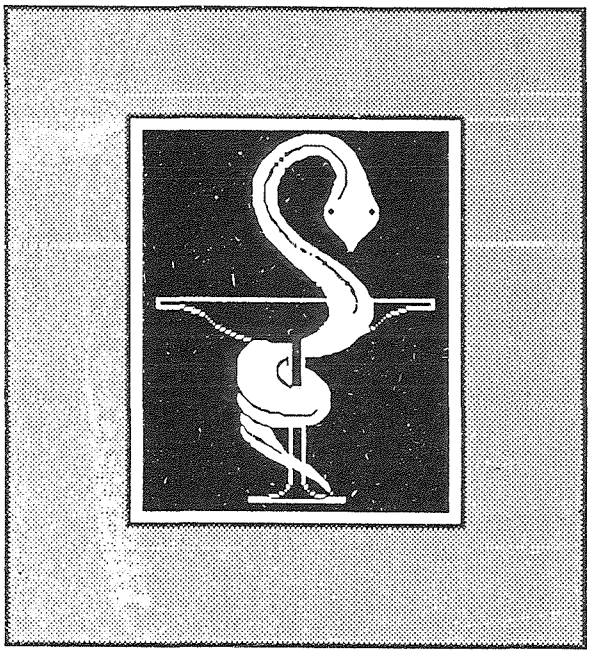

CHAMBER OF PHARMACISTS

MALTA

DISTRIBUTION OF NATIONAL HEALTH SERVICE MEDICINES

APRIL 1989

The aim of this report is to propose the necessary changes to the current system of distribution of Free Medicines. A brief summary of the current system is first given followed by a discussion of the possible alternatives. The guidelines in mind are the policy of the Chamber of Pharmacists and the stated government policy of 'reducing waste' and the distribution of essential medicines free of charge.

Finally the Chamber's recommendations as to the best method of implementation will be provided.

This report has been presented to the authorities concerned and the Chamber is holding discussions with the Free Drugs Scheme Working Committee which has been set up recently to study and give proposals for the setting up of the scheme.

It was compiled by Mrs. M. Brincat B.Pharm.

NOTE: The term 'pink card holders' used in the text includes the blue card holders (diabetics) and green card holders.

Contents

1 — The Current System

1.1 *Group I Patients*: (Yellow Card Holders)

Patients who suffer from a condition which falls under the third schedule of the NI Act. This schedule refers to a series of diseases and conditions in respect of which free medicines are provided irrespective of financial position (e.g. congestive heart failure, hypertension, schizophrenia). Mostly validity is for one year.

No data is available which reflects the actual number of patients using this service.[1]

Table 1 shows the number of applications approved each month in 1984.

1.2 *Group II Patients*:

These patients benefit under the Medical Aids grant of the NI Act. Entitlement is based on a means test. The assessment is based on total household income, however each member must have his/her control card.

Since 1978 renewal every four weeks has been necessary except for people over 60 years — renewal every six months being required.

Data on the actual number of patients benefitting from this grant is not available. The only figures available indicate the number of eligible applicants which totalled 15,087 in 1984.[2]

Table 1

Number of Schedule III Applications Approved Malta: 1984

Month	*Number of Schedule III Applications Approved*
January	1,053
February	1,234
March	1,112
April	885
May	1,093
June	1,097
July	1,021
August	1,124
September	1,074
October	1,115
November	1,370
December	885
TOTAL	13,063

1.3 *The Formulary*[3]

The formulary consists of a list of those drug preparations available for use within the Government Pharmaceutical Service.

There are:

A. General Practitioner list.

B. Open Drugs list — may be prescribed by any medical practitioner working in hospital services. It includes a broader group of pharmaceutical preparations than the G.P. list.

C. Consultant Drugs list — only prescribed by consultants.

D. Designated Drugs list — may only be prescribed by consultants in the field related to the use of the drug.

Non-formulary drugs may only be prescribed after approval by the Drug and Therapeutics Committee.

1.4 *Methods of Distribution*

a. *Direct System*

This is the term referring to those patients

who collect their medicines from the hospital. Too many people make use of the service. In January 1984, 94% af patients using this system were[4] follow ups while only 6% were new cases.

b. *Postal System*

This refers to the collection of packages prepared at St. Luke's Hospital and collected by the patient or his representative from the 'berga'. Of the patients making use of this system 69%[5] were geriatric patients and most of them had their medication collected for them. About a fourth also utilised the direct system because of urgency on the signatures required.

