Pharmacy and the EU

The Impact of European Union Membership on the Pharmacy Profession in Malta

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The Malta Chamber of Pharmacists, as the National Pharmaceutical Association, monitors the developments in local, European and international pharmacy. With the current national developments, the Chamber's primary focus is the impact of EU membership on pharmacists, pharmacy and medicines. The Chamber has in fact been studying the impact of European Union (EU) membership intensively since 1990, at the time when the then Administration had first formally applied for full membership in the EU[1].

In 1998, the Maltese Government reactivated its application for full membership in the EU. Immediately, the Chamber, given that a plethora of EU Commission Directives address the free movement of pharmacists, their right of establishment and the mutual recognition of qualifications in pharmacy and the free movement of medicines in the European Economic Area (EEA), intensified its endeavours in the field, to be in a "pole"position to:

- consolidate its European activities, in the light of the roles played by the Pharmaceutical Group of the European Union (PGEU) and EuroPharm Forum (WHO/Euro) at European level, and the Chamber at European and national levels;
- advise the Government and other relevant institutions and Authorities, the members of the pharmacy profession and the public, on these matters;
- make recommendations to the Government and other relevant institutions and authorities, and the members of the pharmacy profession, on the implementation of the changes to the relevant legislation and practice;
- prepare the profession and the country for full membership through pro-active participation in the updating of the legislation, structures and standards pertaining to pharmacists, pharmacy, medicines and health;
- empower the active participation of the Chamber in all the processes leading to the official negotiations with the EU on matters concerning pharmacists, pharmacy, medicines and health;
- enable Chamber participation in Brussels, the hub of activity, and in other EU countries, on affairs pertaining to pharmacists, pharmacy, medicines and health;
- engage identified European experts with the remit to advise the Chamber Executive Council and to visit Malta to hold intensive meetings with the Chamber Executive Council and workshops/ seminars for members.

The Pharmaceutical Group of the European Union

After the signature of the Treaty of Rome, on the 25th March 1957, which incepted the European Economic Community (EEC) and the European Community of Atomic Energy (Euroatom), few were those professionals who were quick to realise the significant implications and challenges brought about by the "Four Freedoms" (Freedom of movement of capital, services, persons and goods).

European pharmacists were amongst the first to do so, and, in 1957, the "Groupement", the Pharmaceutical

Group of the European Community at that time, was founded, engrouping the then six members of the EEC. This has now evolved into the Pharmaceutical Group of the European Union (PGEU), which is the strong lobby group on pharmaceutical matters based in Brussels, Belgium. It consists of the delegations of the National Pharmaceutical Associations of 15 members (country delegations) together with a number of observers mostly from applicant countries for EU membership and other international and European Pharmaceutical institutions.

The pharmaceutical profession, through the PGEU, maintains relations with the European Commission, the European Parliament, the Economic and Social Council and other European and international organizations of Health Care professionals and stakeholders. Through its founder membership of the EuroPharm Forum (WHO/Euro) in 1992, the Chamber has since established a fruitful collaborative relationship with the PGEU.

The Pharmacy Sectorial Directives

The pharmaceutical profession is mainly regulated by three Directives in the EU.

Directives 85/432/EEC[2] and 85/433/EEC[3] concern the free movement of pharmacists and the right of establishment and the mutual recognition of qualifications in Pharmacy. Directive 85/434/EEC[4] provides for the setting up by the EU Commission of the Advisory Committee on Pharmaceutical Training. Moreover, in May 1994 this latter Committee issued the document entitled "Report And Recommendations On Pharmaceutical Education Undergone At Higher-Education Institutions", the contents of which have been implemented by several member states, albeit it is not a directive[5].

Article 1 of Directive 85/432/EEC lays down in paragraph 1.1 that "Member States shall ensure that holders of a diploma, certificate or other University equivalent qualification in pharmacy which meets the conditions laid down in Article 2 shall be entitled at least to access to the activities mentioned in paragraph 1.2 and to pursue such activities, subject where appropriate to the requirement of additional professional experience."

The activities referred to in this paragraph are outlined in paragraph 1.2 and include:

- the preparation of the pharmaceutical form of medicinal products;
- the manufacture and testing of medicinal products;
- the testing of medicinal products in a laboratory;
- the storage preservation and distribution of medicinal products at the wholesale stage;
- the preparation, testing, storage and supply of medicinal products in pharmacies open to the public;
- the provision of information and advice on medicinal products.

