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Editorial

Introduction

The new international review *Pharmaceuticals Policy and Law*, appears with the aim of studying and evaluating the legal status of medicinal products in the European Union, and its implications in other markets such as the USA and Japan, without forgetting the specific problems of developing countries. The main target of medicinal products is to safeguard people's health worldwide. Hence, the search for an international legal status that facilitates free movement of medicines and guarantees the right to health.

It cannot be forgotten that medicinal products are very special goods. This fact conditions their whole legal status. To begin with, they are the result of scientific and technical innovation. Research policies determine their progress. The pharmaceutical industry is, by nature, multinational. But, next to these global trends, different traditions still remain at a national level. Administrative requirements for market authorisation of medicinal products differ from one country to the another. Within the EU, barriers to free trade in medicinal products still remain despite more than thirty years of harmonisation. The Member States' power of fix prices for medicinal products is a serious distortion of free competition rules. This restriction weakens the challenge for innovation and the ethical need for free movement of medicinal products. From the right to health to social welfare mechanisms there are different systems worldwide. The social dimension of medicinal products is complex and very significant in the preoccupations of our societies.

The specificity of medicinal products conditions their legal status. Legislation regulating other goods cannot be applied to them. Patenting is essential but not sufficient. It has been necessary to introduce the legal instrument of the additional certificate of the pharmaceutical patent. The life-cycle of medicinal products is protected by professional responsibility, required in the general concept of health safety. Therefore, requirements for the training for health professions and the regulation of professional responsibilities are another essential element conditioning medicinal products' legal status. It is important to remember their ethical dimension, including research and innovation in new fields such as genetic manipulation and biotechnology, which requires social consent to preserve human dignity and fundamental rights.

The different aspects of medicinal products need to be treated as a whole and with the co-operation of different specialists in an international context. One of the basic guidelines of *Pharmaceuticals Policy and Law*, will be to study the legal status of medicinal products in the E.U., in view of its necessary and inevitable future world convergence and harmonisation with the American and Japanese markets.

Pharmaceuticals Policy and Law intends to participate in that process helped by a network of academic centres specializing in pharmaceutical law, without neglecting a scientific, economic and social approach to medicinal products.

On behalf of the review and on my own behalf, I would like to thank Fernand Sauer, (Executive Director of the European Medicinal Products Evaluation Agency), Patrick Deboyser (Deputy Head of the Pharmaceuticals and Cosmetics unit at the European Commission), Ms. Linda R. Horton (International Director of International Policy U.S. FDA), Prof. Alfred Hildebrandt (Director of the German National Agency for medicinal products), Mr. Hannes Wahlroos (Head of the Finnish medicinal products National Agency), Prof. Tatsuo Kurokawa (Japan), Prof. Jose Maria Su ñé (University of Barcelona), and Prof. Robert Goyer (Facult de Pharmacie, Universit de Montreal), all worldwide known personalities who do not need to be introduced. Their membership of the Advisory Board of *Pharmaceuticals Policy and Law* is a guarantee of professional competence, knowledge and responsibility.

The wide experience and professional competence of our publisher, IOS Press will ensure a top quality publication and a wide international distribution. We begin our project by tackling one of the essential issues of the pharmaceutical sector: research and innovation. It has been a pleasure and a satisfaction to have Dr. Fracchia, of the European Commission, as guest editor of this volume. He has invited a select group of specialist who have honoured us with their contributions. We will count on them for the future of this forum of debate and international reflection, having in mind the challenge of the European Union as a symbol of progress and unity in diversity, in the pursuit of solidarity and peace.

Professor José-Luis Valvede
Editor-in-Chief