PHARMACY IN THE EUROPEAN COMMUNITY

'Pharmacy in the European Community' was the title of the workshop which was organised by the Malta Chamber of Pharmacists and the European Region of the Commonwealth Pharmaceutical Association, which consists of the member associations from Great Britain, Northern Ireland, Cyprus and Malta. The workshop was held at the Federation of Professional Bodies, Malta between the 28th November - 1st December 1990.

Mrs Sant Fournier welcoming participants during the official opening of the workshop. third from left The Hon. Dr. Noel Buttigieg Scicluna, Malta's Ambassador to the Council of Europe.

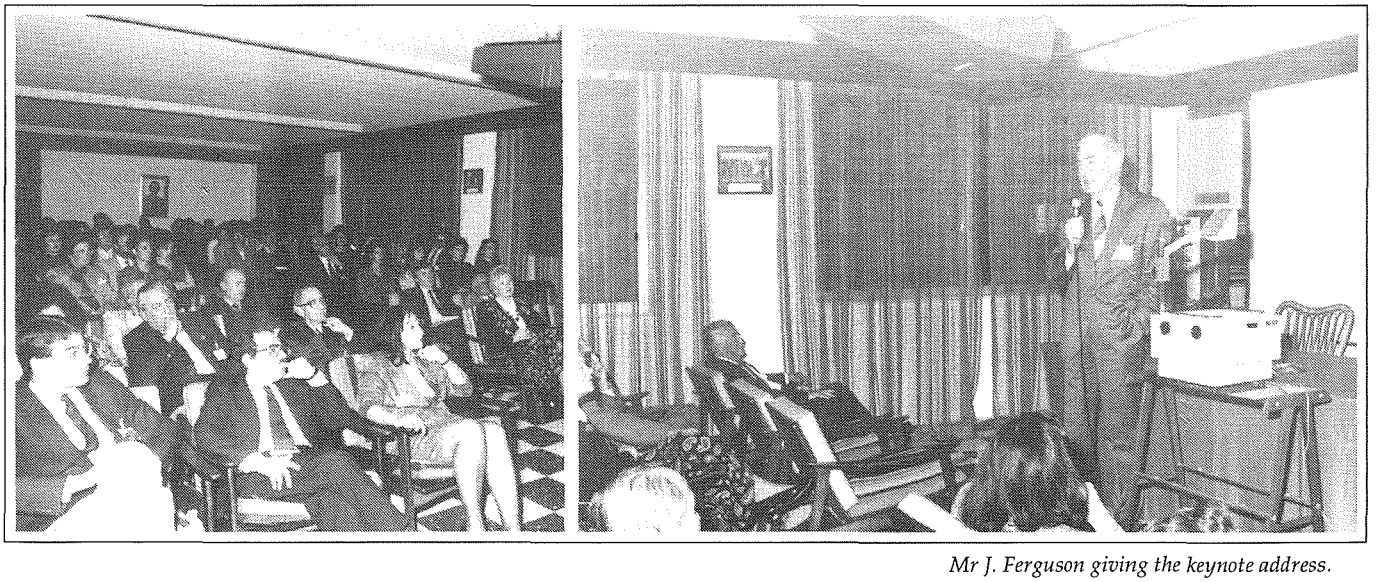
Objectives of the Workshop

1. To confirm the current state of pharmacy legislation within the region.
2. To identify in order of priority the improvements that are needed in the legislation governing pharmacy in each constituent country, especially those that have applied recently (Malta and Cyprus) for full membership in the EC; and those to whom 1992 presents new problems in pharmacy (Great Britain and Northern Ireland).
3. To discuss the implications of the EC Pharmacy Directives.
4. To make recommendations for action with an indication of priorities by member associations, by CPA European Region.

Proceedings

The official opening of the workshop was held on the 28th November 1990 and was attended by the workshop participants together with members of the Malta Chamber of Pharmacists, members of other professions, and invited guests.

Mrs M.A. Sant Fournier, President, Malta Chamber of Pharmacists, welcomed all present and said that it was most opportune for Malta to host such a workshop as at present the Malta Chamber of Pharmacists is looking at the legislation concerning Pharmacy in view of Malta's proposed entry into the European



Mr J. Ferguson giving the keynote address.

Community. Mrs Sant Fournier concluded by reaffirming the Chamber's commitment to continue in its efforts to upgrade the profession of pharmacy in all its aspects.

