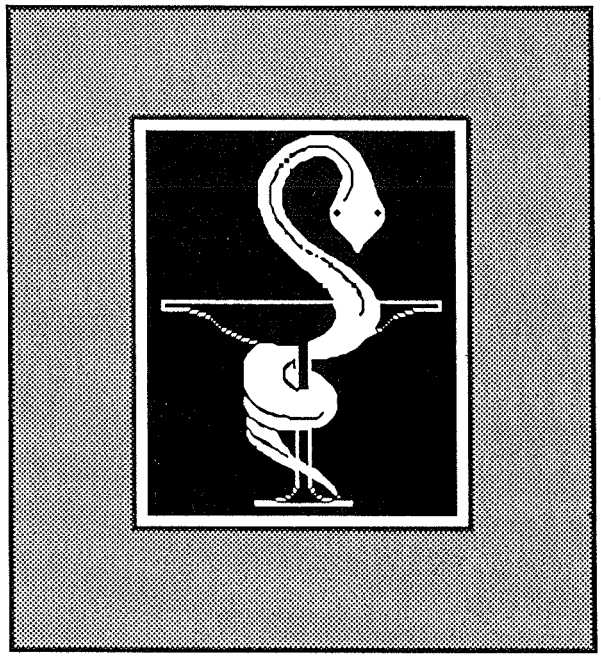

MEMORANDUM

BY

THE CHAMBER OF PHARMACISTS
Trade Union

April 1987

This memorandum is a synthesis of the policy of the Chamber of Pharmacists - Trade Union - a policy which has developed over the years. It has been compiled to bring to the attention of all concerned the problems which face Pharmacy in Malta today. Some of these problems have been with us for many years and it is about time that these be solved without any further delay.

We strongly feel that knowledge of our problems by the politicians, who are the persons responsible directly for legislation and indirectly for the enforcement of this legislation, is the only way that a solution of these problems can be approached. Some of these problems discussed below do not only concern the pharmacy profession and its members per se, but effect the general public, exposing the population to unnecessary risks.

THE PHARMACIST — Definition

It is easy to define the pharmacist as the graduate from a B.Pharm. University course. But this merely describes his academic classification. Indeed, one may ask:

1. Who is the pharmacist?
2. What are his areas of work?
3. What is his role in society?
4. What are his responsibilities?

The pharmacist is the product of four years University education in Pharmacy. The traditional aspects of pharmacy are still there, i.e. preparation of medicines — pharmaceutics. However, there is much, much more to modern pharmacy. These days with the discovery and marketing of so many new and potent drugs, it has become imperative for the pharmacist to have intensive tuition in pharmaceutical chemistry and pharmacology. Furthermore, the increasing clinical involvement of pharmacy has resulted in the emergence of clinic pharmacology, a topic which forms an integral part of the pharmacy students' education.

The image of the pharmacist is most often linked with his role as managing pharmacist in a pharmacy. He is the member of the health care team, with an intensive academic training in drug treatment and therapy. He is responsible for the dispensing of medicines, for patient information and patient education on his therapy. He must see that the correct dosage has been prescribed, and keeps a lookout for drug interactions. Other areas of work are in hospital, industry and as medical representatives.

In hospital, his work may be directly linked to patient care. He may also be involved with administration, procurement and distribution of medicines.

As medical representatives, pharmacists are in a unique position to provide the members of the medical profession with accurate and truthful information on new medication and dosage forms available.

The following is the Budapest Declaration of FIP. This declaration may be regarded as a charter for pharmacy. It is also a charter of safeguards for the patient who is morally entitled to receive his medication via an expert professional — the pharmacist.

We urge all politicians to study this document carefully and take immediate consideration of the suggestions put forward. Only through the implementation of the suggestions included in this memorandum can Pharmacy in Malta make the necessary advance to reach current international pharmacy practice.

