

Editorial

Pharmaceutical product liability systems: Regulatory models and Challenges

Pharmaceutical products have a high social value but, since there is no way to guarantee that they will be completely safe, they may also pose serious health risks to consumers. When these risks materialise, consumer protection requires an effective system to deal with the injuries suffered. The United States, the European Union, Japan and Brazil have all developed different product liability rules based on their particular traditions and legal systems. However, insufficient harmonisation and lack of worldwide regulatory policies have created fear, uncertainty and distortions in the market and this has often made it impossible for manufacturers of pharmaceuticals to implement globally acceptable product designs, manufacturing processes and labelling.

Although the editors of this issue consider that, in order to overcome these problems, further harmonisation should be pursued and, ideally, a new uniform international system of liability for pharmaceutical products should be established, the objective of this issue of *Pharmaceuticals Policy and Law* is much more modest. Here eleven authors from ten different jurisdictions discuss the current situation of liability for pharmaceutical products in various countries, tackle the main problems and explain how products liability for pharmaceutical products has developed in the corresponding jurisdictions over recent years.

The first paper, “Some Comparative Remarks on Pharmaceutical Product Liability” (*Martin-Casals*), tries to establish a general framework for some of the problems that will be dealt with in more detail in the corresponding national reports. Thus, after referring to the traditional tort/contract approach as the main instrument for dealing with liability, it devotes some attention to the alternative instruments of no-fault compensation schemes that have been put in place in some jurisdictions and which operate out of the realm of tort law and replace litigation with administrative procedures. Finally, the paper analyses the main elements of products liability (product, defect, causation) from a comparative perspective and finishes with a brief reference to defences.

Two papers deal with the United States’ model of products liability for pharmaceutical products. The first, “Pharmaceutical Product Liability in the United States of America” (*Michael D. Green/Christopher Robinette*), offers a general overview of a complex system where tort law is State Law and where product liability has developed significantly since the introduction of strict liability for defective products in Section 402A of the *Restatement (Second) of Torts* in 1965. This Section of the

Restatement gave rise to an enormous body of case law and was superseded by the *Restatement of Torts (Third) Products Liability*, published in 1997. This Restatement not only introduced fault liability for design and warning defects, but also specific rules for prescription drugs (§6). The second US paper, “Pre-emption in the case of Pharmaceutical Products” (*Marshal S. Shapo*), deals with a recurrent question that arises when Congress legislates on products liability, which is whether the statute then occupies the field to the exclusion of common law rules. This issue has presented itself in an important number of subject areas. In the area of pharmaceuticals in many cases it has referred to whether FDA approval of labelling for a pharmaceutical product is pre-emptive or not.

Japan, another important player in the world-market of pharmaceuticals, introduced a Product Liability Act in 1994, which provides for strict product liability. The Japanese report, “Pharmaceuticals Products Liability in Japan” (*Fumihiko Nagano/Antonios Karaiskos*), deals with the requirements for the application of strict products liability rules in Japan. It also analyses how the Product Liability Act combines with the application of the general fault-based liability rules of the Japanese Civil Code, and how some compensation schemes offer payment for adverse side effects of pharmaceutical products under certain conditions. The Brazilian report, “Pharmaceuticals Product liability in Brazil” (*Rafael Peteffi da Silva*), explains that Brazil also introduced a strict liability regulation of products liability in the Consumer Defence Code in 1990, which explicitly distinguished several types of defect, and that Brazilian legal scholarship qualifies pharmaceuticals as inherently unsafe products.

Both Japanese and Brazilian legislation on products liability have been clearly influenced by the European Council Directive 85/374/EEC of 25 of July 1985 *on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products* and the following group of reports deals with the national implementation of this Directive in five European jurisdictions.

Thus, “Pharmaceuticals Product liability in France” (*Zoé Jacquemin*), analyses the late and difficult transposition of the European Directive into the French civil code, discussing what the options that the French legislator adopted are, how this transposition has been understood by courts, and how compensation for injuries caused by some pharmaceuticals has been addressed by creating compensation schemes. By contrast, “Product Liability for Medicinal Pharmaceuticals in Germany” (*Ulrich Magnus*), shows how Germany is the only EU member that has managed to keep a specific product liability regime for pharmaceuticals. This regime existed before the Directive and has undergone amendments that, among other aspects, have introduced rules that facilitate the proof of causation to consumers. “Pharmaceutical Products Liability in the United Kingdom” (*James Goudkamp*) analyses the transposition of the Directive in the Consumer Protection Act 1987, the conditions of liability and its practical operation. The group of countries dealing with the transposition of the Directive closes with the reports “Pharmaceutical Products Liability in Poland” (*Piotr*

Machnikowski) and “Pharmaceutical Products Liability in Spain” (*Josep Solé Feliu*). These reports deal with the choices made by national legislatures when transposing the Directive and the interaction between the rules arising from these transpositions and national legislation in the corresponding countries.

Last but not the least, the final report in this issue, “The Development Risk Defence of the EC Product Liability Directive” (*Bernhard A. Koch*), analyses the meaning and scope of this defence, which under the European Directive is optional, and which allows producers to escape liability if, at the time the product was put into circulation, there was objectively no way to detect the defect.

The editors of this issue want to express their gratitude to all contributors and truly hope that these reports will shed some light on the current state of liability for pharmaceutical products in a variety of very representative jurisdictions.

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Editors