Prof. A.H. Beckett, Vice-President, Commonwealth Pharmaceutical Association, said that it was wise for the Malta Chamber of Pharmacists to take the initiative for the workshop to take place and consider the implications that the European Community has for the profession at this early stage. He added that it was most unfortunate that the CPA Founder President, Mr A. Howells and Prof. P.F. D'Arcy, were unable to attend in spite of the fact that they would have very much wished to participate in this workshop. Prof. Beckett expressed his gratitude to the Malta Chamber of Pharmacists for hosting the workshop and for its contribution to the planning and to the Commonwealth Foundation for funding this workshop.

The workshop was then officially opened by the Hon. Dr. Noel Buttigieg Scicluna, Malta's Ambassador to the Council of Europe who said that all professions in Malta including Pharmacy, need to be ungraded to European Community Standards. Dr. Buttigieg Scicluna added that the government was giving great importance to the pharmacy profession. There was an ongoing dialogue between the Malta Chamber of Pharmacists and the Ministry for Social Policy whereby means are being discussed to enhance the pharmacists' role in society.

In his keynote address Mr John Ferguson, Secretary and Registrar of the Royal Pharmaceutical Society of Great Britain, outlined the various aspects of the Pharmacy EC Directives and gave a general direction for the workshop's discussion during the following days.

Mrs Frances Charlesworth (Great Britain) leading one of the Workshop sessions.

Position papers from each participating country and other background papers were submitted before the workshop. The position papers were based on statistics about pharmacists and their major activities. Regulations governing community pharmacies, hospital pharmacies, importations, industry, wholesale and marketing and representation of pharmaceuticals.

The workshop had two main themes: Session 1 dealt with the 'Free Movement of Pharmacists and the Right of Establishment' and was chaired by Mrs Sant Fournier. The function of rapporteur was performed by Mr Josef Grech, Malta Chamber of Pharmacists. Mr John Ferguson participated as the expert on the theme of this session.

The theme of session 2 was 'Free Movement of Proprietary Medicinal Products'. The session was chaired by Mr Raymond Dickinson and Ms Mary Anne Ciappara, Malta Chamber of Pharmacists was rapporteur. Mrs Frances Charlesworth, Director of the European and International affairs of the Association of the British Pharmaceutical Industry was the expert.

The concluding session held on Saturday, 1st December 1990 was chaired by Prof. Beckett, the rapporteurs presented the reports for the two sessions and the preliminary draft of the workshop recommendations was presented by Mr Raymond Dickinson, Secretary, Commonwealth Pharmaceutical Association. (Page 14 - 17)

The workshop brought information from the two experts and from those who have had experience of the European Community to the delegates from the countries who have applied for entry. That

information will be available to the professionals and to the applicant Governments as a very useful information source on all the directives and other proposals relating to pharmacy and to medicinal products.

The workshop identified action that might be taken by all the participating countries. All the directives are based on the promotion of good health, and so the actions that are proposed have tremendous value in themselves as well as being related to the EC.

It is now up to the pharmaceutical associations of Cyprus, Great Britain, Malta and Northern Ireland to take up the recommendations made during this workshop that apply to them and work on them, and more importantly to the positive response from Governments so as to achieve a good pharmaceutical service.

As Mr Dickinson concluded, it is believed that the information obtained from this workshop will be of great benefit to the Governments as well as to the profession. Prof. Beckett and Mrs Sant Fournier also addressed the concluding session.

The workshop was officially closed by the Hon. Dr. George Hyzler, Parliamentary Secretary for Health. Dr. Hyzler expressed his concern that today, the pharmacist still does not form an integral part of the primary health care team and thus the profession is skill not fully recognised by society for the services it is in a position to provide. One of the main areas of concern in community pharmacy is undoubtedly the lack of implementation of legislation. Referring to Medicinal Products, Dr. Hyzler said that Malta is a member of the WHO Certification Scheme. The next step will be the Registration of Medicinal Products which are imported into Malta.