THE BUDAPEST DECLARATION OF THE INTERNATIONAL PHARMACEUTICAL FEDERATION

— Having noted, like WHO, that medicaments are becoming increasingly important, within the health policies of countries world-wide;
— Having noted that many persons who have only superficial knowledge of drugs and pharmaceutical products are engaged in the distribution of pharmaceutical products for profit purposes only;
— Having noted that practically everywhere there is an increasing number of declarations, opinions, erroneous statements, about drugs and pharmaceutical products by persons who although well intentioned are generally poorly informed;

The International Pharmaceutical Federation (FIP) reaffirms and emphasizes that:

1. Drugs and pharmaceutical products should not be regarded as normal items of commerce; they are very complex aids to health care.
2. Only specialists possess an in-depth knowledge of drugs and pharmaceutical products, i.e. their composition, preparation, handling, dispensing, action, side-effects, drug-drug and drug-food interactions, etc. Only such specialists are qualified to give appropriate information and advice to the patient receiving pharmaceutical products on prescription or when the patient obtains them on his own initiative.
3. Pharmacists are the specialists who have the necessary integrated knowledge of drugs and pharmaceutical products. They have completed university studies involving subjects related to this knowledge. Moreover, this knowledge is strengthened through professional practice and the updating of this knowledge.

Consequently, FIP wishes to remind governmental and non-governmental, national and international organizations that it would be in their own and the public's interest to consult and involve pharmacists and their professional bodies, whenever they are called upon to resolve matters concerned with drugs and pharmaceutical products.

1. THE MANAGEMENT OF COMMUNITY PHARMACIES

A pharmacy is not a shop. It is the place where a professional, the pharmacist, practises his profession. He is there not to retail medication but to dispense medicaments whether over the counter or by prescription. He is the public's guardian to the correct use of medication.

There are about 140 pharmacies on the island. Unfortunately of these not even 100 are professionally run. The legislation to regulate pharmacies exists. The legislation defining the running of pharmacies by pharmacists exists, however the will to enforce this legislation has been absent for years. Mismanagement which puts the patient at risk, is allowed to go on uncontrolled. It is of the utmost importance that Pharmacy Inspections are instituted immediately. The **inspectorate** should consist of mature people, with a special appointment and suitable remuneration to carry out such work.

The professional management of pharmacies can only be carried out by pharmacists for the safety and benefit of the general public. No one should be allowed to usurp the pharmacists' role.

2. SATURDAY AFTERNOON BY ROSTER

Pharmacy opening hours extend to over forty hours a week. In addition to this pharmacies are required to open by roster on Sunday morning every few weeks. As can be seen the working hours of a managing pharmacist, are creating hardship for our members.

If a pharmacy is to be professionally managed all the time, if the patient is to get a professional service all the time, then the pharmacist must be continuously present at the pharmacy. We are of the firm opinion that the opening of pharmacies by roster on Saturday afternoon will make it easier for this to be achieved. The same roster which applies to Sunday morning being applicable to Saturday afternoon.

The Chamber has studied the current roster and after taking into consideration the pharmacies which opened over the last few years, has drawn up a new roster which we are positive is much more convenient to the general public.

A copy of the proposed roster is presented in the appendix.

We look forward to the implementation of this proposal forthwith.

3. DISPENSING IN CONTAINERS

In Malta there exists the practice of dispensing medicines in paper bags, both in hospital and retail pharmacy. This practice is lamentable and must be discouraged outright. These paper bags are in no way suitable containers for medicines. They offer no protection from light, or moisture the latter affecting the shelf life of almost, if not all, medicines. Medicines should be dispensed in waterproof, airtight containers.

Three of the most sensitive preparations are glyceryl trinitrate tablets, choline theophyllinate tablets and potassium chloride tablets. All of these three preparations are frequently obtained from the hospital. While choline theophyllinate and potassium chloride tablets are **sometimes** issued in proper containers, glyceryl trinitrate tablets are invariably issued in paper bags. It is widely known that the potency of these tablets is lost within a few days if so dispensed. There are no visible changes, so that the patient only discovers the loss in potency when it is too late.

After repeated initiatives by this Chamber, there has been a recent move in retail pharmacy towards the use of proper containers. We would like to see this move being encouraged at the official level not only in retail pharmacy but also in the government dispensary.

4. DISPENSING FEE

As mentioned already the pharmacist has a great responsibility. He is, in a number of cases, the one to identify potentially serious complaints, suggest to patients to seek medical investigation and when dispensing prescribed medication to the patient ensures that he knows how to take it. This makes him, very often, the first and last member of the health care team to come in contact with the patient. Yet all his professional responsibility and service, is not recognised financially by the official approval of a dispensing fee.