2 — Deficiences of the Current System

The current system has a number of shortcomings which can be grouped under
— waste
— lack of good quality drugs
— complete lack of professional service

2.1 *Waste*

It is a common occurence for people to hoard medicines. Cases are known of people who go to pharmacies to exchange hospital drugs. Also, several instances are known of people who have been repeatedly supplied with a drug therapy, months after the treatment should have finished.

Money is spent on repacking items, some of which would be much cheaper if distributed in an original small pack, as well as of better therapeutic effectiveness when it reaches the patient (cf. Chamber Memorandum dated 1987).

2.2 *Quality of Drugs*

The Chamber has already made detailed comments about this topic in its memorandum. The examples quoted are so serious that a revision of purchasing policy for Government drugs is an immediate necessity. Clearly the requirement of a 'free sale' certificate is in no way a guarantee of quality as amply documented. In addition special consideration must be given to those drugs which present therapeutic equivalency problems

The participation in the W.H.O. certification scheme is a much better safeguard, and in our opinion this is a step forward.

The articles in Appendix II throw more light on the problems in drug purchasing

2.3 *Lack of Professional Service*

There is a complete lack of professional service. Society's Drug Expert, the pharmacist, is not available for patient counselling which is necessary
— to improve patients' compliance
— to advice on drug interactions and avoid drug related diseases
— and to monitor therapy.

Patient Compliance: Non-compliance can be defined as a situation where failure to comply is sufficient to interfere appreciably with attaining the goals of therapy.[6]

Patient compliance is an indirect assessment of the counselling activities offered by the system. The poorness of the current postal system is illustrated by the result (Table 2)[7] from a survey carried out on 300 patients who make use of this system.

Table 2

Survey carried out on patients who make use of postal system.

Sample No. 300

Complaint 59%	Non Complaint 41%

The handwritten labels and overall poor packages also contribute towards non-compliance.

The lack of professional service is also reflected in the kind of packaging used for the drugs. Several preparations deteriorate very rapidly unless properly stored especially in our climate.

The poorness of the service is also reflected in the time spent at the St. Luke's Hospital Pharmacy by patients who have to collect their drugs from the hospital.

Furthermore, currently, most of the postal packages are being prepared by completely unqualified staff resulting in frequent errors

3 — Alternative Distribution

Use of Community Pharmacies

In view of the above shortcomings it is imperative to make changes to the system. The first change that is in the process of being implemented is the dispensing of medicines to outpatients from a specially set up outpatients pharmacy at St. Luke's Hospital.

The postal system should be eliminated. The best alternative method of distribution which will ensure a professional service for the patient is the use of community (retail) pharmacies as

distribution points, the packaging of medicines at the hospital being done away with completely.

3.1 *Methods*

There are various ways of implementing this proposal. These will be discussed under two headings:

1. The 'Cupboard' system
2. Proprietary system or Free Choice system.

3.1a. *The Cupboard System* (D.H. Preparations)

This has been so called because it means the creation of a separate section of medicines in community pharmacies — the D.H. medicines.

These can be directly supplied by the hospital to the pharmacies, or ordered from the importer.

Hospital Supply — involves the organisation by government of a

(i) distribution system

(ii) accounting system

Normal Supply (or Tender System) — The usual distribution routes are used. Government will issue tenders for a particular drug, e.g. ampicillin and all ampicillin to be dispensed on the Government's Health Scheme will be of this particular brand. This has the advantage of having a standard tender price for the particular drug which will be the charge then reimbursed to the pharmacist.

3.1b. *The Free Choice System*

This term is being used to refer to a system where there is complete freedom of choice of trademarks. This means there will be no D.H. drugs at the pharmacies.

This system eliminates the problem of quality which to date seems to be part of generic drugs purchased by the hospital. In addition normal sources of medicines are retained. Also normal market prices will be retained for medicines dispensed.

4 — Finances

4.1 *Payment*

Payment must include the accepted markup on the cost price of the drugs together with a professional fee on every item dispensed. The latter will cover the paper work involved in dispensing together with the professional advice and patient monitoring by the pharmacist.

There are various ways in which this can be done:

1. directly by Government
2. through a finance bank
3. by the patient who is then refunded.

4.1a. *Directly by Government*

The pharmacist sends the bills to the government who will eventually pay them.

Any bureaucratic delay in payment will put a significant strain on pharmacy finances. For this reason, we are not in favour of this idea.

4.1b. *Finance Bank*

The government sets up a special fund for payment of pharmaceutical services. The pharmacist then sends all bills to the bank for settlement.