Article 2 of Directive 85/432/EEC specifies that training leading to the formal qualification shall ensure adequate knowledge:

- of medicines and the substances used in the manufacture of medicines;
- of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products;
- of the metabolism and the effects of medicinal products and of the action of toxic substances and of the use of medicinal products;
- to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge;
- of the legal, ethical and other requirements associated with the practice of pharmacy.

Briefly, therefore, any person who holds a qualification listed in Article 4 of Directive 85/433/EEC, gained by successful completion of a course of study complying with Article 2 of Directive 85/432/EEC, or who meets the criteria for established rights in Article 6 of Directive 85/433/EEC (Table 1) is entitled to access in any country of the EEA to any activity in Article 2 of Directive 85/433/EEC.

Having taken into consideration all of the above, the Chamber has made the following strong recommendations to the Government.

Mutual Recognition of Qualifications

The Government must ensure that Maltese pharmacists who qualified before the implementation of Directive 85/433/EEC benefit from the "established rights" provisions of Directive 85/432/EEC, and that the "cut off point" should be the date of EU accession.

Established Rights and Regulated Areas of Practice - The Case of Pharmacist Medical Representatives

With further reference to the established rights provision in Directive 85/433/EEC, suitable safeguards must be in place for those pharmacists who do not comply with Directive 85/432/EEC nor with the acquired rights provisions of Directive 85/433/EEC because they are not practising in a regulated area of practice.

A case in point is that of pharmacist medical representatives. It is vital that medical representation is immediately designated by the Government as a regulated area of practice and that a register of pharmacist medical representatives is held by the Pharmacy Board.

Moreover, the necessary structures for the keeping of registers for existing specific areas of practice, including the managing pharmacists of community pharmacies, pharmacists in hospital practice, administrative pharmacists, pharmacists practising in laboratories, the qualified persons (pharmacists) designated as responsible pharmacists of the pharmaceutical activities of wholesale dealers of medicines, and the qualified persons in the manufacturing of medicines, should be set up without delay.

In-Service or Pre-Registration Training - The Case of the B.Pharm. (Hons.) Class Of 2000

Besides the specifications on the adequate knowledge required in the training leading to the formal qualification mentioned above, Article 2 of Directive 85/432/EEC imposes a further minimum period of six months in-service training in a hospital or a community pharmacy towards the end of the University course leading to the qualification in pharmacy[6]. In 1993, the Advisory Committee[7] laid down the principles according to which the monitoring, evaluation and content of in-service training were to be determined. The Chamber has studied the documents of the Advisory Committee on Pharmaceutical Training of the EU and other recommendations of European advisors and has strongly recommended to the Government and the University that Malta should immediately develop the appropriate supervising and training infrastructure with appropriate pharmacist mentors in both hospital and community pharmacy. However, this is a short term priority, since there is no provision for in-service training as yet . Thus, students in the course at present and who will graduate this year, are not in line with Article 2 of Directive 85/432/EEC[3] and on accession, these will not have freedom of movement unless provisions in this regard are immediately taken.

Accession to Activities in Pharmacy by a National of a Member State

The Chamber has strongly recommended that the Licensing Authority request proof of qualification (University degree), pre-registration training, licence to practice (warrant), proof of actual practice experience, and certificate of good conduct (civil and professional conduct and repute, perhaps reflected in a current licence to practice and "history" thereof), from the member state. This is an example of practice in various member states.

Linguistic Knowledge

It is an ethical requirement that there is good communication and understanding between the pharmacist, indeed any health care professional, and the patient. Moreover. the Chamber insists that nationals of Member states applying for registration in Malta should be requested to have a good working knowledge (spoken and written) of the Maltese Language since this is the national language of the Maltese population[8].

Table 1: Established Rights Criteria
Article 6: Directive 85/433/EEC

6.1 Diplomas, certificates and other university or equivalent qualifications in pharmacy which were awarded to nationals of Member States by Member States and which do not satisfy all minimum training requirements laid down in Article 2 of Directive 85/432 EEC shall be treated as diplomas satisfying these requirements if:

- they are evidence of training which was completed before the implementation of the said Directive, or
- they are evidence of training which was completed after but which was commenced before the implementation of the said Directives.

and, in each case, if

- they are accompanied by a certificate stating that their holders have been effectively and lawfully engaged in one of the activities referred to in Article 1 (2) of Directive 85/432/EEC in a Member State for at least three consecutive years during the five years preceding the award of the certificate, provided that this activity is regulated in that State.