The introduction of a dispensing fee in Malta is long overdue. For all his responsibility and care of the patient he is remunerated even less than if he had to sell a cosmetic preparation.

5. TARIFFS FOR DISPENSING OF EXTEMPORANEOUS PREPARATIONS

On January 19th at an extraordinary general meeting the Chamber of Pharmacists - Trade Union approved a list of tariffs with the aim of

standardising the fee charged for extemporaneous preparations. The implementation has been postponed pending discussions with the Department of Health which discussions have already commenced.

The extraordinary general meeting also approved a fee to be charged when psychotropic and narcotic drugs on the control card system are dispensed. The implementation of this fee has also been postponed pending discussions with the Department of Health. The aim of this fee is to compensate the pharmacist for his responsibility and for the large amount of paper work involved every time such a preparation is dispensed.

6a. LEGISLATION — REGULATION OF PHARMACY LICENCES

Much needed legislation re the opening of pharmacies came out in 1984. However volumes of legislation are worth nothing unless they are enforced. Together with enforcement, it is necessary not to treat legislation as an elastic object, to be amended and stretched to meet anyone's special needs. This happened recently when the regulation re the population ratio per pharmacy was amended to the effect that in tourist areas half the hotel beds in the area are added to the number of residents.

As if to add insult to injury, another amendment to the regulations was recently approved by the Minister of Health. This amendment removes regulation 5(5) of L.N. 31 of 1984 which said "No licence shall be granted or transferred unless licensee or transferee of the dispensary is a person who is qualified to practice as apothecary under the provisions of the Ordinance, or in the case the transferee is the husband or wife or a descendent in the direct line of a deceased licensee."

The Chamber considers this regulation as being fundamental to these licensing regulations. We regret that regulations which were issued after much consultations by the Department of Health and upon recommendations by the Chamber, were so capriciously removed without any consultation at all.

We must insist that the deleted regulation be reinserted forthwith. Furthermore, the following points should be considered for inclusion in pharmacies licensing regulations.

i. the ownership of pharmacies by pharmacists;
ii. the definition and regulation of pharmacies owned by companies. It is to be remembered that these are not mentioned at all in the existing legislation;
iii. in such company owned pharmacies, pharmacists should own at least 51% of shares;
iv. in current legislation, two licenees are required for the opening of a pharmacy — a police licence and a licence by the health department. These licences should be issued to the same person, a pharmacist.

The Chamber cannot fail to emphasize that had the prexisting law been enforced there would have been little need for much further legislation.

6b. LEGISLATION — CONTROL CARDS

In view of the current problems on drug addiction, the introduction of the control card system is understandable. It is a time consuming method, which is proving to be costly in the time involved in its implementation by the pharmacist.

The system requires monitoring by the Health Authorities and there are a number of points which must be looked into:

i. Cases have been met of two control cards being issued to the same person.
ii. Mistakes in the ID card number or address of the patient have been found.
iii. The Control cards have no serial number. They do have the I.D. card number which can be used instead of a serial number. However this is not so to date, otherwise it would certainly not be possible for one person to have two control cards.
iv. The cards bear no water mark.
v. The three days 'urgent' period is too short. A more reasonable extension is a seven day period.
vi. In some cases doctors are applying for the control cards. When these reach the patient, the patient is turning up at the pharmacy without it being signed by the prescribing doctor.
vii. It is strongly suggested that doctors prescribing narcotic and psychotropic drugs do not prescribe for more than one month.
viii. It is strongly suggested that when the Control Card is full or expires, it is to be returned to the Medical and Health Department before a new one is issued. At least at this stage, the authenticity of all signatures should be checked.
ix. Since it was felt necessary to introduce the

Control Card system, it is imperative, that when the authorities learn that a patient is misusing drugs, managing pharmacists are to be informed accordingly. It is hoped that the relevant authorities have the necessary organisation to spot such cases.

x. Had the Green Prescription forms been suitably computerised, then the control card system would never have been necessary.

xi. A register of all doctors' and pharmacists' signatures should be sent to all managing pharmacists in the immediate future.

7. DRUG IMPORTATION

The Chamber would like to emphasise that drugs are not ordinary items of commerce. The health of the patient is the primary aim. Professionals in the medical field particularly pharmacists know that a number of medicines can be obtained from different sources. Great care must be taken in choosing the right source. This is of particular importance with Government's purchasing of drugs by tender. Cheap substitutes instead of original products are generally purchased.