This would seem to be faster than having the civil service handling payment.

4.1c. *Payment by Patient*

The patient foots the bill. Expenses will then be refunded by tax deduction or in the form of an allowance to the individual.

This method has the advantage of not needing a new set up. The original payment by the patient is only a temporary expense which it is hoped will have the effect of discouraging waste.

4.2 *Costings*

It is impossible to draw up an estimate of the actual total cost of the system. In 1984 total drug imports amounted to more than Lm4.2 million[8]. It has been estimated that Government consumed about one third of these imports[11] i.e. more than Lm1.4 million. However if the list of Government health service medicines is based on a list of essential drugs and a system of payment and free distribution is introduced as we suggested here, then the cost can be contained. Furthermore it should be possible to ensure that only good quality medicines are used.

The poor remuneration of the pharmacists involved must be kept in mind since the success of the scheme depends largely on them. Also the pharmacist's tremendous importance in the success of therapy must not be forgotten.

5 — Recommendations and Implementation

1. The number of people making use of the current free medicine service is such that it

can readily be handled by the community pharmacies.

2. There should be freedom of choice of pharmacy by the patients and also pharmacies should be free to decide whether to participate or not.
3. A compromise of the two systems discussed under alternative distribution should be adopted. This is the definition of a list of essential medicines which will be available on the Government Health Scheme, the usual supply channels for pharmacies being used.
4. This list of essential medicines will be the core of the National Formulary and will replace the current G.P. list, and in whole or in part the open list of drugs. The categories of Consultant Drugs and Designated Drugs currently in the formulary should be retained. Also the possibility of prescribing non-formulary drugs after approval by the Drugs and Therapeutic Committee should be retained.
5. The W.H.O. definition of essential medicines is *those drugs which are of the utmost importance and are basic, indispensable and necessary for the health needs of the population.*[10] The current WHO list cannot be transplanted to Malta because, as the WHO itself states, the differences between the countries make it impossible to draw up a list of uniform, general applicability and acceptability. The best current set up to take care of drawing up the essential medicine list is the Drugs and Therapeutics Committee in consultation with the Chamber.
6. The current category of pink form holders should be revised We are of the opinion that to reduce waste it is best to retain eligibility for completely free medication only for special categories of people.
7. The list of diseases for which medicines are currently distributed free irrespective of income level should be retained. Some of the medicines for these diseases will not be included in the essential drug list. However, financial help should still be provided, though we once again recommend that only special categories of people should be entitled to total free medication.
8. It must be ensured that only effective medication reaches the patient. It is of little use to provide free medication and then deliver therapeutically ineffective or partly effective medication.
9. The choice of make (trademarks) should be left up to the Health practitioners.
10. Diversion of pink form holders to community pharmacies should be the first step. Those follow up patients making use of the direct system should be diverted to pharmacies after the intention of having specialists at polyclinics to follow them up has been implemented.[11]
11. Reimbursement for medicines dispensed. As already stated, it is important that financial strain is not thrust on pharmacies. The patient should pay for the medicines he collects and then he is reimbursed for his expense in whole or in part by the government, either by tax deduction or direct payment.
12. Quality control facilities must be improved. They must be at least as good as those of the local industry the products of which are checked by the government as part of the WHO certification scheme.

6 — Appendix I

6.1 *Foreign Experience*

Some International Experiences with National Health Service Drugs.

A common factor in all National Health Insurance providing drugs is the ever increasing expense of the system. It is noticeable that in most systems there is some kind of payment by the patient. Often a list of drugs which are not included in the scheme also exists. The examples provided here are:

a. The Swedish System
b. The Italian System
c. The British System

6.1a *The Swedish System*[12]

The national insurance system provides injury, disablement and sickness benefits, invalidity and retirement pensions etc. It also provides an allowance covering a part of the doctor's and dentist's bills as well as medicine. The patient obtaining a medicine on prescription pay up to SEK 20 and half of the exceeding amount to SEK 50. Free medicines are provided for some chronic and severe diseases. Finally, high medical care and medicine costs are covered through a high cost protection provision. Oral contraceptives are also covered by the scheme, but not prophylactic use of drugs. Recently, antitussives and expectorants have been exempted from the drug benefit scheme. This restriction might be seen as a first step on the

way to a negative list, where analgesics are thought to be the next group to be removed from reimbursement. Today patients pay 18% of the costs of a prescription drug on average. Medical care drugs which are not included are tax-financed to more than 90%. The costs have expanded at a faster rate than the GNP and account today for 10% (against 3% in 1960). The total drug costs amount to 8% of the medical care costs.