Source: Council Directive 85/433/EEC. O.J.No.L 253, 24.9.1985. pp 0037-0043.

Advisory Committee on Pharmaceutical Education and Training

This Committee comprises, from each country, three members and three deputies, representing the competent authorities, academic pharmacy and the practising pharmaceutical profession. It is the Chamber's strong opinion that the Government should consult the Chamber in the appointment of the member and deputy to represent the Maltese practising phamaceutical profession on this Committee.

Specialisation

There is the requirement in the first directive (85/432/EEC) that the Commission must make proposals for specialisation to be undertaken by pharmacists already registered to practise pharmacy in the EU. The EU Advisory Committee on Pharmaceutical Training has issued documents with respect to Specialisation in Community Pharmacy[9] but this has not taken the form of a Directive; the Committee is at present working on Specialisation in Hospital Pharmacy and Specialisation in Clinical or Medical Biology.

In this context, the Chamber has urged for work to start immediately to provide for specialisation of Maltese pharmacists in the various areas of hospital pharmacy including clinical pharmacy, community pharmacy, pharmaceutical industry including marketing of medicines and wholesale distribution, laboratories, and academia. This is so as to safeguard the position of Maltese pharmacists vis a vis EEA citizens who already have a history of specialisation.

The Right of Establishment

The preamble to Directive 85/432/EEC, states that "The geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be a matter of the Member States...". This national autonomy is further recognised by paragraph 7 of Directive 85/433/EEC which states that: "Whereas, under their national policies in the sphere of public health, which seek inter alia to ensure the satisfactory dispensing of medicinal products over their entire

territories, certain Member States restrict the number of pharmacies that may be established...".

The EEC Treaty (Treaty of Rome) which aimed at the attainment of absolute freedom of circulation of merchandise (Article 9-11) of the labour force (and hence, professionals including pharmacists) (Article 48-51) and freedom of establishment of workers anywhere in the EU (Article 52-58) freedom of services rendered (Article 59-66) accepts as lawful any restrictions imposed by member states on these matters for reasons of public order, public security and public health (Article 48, par. 3, Article 56, par. 1, Article 68) in which said restrictions are also included any regulations concerning the pharmaceutical profession.

In fact, based on the principle of "subsidiarity", which is an important principle in EU law, all EU countries have restrictions on the opening of pharmacies for reasons of public health. All countries therefore organise the licensing of pharmacies according to their needs (Table 2). There are no grounds whatsoever to believe that this would be challenged by the Commission either in the course of negotiation for entry or on entry itself (PGEU, 2000).

In this context, the Chamber is strongly insisting that the legal provisions that were submitted to the Hon. Minister of Health in 1999 are implemented at law, ensuring that there are no loopholes in the system. Suitable safeguards must also be addressed such as the definition of a new pharmacy and the practice by some States to bar non-nationals from acquiring and opening a pharmacy. This report also relaxes the existent criteria whilst keeping to the principles of geodemographic organisation. The report fully liberalises the transfer of

Table 2: State of the Art of Pharmacy Organisation in the European Union

1. In the majority of member states of the EU, including Denmark, France, Greece, Italy, Portugal, Spain, Luxembourg, Finland and Austria, community pharmacy organisation is based on geographical/demographic considerations; and legislation provides for pharmacist ownership only.
2. The UK, Ireland and Belgium allow non-pharmacists to own a pharmacy, but the allocation of dispensing contracts under the NHS, in the first two countries amounts to distribution control, whilst Belgium has distribution controls. The Dutch government has recently legislated to allow the ownership of pharmacies by non-pharmacists.
3. In Germany, only pharmacists can own a pharmacy but there are no distribution regulations.
4. The Swedish system is totally alien to any of the above situations and to current thinking and practices in the EU (and locally.)

Reference

PGEU, letter from the President, Prof. Dieter Ahlgrimm, to the President of the Malta Chamber of Pharmacists, April 1996; PGEU, letter from the Vice-President, Mr. Aidan O'Shea, to the President of the Malta Chamber of Pharmacists, March 2000 and from Mr. John Ferguson, (UK) April 2000.

licence. However, the Chamber is urging the Government to provide the necessary safeguards, with urgency, in the incumbent accession negotiations on free movement of persons and the right of establishment, so that no non-Maltese citizen will open a pharmacy in Malta - and that Parliament should legislate in favour of planned distribution of pharmacies, without any loopholes. This is because under other circumstances, that is, in the absence of geodemographic regulation, citizens of member states and others who are not allowed to open pharmacies in their country by their own Government would be tempted to open in Malta.

