E.C. HARMONISATION AND THE FREE MOVEMENT OF PHARMACISTS AND PHARMACEUTICAL PRODUCTS

David Camilleri

With the 31st of December 1992 being so close at hand, the Administrative Institutions of the E.C. are hard at work in drawing-up, adopting, and enforcing Community law so as to fulfill their commitment towards the formation of a Single European Market by the deadline indicated above.

The principal aim and goal of the single European Market is the birth of a European area through which goods, persons, capital, and services can move freely without having to overcome the physical, technical and fiscal barriers to trade, which currently exist between the different European nations.

Like all other sectors, the Pharmaceutical environment will be greatly effected by the changes resulting from a united Europe.

In view of Malta's application to join the Community, the Maltese Pharmaceutical sector should, and has the obligation to identify these changes and take the appropriate measure to bring the Maltese Pharmaceutical environment in liason with that of the E.C.

In this respect, two main areas of concern are identified:

a) The free movement of pharmacists, and
b) The free movement of pharmaceuticals and medical/surgical products

A) The free movement of pharmacists

The social Charter of the E.C. is aimed at guaranteeing the free movement, and equal treatment of workers throughout the Community. It encompasses the basic rights for workers so as to ensure that workers can work, look for work, reside, etc... in any one of the 12 Member States without prejudice.

In respect of professional workers, the Community has taken measures to ensure that Diplomas & Professional Qualifications obtained in any member state is recognised in all the other member states.

For pharmacy, 3 main Directives were adopted so as to:

i) facilitate the free movement of pharmacists (Dir. 85/432/EEC)
ii) have a mutual recognition of Diplomas (Dir. 85/433/EEC)

iii) set up an Advisory Committee on pharmaceutical training requirements (Dir. 85/434/EEC)

The adoption of these Directives has enabled the free movement of pharmacists throughout the Community by eliminating the 'visible' barriers which limited the free movement of pharmacists within the E.C.

Apart from these barriers, there also exist 'invisible' barriers, such as the local language, environment, lifestyle, etc... These barriers are being tackled through the implementation of various programmes (e.g. Lingua, Erasmus, Comett) aimed at promoting the 'European' concept.

When looking at Malta, one notices the existence of several barriers limiting the free movement of pharmacists. These barriers include:

- Pharmacy Diploma recognition. Maltese Pharmacy Diploma is not recognised in all of E.C.'s member states, thus limiting the movement of Maltese Pharmacists.

- Pharmacy course content. This is still not up to the minimum Diploma requirements as described by E.C. Directives. This problem has been identified and various steps are being taken in order to bring current course content in line with that stipulated by the E.C.

- Immigration barriers, including work permits, residence permits, etc...

Language barrier.Very few foreign Pharmacists know the Maltese language, thus limiting the possibility of their working in the Maltese community.

- Wages, which are not as attractive as those in other E.C. member states.

B) The free movement of Pharmaceuticals

In this sector the main barriers are the so called Technical barriers of which there are three:

i) Differences in national standards

ii) Differences in national regulations
iii) Testing and certification procedures

The Community is working to remove these barriers through the harmonisation of laws and regulations governing pharmaceuticals and the standardisation of requirements for pharmaceuticals. These efforts may be grouped in two:

1) Efforts to harmonise required standards

Here, one can mention the elaboration of the European Pharmacopeia, European/Community patent, defining the legal status of the various drug classes, the setting up of a Common Market Authorisation procedure (based on two systems; the centralised and the decentralised systems).

2) Efforts to harmonise testing and certification

Efforts in this field are mainly aimed at encouraging mutual recognition of existing national testing and certification methods, and the issuing of guidelines for GMP, GLC, GCP etc...

The establishment of the European Organisation for Testing and Certification, is aimed at realizing this goal by promoting and implementing agreed criteria and procedures from the technical capabilities, operational performance and maintenance of competence of operators.

It is important to realise that the Community makes these efforts in liason with similar initiatives taken by international Organisations (e.g. ISO, IEC, WHO). In fact, on several occasions guidelines issued by these organisations have been adopted (in part or in full) by the Community.

One can mention the participation and co-sponsorship of the FIRST INTERNATIONAL CONFERENCE OF HARMONISATION (ICH), in which various possible areas for international (E.C., USA and Japan) cooperation in this field were identified and discussed.

Thus it can be concluded that 1993 will mark the formation of one big European Market in which:

1) Pharmaceuticals can move freely
2) Cooperation between nations is promoted

3) The E.C. has one big say in cooperation initiatives on a world-wide level (e.g. participation in the GATT [Uruguay] talks).

Looking at Malta one immediately realises the need for the setting up of a Drug Regulatory Authority and a Testing and Certification Body. Further studies in this respect are needed. Help from WHO &/or the E.C. can be asked for in this respect.

Conclusion

The completion of a European single market will benefit Pharmacy such that there is a greater exchange of ideas, knowledge, and experiences between the different national pharmaceutical societies.

Pharmaceuticals will have facilitated mobility within Europe and possibly world-wide (through cooperation with other international organisations such as EFTA, NLN, USA, Japan).

Unless MALTA starts now to enact legislative and administrative changes needed to bring its pharmaceutical sector in closer cohesion with that of Europe it will be left lagging behind. This will go against our obligations to protect and safeguard national health and safety standards and the need to improve them.