Harmonization of Quality Control and Product Licencing in Europe

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In the last decade haemophilia treatment has made important progress through orthopedic surgery of locomotor disabilities, rehabilitation by means of suitable physical therapy, etc. Undoubtedly, however, the basic aspect of haemophilia care always remains haematologic treatment with factor VIII concentrates, i.e., treatment with drugs. It was the development and production of these drugs, achieved in the last decade, which brought about a real change in the haemophiliacs' life and made it possible to undertake surgical treatment, unimaginable in the past.

Progress in the production of anti-haemophilic concentrates was characterized not only by an increase in the production of these drugs, and therefore by their greater availability which allowed suitably intensive care of haemophilia, but also by an ever greater purification of the drugs themselves, achieving a higher concentration and biological activity, a lower risk of side effects, and easier handling and use.

These are the achievements which enabled haemophiliacs, and the physicians who treat them, to avail themselves of modern methods of therapy, such as self-treatment, which freed haemophiliacs from the need to go to hospitals, clinics, or first aid stations for simple intravenous injections, and restored them to a normal social life.

I believe that we can state that the availability of modern and suitable factor VIII and factor IX concentrates and the most recent concentrates for the treatment of haemophilia with inhibitor, used according to modern methods of clinical treatment, has allowed haemophiliacs to achieve a good quality of life which not many years ago would have appeared as a dream. Unfortunately, these conditions are not at present a reality in all countries, even in comparatively developed areas such as the European Economic Community (EEC).

Haemophiliacs rightly wish that these health barriers might be broken down, so that they might enjoy the same quality of life wherever they live.

The EEC Committee for Proprietary Medicinal Products, of which I am honored to be Deputy President, has for a long time made all possible efforts to reach the harmonization of drug registration procedures

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as a preliminary step to allowing equal drug availability in the EEC countries and their free circulation in all of them.

It is well known that under the Treaty of Rome, the countries of the European Economic Community have been actively engaged since 1964 in taking steps to achieve the free circulation of medicines within this community. To achieve this objective, it is a prerequisite to harmonize the existing legislation on medicines and for that purpose the EEC Commission issues directives. It is appropriate to describe briefly the general manner in which this Commission operates. The EEC organization has the authority to promulgate rules and issue directives. These rules are compulsory for all member states in all their aspects and are directly applicable in each member state. They are limited to situations which require complete uniformity. On the other hand, when a harmonization of the existing legislation is regarded as sufficient, which is the case for pharmaceutical drugs, directives are issued.

Now, article 34 of the EEC directive 75/ 319 states that the provisions of directive 65/65 and those of the above directive 75/ 319 'are not to be applied to medicinal specialties consisting of vaccines, toxins, sera, those containing human blood, blood components or radioactive isotopes, not homeopathic medicinal specialties'.

This implies that as long as no new community provision is issued, the matter remains ruled by national legislations.

This article 34 clearly excludes from the present community rule medicinal preparations containing human blood and blood components. Components meaning the products obtained from various degrees of 'fractionation' of human blood.

The issue of preparations excluded from the rulings set up by the directives was submitted to the Pharmaceutical Committee for examination in the meeting of March 27–28, 1979.

This discussion contrary to what had been anticipated, was not completed, being limited to immunological products (sera and vaccines). It became clear that the problem, which has been worrying the Commission since 1975, was extremely complex and that there were greatly divergent viewpoints on the matter. It was therefore deemed advisable to discuss the problem again in subsequent meetings, so as to enable the various delegations to develop a final position. In the opinion of some countries, intervention in this sector should not have high priority. It is, however, necessary that drugs derived from human plasma, and among them anti-haemophilic concentrates produced by the pharmaceutical industry may, in the not too distant future, be included in the harmonization framework. They are, in fact, particularly delicate biological drugs, for which the way to the harmonization of compulsory registration procedures is reached via harmonization of quality controls.

Harmonization of registration procedures does not necessarily mean equal prices in different countries, the economic aspect being strictly tied with a series of economic conditions which, within the community itself, differ greatly from one country to another. The different cost of labor in the various countries, and different levels of applied technology, inevitably result in different production and distribution costs which are bound to be reflected on the prices of pharmaceutical products. What is of paramount importance is that pharmaceutical products in general, and in par-

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ticular those derived from human plasma with labile biological activity and serious side effects, be subjected to high quality control standards, which are equal or similar in every country. This is a development to which EEC bodies, health authorities of the member countries and industrial

pharmaceutical producers are equally committed in order to service the increasing availability of high quality haemophilia care.

What we shall be able to achieve within the European Community could, in my opinion, be easily extended, via the necessary adaptations to other countries and regions where this problem also exist. Those individuals involved in such work are achieving an increasing mutual acquaintance and familiarization through meeting such as this conference. The elimination of political frontiers must be accompanied by the social and, above all health frontiers.

Stimulus in this direction might come from the problem of haemophilia treatment, a condition of high social significance. Haemophiliacs can achieve this goal through their own initiative, their organization, the World Federation of Hemophilia and the attention they have gained in the medical world.

The goal, harmonization of the quality control standards for registration procedures of antihaemophilic drugs is not only a wish of all haemophiliacs. It is a pledge I take upon myself and a personal commitment to bring the problem to the attention of the EEC, CPMO, and other community bodies.