Left *Mr Dickinson presenting the workshop recommendations during the closing session. Fourth from left, The Parliamentary Secretary for Health, The Hon. Dr. G. Hyzler.*

Bottom *Workshop delegates and Council, Malta Chamber of Pharmacist with the Hon. Dr G. Hyzler, Parliamentary Secretary for Health, during a reception at Palazzo Castellania. (left to right) Prof. A. Beckett, Mr A. Tonna, Mr J. Kerr, Ms M. Pisani, Mr E. Zammit, Ms M.A. Ciappara, Mr J. Grech, The Hon. Dr G. Hyzler, Ms M.A. Sant Fournier, Mr R. Dickinson, Dr P. Storie Pugh, Mr J. Fergusson, Mr C. Ionnides, Ms M. Abdilla.*

PHARMACY IN THE EUROPEAN COMMUNITY

CPA European Region Workshop
Nov. 28 - Dec 1, 1990
Recommendations

1. Free Movement of Pharmacists and the Right of Establishment

Major proposals for the education and training of pharmacists to achieve comparability of standards before EC entry.

1.1 Preamble to Directive 432 relates to the broad comparability of education and training of member countries of the EC. It is in the interests of Malta and Cyprus to achieve a similar comparability to enable pharmacists to benefit from the movement if they so wish. This education and training will have an effect on the quality of the pharmaceutical services in the future.

1.2 Considering that the Advisory Committee on Pharmaceutical Training is now looking at the quality of education and training in terms of content and resources (staff and equipment) whose work will continue during the next several years. The workshop felt that the Pharmacy School in Malta should continue to develop further the academic framework of the pharmacy course to bring it into line with the broad comparability of other EC courses.

1.3 Since it will take several years to implement the changes that will be required, it is necessary to start now if they are to be made before entry into the EC. *Even if EC entry were to be deferred, these standards would, in any event, relate to the equivalent UK standards thereby achieving academic equivalence between the Maltese and UK pharmacy degrees.*

1.4 The workshop felt that it is essential that there should be an independent assessment of the developments that are needed in the academic framework. *CPA is therefore offering to the Malta Government, to coordinate a visit to the University by appropriate experts, with funding obtained from the Government, in collaboration with CPA, from such organisations as the Commonwealth Fund for Technical Cooperation, the Commonwealth Foundation or the British Council.*

The visit should not only relate to the changes that are needed in academic standards per se, but should take into account the practice developments required to achieve a well developed pharmaceutical service. It is suggested that the visiting panel should include members who were involved in the Nuffield Foundation Inquiry into pharmaceutical services in the UK, which made a very detailed study of the contributions that pharmacy can make to the health services and general health of the population. It is envisaged that two pharmacists and a medical doctor, representatives from that Inquiry, and two academic pharmacists who are currently serving on the EC Advisory Committee who will be involved in future EC quality considerations, will form part of this visiting party.

It is proposed that this relatively small visiting party would cover all of these factors and each aspect of the pharmaceutical sciences. Their report would be of great benefit to the country and the profession as a first step in the process of reaching comparability.

1.5 The EC advisory committee on in-service training is about to look at the detailed structure of the training period and has already agreed on the principles upon which it should be based. *Malta needs to develop an appropriate supervising and training infra-structure with appropriate pharmacists in both hospital and community practice.*

1.6 With regard to Cyprus, the situation is quite different. There is no pharmacy school in Cyprus and they recognise qualifications from the UK, Greece and Turkey and any other qualification which is approved by the Cyprus Pharmacy Council as being equivalent. The workshop expects to see for Cyprus a similar situation to that which applies to Luxembourg which also has no pharmacy school. On EC entry, Cyprus will, no doubt, automatically recognise

the qualifications in the other member countries.

2. Proposals to enable pharmacists to specialise

2.1 There is a requirement in the first directive that the commission must make proposals for specialisation to be undertaken by pharmacists already registered to practice pharmacy in EC countries.

Specialisation in hospital pharmacy has to be given priority so as to enable the services in hospitals to respond more rapidly and effectively to developments and thus benefit patient care.

The Advisory Committee will soon be looking at proposals for additional specialisation in community pharmacy – to enable pharmacists to act more effectively as a filter for minor ailments and to liaise with medical colleagues to encourage more rational prescribing.

2.2 The workshop urges the Governments in Cyprus and Malta to take on board the philosophy of these specialisations in Pharmacy now.

3. Composition of the Advisory Committee

The composition of the Advisory Committee on Pharmaceutical Training comprises, from each country, three members and three deputies representing competent authorities, academic pharmacy and the practising pharmaceutical profession. *It is the strong view of the works that the Malta Chamber of Pharmacists and the Pancyprian Pharmaceutical Association should be consulted by the Government when the member and deputy is appointed to represent the practising pharmaceutical profession.*

4. Geographical Distribution of Pharmacies

The preamble of Directive 433 recognises that some countries have introduced a requirement "to ensure the satisfactory dispensing of medicinal products over their entire territories".

