

## Acknowledgement

This monograph of Pharmaceuticals, Policy and Law is focused on the issues concerning the Information Society in Pharmaceuticals. We have had the very valuable collaboration of Esteban Gonzalez-Juarros, from the Pharmaceuticals and Cosmetics Unit within the European Commission. Esteban Gonzalez- Juarros has co-ordinated this edition, selecting the subjects and advising the authors. We are grateful to him and to all the authors that have enriched this volume with their contributions. We would also like to express our recognition to Mr. Liikanen, European Commissioner responsible for the Information Society who has kindly participated in this publication. This number of our publication also wants to recognise the excellent work done by the EU in promoting and regulating this particular area.

The Pharmaceutical use of the Internet has come a long way in a short time. The sale of consumer products over the Internet has grown rapidly. Online drug sales present a risk to purchasers and some unique challenges to regulators. As electronic commerce embraces global markets, we should strive for consistent principles across States, and international borders, regardless of the jurisdiction in which a particular buyer or seller resides. The United States and the E.U. have enacted laws to regulate the pharmaceutical and medicinal practice in order to protect patients from harm. The unauthorised sale of prescription and unapproved drugs poses a threat to the health and safety of consumers.

The information society represents a fascinating challenge. The progress of science and technology is not the problem. The problem arises when these new tools are misused. We should fight the idea that anyone can misuse the Internet. Nobody should be able to disrupt the social control established to ensure the security of people, properties and rights, comprising the right to health.

Governments, social forces, and citizens have to react against the idea that everything is possible on the Internet, without taking on board the responsibility for its effects. International organisations also have to give their response and, in principle, they have given this response in due time and form. For instance, the World Health Organisation (WHO) presented in May 1998 an excellent resolution on “cross-border advertising, promotion and sale of medicinal products through the Internet”. Likewise, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), released its position on “The use of the Internet for pharmaceutical information”. Other professional associations like the World Medical Association have also adopted guidelines. These combined actions can constitute an excellent ethical code to a world level. The main problem is still Governments reluctance to react in time and assume their responsibilities to assure people’s rights. Nationalism is also a barrier to create efficient solutions. Perhaps it would not even be necessary to enact new legislation but to implement the one already adopted. Governments

should be the first to assume these new technologies, providing the administration with adequate means and experts that understand and are used to an Internet related environment. Prosecutors and judges cannot ignore the fact that traditional offences are now committed by new resources and weapons. This is the problem, not the Internet as a new technology. It cannot be forgotten that the World Wide Web and the Internet are merely tools to accomplish certain tasks. Many of the old systems are still applicable to new media. Factors involved in governing the Internet are respectively personal morality, government and business ethics, public law and regulation.

The WHO's resolution set out recommendations for Member States, industry, healthcare professionals and consumer organisations. The spirit of the resolution is to foster collaboration between the Agencies involved, in order to encourage the monitoring of Internet activity and the maintenance of legal and ethical standards.

The WHO calls the governments to assume their responsibilities, revising if necessary existing legislation, regulations and guidelines to ensure that they are applicable and adequate to cover the advertising, promotion and sale of medicinal products over the Internet. Develop, evaluate and implement strategies for monitoring surveillance and enforcement. It also calls to collaborate in matters raised by use of the Internet, especially, specific national measures for enforcement as well as to designate contact point for international collaboration.

Above all it is important for Member States to take regulatory action against violation of their national laws. The Director General of WHO has been entrusted to encourage the international community to formulate self-regulatory guidelines.

The resolution is also addressed to Industry, Health Professionals, Consumer Organisation and other interested parties to encourage their members to promote the formulation and use of good information practices, consistent with the principles embodied in the WHO Ethical Criteria for Medicinal Drug Promotion.

Information should flow freely on the Internet, but this information must be scientifically accurate and reliable. Patients need to be protected from misleading information. Internet content should be fair, honest and balanced in the same way as other media, and the existing regulations apply both to traditional and "new" media. Good information practices and validation of sites are amongst the most important Internet consideration. People who misuse the Internet or try to bend the rules should be visibly punished.

Enforcement activities by Governments should focus on the physical movement of goods. Laws, regulations and medical culture differ in different parts of the world and the evolution of the Internet has brought the need for greater harmonisation.

The globalisation of the economies and the society of the information displays once more the need to conjugate the unity in the diversity, to accelerate the processes of integration by geographic, historical and cultural affinities, using the means of general federalism. In this general challenge, the medicinal products, that are not current goods and require a global approach for their own nature can be a factor that helps the countries to integrate in spaces of peace, prosperity and freedom ever-greater and, through the continental processes of integration, to promote at the same

time co-ordination and arbitration on a world level. The United Nations are called to play that role. The national Governments must assume to drive that platform of integration on a world level, overcoming the current phase of simple co-operation among States. To give limited but effective powers to the United Nations in the area of world trade, prevention of conflicts and vigilance of the self-control of the society of the information, may be excellent steps. Society requires it.

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