The Chamber would like to draw attention to the danger the patient is exposed to when price is the sole criterion employed. The Chamber carried out a study and collected information re various preparations used in the government hospital services. These are some of the results:

Cimetidine (Italian Generics)

Tests on batches of Cimetidine showed:

i. The cimetidine content was within SK & F limits.

ii. However all the batches tested failed to comply with **disintegration** specifications for Tagamet tablets. Tagamet tablets have a disintegration time of 15 minutes. The Italian generic had considerable batch to batch variation, one of the batches disintegrating after two and a half hours.

iii. **Dissolution** specifications for Tagamet are 85% of the cimetidine content is dissolved after 15 minutes. In the case of the substitute cimetidine there was considerable batch to batch variation, the batch having a disintegration time of two and a half hours yielding only 60% of the drug content in solution after one hour.

For some time after the above reports were presented to the Health Authorities, Tagamet was purchased by the Department of Health. Later a tender to another Italian firm was granted which never reached the island because the particular firm had no free sale certificate from the Italian Ministry of Health for cimetidine.

Recently there was dissatisfaction with salbutamol syrup being issued from the hospital with the result that a recent call for tenders, requested only the original brand of Salbutamol (i.e. ventolin) syrup. This is a step in the right direction.

More examples are given in the appendix.

What is necessary is to improve the present system of quality control. To date, the requirements are the presentation of a certificate of free sale in the country of origin. False free sale certificates have been known to have been presented. Though a policy of blacklisting of such firms is said to exist, it is also known that, orders from firms, after such blacklisting, have been placed.

A further problem with the use of ineffective generics is that, a failure of therapy makes it essential for a switch in medication to another product, often a newer and more expensive product.

What are the Chamber's proposals on this subject?

1. There should be no monopoly on drug importation either by government or by anyone single entity in the private sector.
2. Improved quality control — one way of implementing this is by carrying out random checks on the **received** consignment at an independent laboratory. If too expensive to be carried out here, then the foreign company should be made to pay for these tests. Surely serious companies are prepared to pay for such tests when for them the financial benefits are tenders worth thousands of Maltese pounds.
3. Even importation of the original product is sometimes not a sufficient guarantee. Some products need to be specifically manufactured for our climate. An example is the use of Flurazepan Monohydrate for countries in tropical zones. At one time, Dalmane purchased from a Britsh wholesaler was bought by the hospital. Such batches meant for the British climate are of insufficient stability for Malta.
4. There should be no delay in the granting of licences, so long as the requirements for quality control, and therapeutic activity are met.

8. DRUG ADDICTION PHARMACISTS AGAINST DRUG ABUSE (PADA)

A year ago a sub-committee **Pharmacists Against Drug Abuse (PADA)** was set up, with the aim of organising pharmacists in the fight against drug abuse through the organisation of various activities such as seminars and fora on the subject. Last year a very well attended course on Drug Addiction was held, as well as a forum entitled "Is legislation helping up to fight drug abuse?"

This group of pharmacists work in close collaboration with CARITAS. It is the intention that PADA will not remain only involved with pharmacists but will extend its activities to the whole society by equipping pharmacists with essential continuing education on this important subject.

The Chamber of Pharmacists encourages Government to keep pressing on with its fight against drug abuse:

i. by increasing police efficiency in catching pushers. Heavy penalties in themselves are no safeguard against drug abuse. The best deterrent is a surety of police efficiency in catching the culprits. (Magistrate Scicluna - Forum - Is Legislation helping us to fight Drug Abuse).
ii. through continuous education of both parents and children about the problem.

Moreover the Chamber encourages Government to recognise the contribution pharmacists can make in this field, by including pharmacists in boards which are in any way involved with drugs and medication because the pharmacist is society's expert on drug therapy.

The Chamber reiterates that the pharmacist has a unique role to play in the fight against drug abuse. He is in a key position to educate the general public and reinforce the correct use of medicines. It is a serious irresponsibility of any administration which allows unqualified people to play his role, people who, due to their lack of suitable qualification, cannot in any way give the proper guidance and advice which the pharmacist can give.