The Drafting of a Pharmacy Act

The changes and challenges faced by the Pharmaceutical Profession during the last century and the Government's thrust towards EU membership in the last decade have brought about the urgent need to draft a Pharmacy Profession Act to govern pharmacists in all areas of practice.

The Chamber made detailed submissions regarding this issue in April 2000 (10) at the invitation of the Director General of Health, since the Ministry of Health had embarked on the redrafting of Chapter 31 of the Medical and Kindred Professions Ordinance. In the context of EU membership, it is relevant to highlight the Chamber's stance on the following principles:

- that there should be a Pharmacy Professions Act regulating pharmacists practising in the following areas: community and hospital pharmacy, pharmaceutical industry including manufacturing, importation and wholesale distribution, advertising and marketing (medical representation) of medicinal products without distinction of whether pharmacists practise in the private or public sector;
- that in transposing the EU directives into the main body of the legislation, there will be no loopholes with regard to the recognition of all pharmacists on the register on the date of accession to the EU, so that all may benefit from the established rights provision of Directive 85/433/EEC, even those who do not comply with the provisions of either Directive 85/432/EEC or Directive 85/433/EEC;
- that special areas of practice are immediately designated and that provisions for the establishment and keeping of registers by the Pharmacy Board for different existent areas of practice are immediately implemented, i.e., for the Qualified Person (QP) pharmacist in pharmaceutical manufacturing; the Responsible Pharmacist (RP) in pharmaceutical wholesale activities, (termed QP by the DH circular bringing the requirement into force); pharmacist medical representatives practicing pharmaceutical marketing, and of course, managing pharmacists in community and hospital practice;
- that the necessary legal provisions are implemented to ensure that medical representation is a regulated area of practice, prior to the EU accession date;
- that the requirement on wholesale distribution of medicines should be transposed into the law to state that the "Responsible Person" is a pharmacist;
- that the law should clearly state that the "qualified person" responsible for the manufacture of medicinal products and for the release of same is a pharmacist. In this respect the provisions in MKPO CAP 31; Part X Section 96; subsection [2] for persons with "competency in chemistry" should be appropriately amended;
- that the recommendations mentioned above on the Licensing of Pharmacies are transposed into the law, without loopholes, in the interest of public health and in the light of the provisions of the EEC Rome Treaty and the preamble to Directive 85/432/EEC to introduce safeguards on the right of establishment of pharmacists;
- that the existing Pharmacy Board is replaced with a Pharmacy Council, in view of the need for the true self-governance of the Pharmacy Profession, based on the principles of self regulation, autonomy (financial and administrative), and transparency of judicial review and other decisions. The new Pharmacy Council will have a new composition which reflects professional autonomy and self-regulation, new structures and resources reflecting the evolution of practice and new ethical needs; the new roles, such as mutual recognition of qualifications and specialisation, monitoring of the undergraduate pharmacy curriculum, setting up the provisions and the monitoring of in-service training, the Pharmacy Inspectorate and other activities in the light of EU accession. Thus the restructuring and review of the raison d'étre of the Pharmacy Board is not only of significance to the Maltese Pharmaceutical Profession and the public but also to the European pharmacists who will be approaching it as the Authority to evaluate their eligibility to practice and to discipline them. The Chamber has also made strong and consistent representations with the Minister of Health to this effect.

Conclusion

Irrespective of the EU accession exercise which is currently underway, the changes to legislation governing Pharmacy and the moving toward the attainment, in particular, of structured in-service training and specialisation have long been felt. There should also be a joint effort to attain harmonisation in education and training. In Europe it is being advocated, particularly by the EuroPharm Forum[11] and the European Association of Pharmacy Faculties, that this may be best achieved through partnership of Faculties of Pharmacy and National Pharmaceutical Associations i.e., by academics and practitioners. This objective is fully supported by the PGEU and EPSA[12]. It is of course a moot point that such an initiative is fully and proactively nurtured by the Malta Chamber of Pharmacists[13]. ✶

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Malta Chamber of Pharmacists

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