitious and efficacy international structure to benefits the harmonization for better global health. The value and benefits of ICH to regulators have been realized. ICH brings together the drug regulatory authorities of Europe, Japan, and the United States, along with the pharmaceutical trade associations, to discuss scientific and technical aspects of product registration. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

The Common Technical Document (CTD) has revolutionized the submission procedures. Afford significant savings in time and resources as complex multiple submissions were replaced by a single technical dossier submitted in the three ICH regions. The electronic CTD (eCTD), ICH could turn its sights to disseminating guideline information to non- ICH countries. Moreover, implementation of the CTD in 2003 promoted the involvement of drug regulatory authorities (DRAs) not initially part of ICH. The development of the Global Cooperation Group, which includes representatives from five regional harmonization initiatives and the newly established Regulators Forum, created to promote participation by non-ICH countries interested in implementing ICH's strategies, have also helped incorporate the CTD into regulatory processes, creating a common regulatory language life-saving treatments to patients beyond ICH regions.

This experience need to follow in other areas of pharmaceuticals law. We need one single global legal statute for medicinal products.

3. The Transatlantic Economic Council

The Transatlantic Economic Council is a political body to oversee and accelerate government-to-government cooperation with the aim of advancing economic integration between the European Union and the United States of America At the EU-US Summit on 30 April 2007, Commission President Barroso, German Chancellor Merkel and US President Bush signed the "Framework for Advancing Transatlantic Economic Integration between the United States of America and the European Union". In this Declaration recognized that the European Union and the United States are each other's most important economic partners, reflecting historical ties as well as a wide range of common fundamental values, such as the importance of free enterprise, rule of law, property rights, free trade, and competition, and the protection of health, safety and the environment.

Provides a chance to bring closer the two biggest pharmaceutical markets in the world, lowering costs by reducing unjustified regulatory divergences.

Between the Areas of cooperation are Regulatory cooperation in Health and Consumer Protection, Intellectual Property Rights, Counterfeit and Piracy; Innovation and Technology, eHealth; Radio Frequency Identification (RFID); Biotechnology Research; Bioproducts.

We hope that this framework for advancing transatlantic economic integration between the European Union and the United States of America will adopt similar structures of work that have been place in practice for the Conferences ICH and will be possible, in the next future, the incorporation of Japan and promote the participation by non-ICH countries interested.

Globalisation bring new competition from India, China and other Asian countries These countries have already become centres in producing Active Pharmaceutical Ingredients (APIs) and prime sources for European imports of those substances. The EU should work towards the implementation and enforcement of the WTO framework

4. Pharmaceutical patents and the TRIPS Agreement

The EU has also taken steps to enable international companies to provide medicines at substantial discounts to developing countries, while ensuring that these preferential prices do not lead to negative repercussions in the EU market by reimportation.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. The main rule relating to patentability is that patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability – namely, novelty, inventive step and industrial applicability. In addition, Members are required to make grant of a patent dependent on adequate disclosure of the invention and may require information on the best mode for carrying it out.

In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and the creation of new medicines. Recognize flexibilities as the right to grant compulsory licences and to leave each Member free to establish its own regime for the exhaustion of intellectual property rights.

5. The protection of the economic interest in the health policy

An increasingly consumer-oriented, globalised economy, need one strong protection of the right of the consumer and patients. It is other global problems.

The OECD in its recommendation on consumer dispute resolution and redress encouraged its member countries to provide consumers with access to different means of redress, including collective redress mechanisms.

The proposal for a Directive on Consumer Rights will address the issue of legal certainty on substantive rights.

The Directive focuses on the resolution of mass claim cases and aims at providing effective means of collective redress for citizens across the EU. This means mechanisms by which a large group of consumers affected by a single trader's practice can effectively obtain redress wherever the trader is located within the EU.

As mass consumer markets expand in size and even become cross-border, very large numbers of consumers can be harmed by the same or a similar practice of a trader.

The lack of an effective legal framework enabling consumers to ensure adequate compensation in *mass claim cases* is detrimental to the market and creates a justice gap. The effect of a malpractice may be so widespread as to distort markets.

It may be necessary to improve the effectiveness of mass claim cases in the fields of general business to consumer interaction. For the health sector the interest it is in relation in the pharmaceutical sector, alternatives medicines, cosmetics, and special food health claim. The health claims it is a very worse situation for the consumer. The mass claim in these sectors it is not only question of in relation to *personal injury claims*, based on product liability. The problems it is more general. It is too in relation of the lag of efficacy and quality. There are a lot product in the market in the area of miracle products, miracle medicament and infinity of products from the alternatives medicines.

The health sector will be one of the more interested in this new legislation.

Currently, when consumers affected by a malpractice want to pursue a case, they face barriers in terms of access, effectiveness and affordability. The mechanisms have been applied in relatively few cases. It is the proof of his irrelevance. As a consequence of the weaknesses of the current redress and enforcement framework in the EU, a significant proportion of consumers who have suffered damage do not obtain redress. In mass claim cases that affect a very large number of consumers, although sometimes the harm may be low for the individual consumer, it can be high for the size of the market.

Action by national public enforcement authorities such as those of the Consumer.

Protection Cooperation network no provide efficient redress. The activities of the Direction for Health and Consumer Protection of the European Commission, had demonstrated few result in this area. The objective of better monitoring of consumer markets and national consumer policies lag of efficacy and even of general information. *The Unfair Commercial Practices Directive* no has had clear effect in the unfair commercial practice. The Directive no protects the economic interest of the consumer In the European markets are thousand of products that contains false information and is therefore untruthful.

Within the Directive, certain commercial practices are prohibited since they are considered unfair and are likely to affect especially vulnerable consumers in that case. Examples of such practices include: Falsely claiming that a product is able to *cure illnesses*, dysfunction or malformation.

The banalization of this problems appear even in one booklet prepared by the Health and Consumer Protection Directorate-General of the European Commission that contain the information that “The advertising of magnetic bracelets which can relieve pain may be targeted at the general public, only vulnerable consumers are affected by it”. This paradigmatic case it is only one between others thousand. It is not possible to now what is the extension of the market of the health fraud in European Union. This situation it is unacceptable.

Health and consumer Authorities permit manufacturers to sell products provided that their labelling adequately instructs consumers in the product’s safe use. But this it is not sufficient; if a product doesn’t work, the only truly adequate instruction for use is to avoid it.

We need a binding EU measure to ensure that a collective redress judicial mechanism exists in all Member States.

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