9. PHARMACY BOARD

The Pharmacy Board is the regulatory board of the pharmacy profession. "Is" is perhaps the wrong verb. It is perhaps better to state should be the regulatory board of the pharmacy profession, because repeated amendments have reduced this board of incompetence.

The Pharmacy Board was set up with the aim of regulating the practice of the pharmacy profession and ensuring the observance of the ethics which were issued by the same board shortly after it was set up.

The previous composition of the board was: Chairman, C.G.M.O., S.M.O., two pharmacists representing Government, three elected pharmacists, one pharmacist representing University, and two elected pharmacy technicians. Recent admendment to the composition of the board have resulted in a board of sixteen, while the quorum is still of six people. There are now so many non pharmacists on the board that even without a single pharmacist present, there can be a quorum.

We strongly urge that this board should be brought to its former proper balanced functioning composition immediately.

10. COUNCIL OF HEALTH — PHARMACIST REPRESENTATION

The Council of Health is the body which advises the Minister of Health on prospective legislation and regulations which fall under the Medical and Kindred Professions Ordinance.

The pharmacist is a member of the health care team, and the practice of his profession falls under the jurisdiction of this ordinance. Like doctors, and dental surgeons, he should be represented on this Council.

It is ridiculous that proposed legislation re pharmacy is put to this Council for comments and suggestions, when no member of this Council is competent in pharmacy.

11. HOSPITAL PHARMACY

The field of hospital pharmacy suffers regularly from a shortage of pharmacists. The primary reason for this repeated drain is the lack of incentives given to pharmacists in government employment.

To build a strong hospital pharmacy service one needs:

1. An adequate number of suitably qualified and adequately remunerated pharmacists.
2. A number of pharmacists should be encouraged to specialise in hospital pharmacy, if necessary by taking courses abroad.
3. It is time to recognise the hospital pharmacist as being of a professional grade both in terms of professional responsibility and financial remuneration.

12. STUDENT WORKER SCHEME

The student worker scheme in Pharmacy was introduced in 1978. Several problems came up on introduction of the new system.

Outlined breafly these are:

i. A reduction in the number of contact hours.

ii. A number of students found themselves doing work which is unrelated to their studies.

iii. The five-and-a-half month work phase is too long a period to be out of touch with study.

iv. There is a waste of the very limited University resources, because of the repetition of the academic lectures, tutorials, etc.

v. There is lack of adequate supervision during work.

The Chamber makes the following recommendations:

i. There should be an eight month study phase and a four month work phase which will increase the number of contact hours and provide adequate study time.

ii. The introduction of a pre-registration period to make up for the decreased work period.

iii. An agreement between sponsors so that students can gain experience in the various field of pharmacy, and not only in the field of their sponsor.

iv. The study and work phases should be concurrent, this will permit better utilisation of the academic staff available.

A more detailed analysis of the student worker scheme in pharmacy is presented in the Chamber's Report of June 1986.

13. HEADSHIP OF THE PHARMACY DEPARTMENT

The University is the breeding ground for new pharmacists. Only pharmacists can impart the right approach to the pharmacy profession.

The pharmacy department has been without a head for years now. Furthermore the current acting head is qualified in the medical field and has little knowledge of what pharmacy is.

The Chamber must insist that:

i. a head be appointed.

ii. the head of department should be a pharmacist with suitable qualifications in the academic field.

14. DISTRIBUTION OF FREE MEDICINES

The current system of distribution was introduced to reduce the load of people going to St. Luke's Hospital. It involves the sending of a prescription of the required medication together with the relevant pink/or yellow cards to the hospital, and later collecting the month's supply of medication from the local clinic.

When the system was introduced, there was an increase in the demand for free medicines from the hospital. The eligibility of patients for free medicines is dependent on income and on the kind o disease. Both criteria are changed from time to time.

The costs involved are:

a. The cost of the medication itself.

b. The cost of packaging each individual patient's medication (labour costs).

c. The cost of transportation and distribution at the local clinics (labour costs).

d. Professional costs are minimal because very few pharmacists are involved in the system.
— There is no patient counselling at any stage re the medication prescribed.
— There is inadequate monitoring of the requirements or otherwise of repeats. A case in point is that of a patient known to have received a supply of ampicillin for six months. Several patients do not take the medication. They either hoard the tablets or try to exchange them at retail pharmacies. A report reached the Chamber of a patient going up to his local pharmacist to exchange six boxes of Voltaren tablets.