It is therefore essential that countries such as Malta, that have geographical distribution legislation should ensure that it is properly implemented and that there are no loopholes in the system.

5. General Standards of Pharmacy Practice

There have been two important developments, one linked with Europe, namely the production of an updated Charter for Pharmacy Practice by the EC Pharmacy Group. This has been complemented by a WHO document published within the last two or three months on the 'Pharmacist in the Health Care System'. *The workshop recommended both of these documents to the professions and the governments of the participating countries.*

5.1 Supply of National Health Service Medicines through Community Pharmacies

The workshop is disappointed to learn that the Government of Malta has not implemented its policy for the distribution of National Health Service Medicines from the Community Pharmacy of the patient's choice. The workshop urges the recognition of the value of the community pharmacist, in terms of ease of access; advice and in-formation to chronic patients; improvement of compliance and the more cost effective distribution of medicines – by the early introduction of these arrangements.

6. Proposals relating to the Free Movement of Medicinal Products

6.1 Pharmaceutical associations should discuss with their Government the range of consultations that will take place on EC proposals. Directive 432 clearly states in the preamble that "Pharmacists are specialists in the field of medicinal products". Therefore, the consultation with the pharmacy profession should be on every aspect of pharmacy and of medicinal products.

6.2 The workshop recommended that the pharmaceutical associations of the participating countries should study carefully the definition of medicinal products which appears in the EC documents and adopt it in their legislation.

6.3 An immense amount of effort is put in by the pharmaceutical industry in the accumulation of scientific data on packages which are appropriate to particular medicinal products particularly to high technology products. It is essential in the practice of pharmacy to preserve the integrity of the manufacturers' package throughout the complete chain from manufacturers to patient, to ensure the stability of a product until it is taken by the patient.

Pharmacists and doctors have to meet and reach some accommodation for dispensing the amount of tablets prescribed so that in future original packs will remain intact.

In the case of the Government Health Services, pharmaceutical associations should liaise with the Government to reach some agreement.

6.4 Each country must have the required medicines control authority to protect public health. As there is no Medicines Control Agency or Specific Registration Authority in Malta, the workshop urges that work should begin immediately to establish arrangements that are appropriate to the country and the range of the country's activities. The best arrangements can be achieved for Malta in the interim period before EC entry.

The workshop urges that work should commence now and that CPA will be happy to help Malta to liaise with overseas agencies that have the necessary experience and expertise.

6.5 Training for inspectors can be arranged through the World Health Organisation and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

6.6 In Cyprus, this regulatory machinery exists but some amendments to the existing legislation may be necessary to bring it in to line with the respective EC Directives.

6.7 There is going to be a Wholesale Directive. In addition to requirements relating to premises, good housekeeping and record keeping, there will be a requirement for a suitable 'qualified' person responsible for each wholesale depot. The workshop feels that this suitable 'qualified' person should be a pharmacist.

6.8 A Directive on the legal status of medicines is imminent. The workshop urges that the pharmaceutical associations of the participating countries should immediately collaborate with the government in a review of the mentioned legislation in order that these EC standards are met.

6.9 The workshop reaffirms that the laws relating to the legal status of medicines should be implemented and more importantly, should be effectively enforced. National law can sub-divide the category of non-prescription medicines into over-the-counter and a pharmacist-recommended list so as to enhance the role of the pharmacist in the treatment of minor ailments.

6.10 There is a Draft Directive on Advertising and Medicinal Products. The workshop supports the moves being taken by the Malta Chamber of Pharmacists to introduce professional rather than bureaucratic controls, over the advertising of medicinal products with a considerable dimension of control by peer pressure. The workshop feels that this should be upheld in the other participating countries.

6.11 The second Directive on medicinal products states that each of manufactured or imported medicines should carry the certificate of a 'qualified' person before it is placed on the market. Maltese law stipulates that the ultimate person responsible for the safety, efficacy and quality of medicinal products should be a registered pharmacist. The workshop would like to impress upon the Government that the 'qualified' person should be a pharmacist as their education comply with the Directive knowledge requirements and they are subject to their own professional codes of practice and discipline.

6.12 When a medicinal product reaches the market, adverse effects must be closely followed. Future proposals within EC requires that there shall be notification of serious and life threatening reactions. In Europe, there has to be a network of pharmacovigilance data. The workshop urges that Malta should consider an adverse drug reaction reporting system involving both doctors and pharmacists.