

The need of one International Statute for Medicinal Products

Medicines has a worldwide vocation, due to its scientific nature and its aims, directed at the alleviation and cure, so far as possible, of people's sufferings.

In the sphere of medicines we must necessarily be concerned with the scientific, medical, economic and legal dimensions, although we must not forget the ethical.

The legal dimension of medicinal products conditions the whole sector and it acquires a global dimension through the demand to protect people's health. Hence it is necessary to go forward to total harmonization of all its aspects. A global legal statute for medicinal products is justified by the very nature of the product, by its social control and the need for it to circulate freely, although limitations can be accepted, for reasons of solidarity with less favoured populations.

The legal statute of medicinal products is now harmonized in the countries of the OECD. The differences between the legal statute of medicinal products among the USA, Japan and the EU are minimal. The greatest differences come from the political, administrative and social systems of the respective societies.

The requirement to protect the right to health and to facilitate access to the health system brings with it the need to put into effect equitable social policies, so that the problem is a global one.

The need to go forward to free circulation of medicinal products at the world level brings with it many difficulties, since the specific problems of developing countries must be taken into account and there are several gradations among these. Hence the need for world agreements to establish universally respected exceptions.

Recent experience has shown the indivisibility of health care priorities. With the process of globalisation and the growing mobility of citizens, no infectious disease can be considered as geographically limited. Demographic and economic tendencies have increase the vulnerability to epidemics (such as SARS, tuberculosis, influenza or avian influenza), which can affect millions of people in the developed and developing world. This reality is leading the developed countries increasingly to take more measures in the international sphere.

We must be aware that the challenge for health care is not going to find an adequate answer at the world level without a qualitative change in the world organization of the UN.

At the present moment, few countries can be self-sufficient and even those who have adequate resources cannot live in isolation but must be interrelated with others. Any international problem or accident ends by affecting us all. Diseases know no

frontiers. The globalised world we live in demands reinforced continental solidarity, if we are to confront the common problems and bring about international order.

A scientific technical Code on the quality of medicinal products is essential for a statute on medicines. That Code is the Pharmacopoeia. The WHO understood this from the outset, and tackled the work for the drawing up of an international Pharmacopoeia. The contents of the WHO Pharmacopoeia is limited, but there exists the experience and technical capacity to create, with the cooperation of the USA, Japan and Europe, what is fundamentally an authentic pharmacopoeia, which covers the needs of developed and developing countries. In spite of its limitations, the WHO Pharmacopoeia deserves recognition. Governments with scant resources should adopt it as their national Code; this would create a broad platform of official users. For their part, developed countries must continue the march to scientific technical harmonization to achieve an authentic world *Pharmacopoeia*.

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