Reduction of Costs

The distribution of free medicines to those who cannot afford them or have certain diseases is an important service. It is a service which takes up a significant portion of the health care bill and it is understandable that an attempt be made at reducing costs. This generally is done by

i. adjusting the criteria for eligibility for free medicines;

ii. using cheap generics.

Chamber's recommendations:

a. **Fee per prescription**
The general public's attitude is: if something is provided for free then take it even if only to throw it away; if the individual has to pay for it then he will buy it if he needs it and will take great care not to waste.

In view of this it should perhaps be reconsidered whether it is better to **charge a fee per prescription** in order to discourage waste as much as possible.

b. **Exclusion of certain items in favour of a better service in other areas**
With regard to certain items like acriflavine solution, plaster, glyceryl trinitrate tablets, does the end product reaching the patient cost more than the equivalent bought at a retail pharmacy? Furthermore, in the case of glyceryl trinitrate tablets, is the cost justifiable when the way these tablets reach the patient is a guarantee that these will lose their potency within a few days? It is perhaps wiser that items which cost only a few cents are excluded from the list in favour of more essential and more expensive items.

c. **Use of effective medication**
The use of cheap generics is not professionally acceptable unless measures are taken to ascertain that the generics are of the required therapeutic level. Furthermore, the use of cheap, ineffective generics results in either administration of a higher amount e.g. administration of two diuretic tablets instead of one; or a switch to a newer and a more recent medication e.g. the switch to atenolol because of the ineffectiveness of generic propranolol. This reduces or annuls any economic gains made when using cheap generics. Not to mention also, the danger to the patient, a matter discussed under drug importation.

d. **Distribution from Pharmacies**
In recent years a suggestion was put forward by the Chamber of Pharmacists that retail pharmacies should be used as a distribution points for these medicines. This will give the patient the professional pharmaceutical service required because the pharmacist present can answer any queries re therapy. This could be done against a dispensing fee.

Another method is for patients to obtain medication directly from pharmacies, the cost being then met by government. This saves on the time spent in hospital preparing the packages, and at the same time reduces the risk of mistakes being made. The patient can either pay the full cost and then receive a refund from government or pay part of the charge, the rest being paid by government to the pharmacies concerned.

15. MEDICAL REPRESENTATIVES

As already stated in the introduction, pharmacist medical representatives are in a unique position to provide the members of the medical profession with accurate and truthful information on new medication and dosage forms available.

Unfortunately unqualified people are regularly permitted to work as medical representatives. Some of these have in their possession restricted drugs, which goes against the provisions of the medical and kindred ordinance. These people with their lack of knowledge in pharmacy give the false impression that Medical representatives are mede salesmen.

The Chamber of Pharmacists also believes that doctors should not be allowed to work as medical representatives. The reasons substantiating this Chambers's objection are so glaring that we feel it is quite superfluous to list them here.

16. PHARMACY TECHNICIANS

The pharmacy technician, was previously called the assistant apothecary. The new nomenclature is a direct reflection of requirements of modern pharmacy. The shift to pharmacy practice requiring an in depth knowledge of the pharmacology of the modern and very often potent drugs has made the pharmacy technician redundant in community pharmacies.

The need for pharmacy technicians exists only in hospital, and this is where their line of work should be restricted to.

CONCLUSION

The Chamber of Pharmacists - Trade Union is committed towards the proper recognition of the status and role of the pharmacist in society to which the pharmacists' services are indispensible.

The Chamber works continuously at fulfilling this commitment by

- constantly tackling the problems facing pharmacy in Malta
- the organisation of continuing education programmes for pharmacists
- the publication of The Pharmacist
- the setting up of PADA (Pharmacists Against Drug Abuse) working in close collaboration with CARITAS (Malta).

It is of course impossible for significant progress to be achieved without the necessary contribution from legislators, and all administrators responsible for the enforcement of legislation. Attention must here be drawn to the fact that the lack or insufficient enforcement of legislation is a recurrent theme in this memorandum.

This Chamber urges all politicians, and all others who are in some way involved directly or indirectly with pharmacy to study this memorandum carefully and looks forward to immediate discussions on it with all those concerned particularly with the political parties.