6.1b *The Italian System*[13]

The 'ticket' is the small detachable part of the outer packaging of patent medicines which carries the 'tariff' to be paid by the patient to the pharmacist — the balance of the cost of the medicine is then reimbursed by the Government to the pharmacist.

This 'ticket' which in 1984 stood at 150 Italian lire has been increased to 250 Italian lire for every 1000 lire of the cost of the medicine dispensed. Also, each prescription cannot refer to medicines the total cost of which exceeds 39 thousand lire. Moreover, the dispensing or professional fee per prescription has increased from 1300 to 2000 lire as at 1986). The exemptions from payment are as follows:

Persons per household	Income (not more than)
1	5 million lire
2	8 million and thousand lire
3	10 million and 800 thousand lire
4	12 million and 900 thousand lire

It may be interesting to note that each taxable Italian citizen pays at source or on income an average of 648 thousand lire (1984 figures) to finance the national health system of the country. The overall national health care expense (including medical assistance, hospitals, pharmaceuticals, prevention, public health) amounted to 37 billion lire.

Shortcomings of the Italian System

The difficulty with the above system lies in that although the balance should be reimbursed to the pharmacist within thirty days in reality there is a great delay in the effective payments this being of great financial burden on the pharmacists. Indeed, not too long ago and on several other occasions the Associatin of Italian Pharmacists has had to resort to a call for strikes in order to bring pressure to bear on the authorities for payment to be effected.

Ic. *The British System*[12]

There has been a change in the community pharmacist's function so far as dispensing is concerned. The way in which medicines are now compounded has reduced the calls on the pharmacist's manipulative skills, while the change in the nature of drugs has increased the potential demand on the pharmacist's knowledge.

The future

We claim no greater prescient powers (than others) but, confining ourselves to the next twenty years or so, we would venture the following predictions:

a. The discovery and development of new drugs will continue, some of which will be more complex and, unless used with the appropriate advice, potentially more toxic than their predecessors. New delivery systems will continue to be introduced, as well as further developments of existing systems. There will be an increasing need to match the individual medicament to the individual patient.
b. The cost of treatment will continue to rise. Successive governments will continue to look for ways of reducing expenditure, including the transfer of treatment, wherever possible, from hospitals into the community. As a result general practitioners and community pharmacists will handle potentially more complex medicinal treatment.
c. The proportion of the elderly in the population will increase. The elderly require both greater and more specialised attention.
d. The use of information processing facilities, such as computers, and of improved electronic means of communication within the health services will greatly increase.
e. Exploitation of the potential of the new treatments will lead to increasing cooperation between the professions engaged in health care.

The giving of advice and treatment to members of the public in respect of minor ailments was, prior to the introduction of the NHS, a major part of the pharmacist's role.

We believe that the service provided by the pharmacist is one that could be more extensively used and we therefore welcome the steps taken by the National Pharmaceutical Association

to draw people's attention to it. We consider it important that the pharmacist should be properly educated and trained to perform this role which includes the ability to assess when an inquirer should be recommended to seek medical advice. It will be for the public to decide the extent to which they wish to make use of the pharmacist's services.

Responding to special needs

The final stage of dispensing is the handling of the medicine to the patient. It is important that advice should be available to those who would benefit from it.

One such group is the elderly who are due to form an increasing proportion of the population. They consume far more drugs than the population at large. It has been observed that there was a much higher prescription rate among the elderly (particularly women) but that this was not matched by a higher consultation rate or increased purchases of medicines over the counter. Age concern have reminded us of the substantial proportion of the elderly who live alone.

There is thus a strong case, in the interest both of ensuring that medicines are properly used to the benefit of the patient and of reducing NHS costs, for the pharmacist to be able to provide such counselling services to the aged. A study carried out for the Royal Commission on the National Health Service showed that, in two parts of the country, 69 per cent and 80 per cent respectively, of the elderly used one particular pharmacy. We think there is scope, therefore, for encouraging older people to register with a single pharmacy in which medication records would be kept and from which they could expect to receive special advice and assistance in handling their medicines. In individual cases, and within the rules of professional conduct, it would be desirable for the pharmacist to cooperate with members of other professions involved in the provision of primary care.

As a generalisation it can be said that anyone who is chronically sick or mentally handicapped, and who has to rely on a continuous drug regime, should be a candidate for additional support and help from the pharmacist. In most cases it will be the individuals themselves to whom such help should be given, but in some cases it will be the people looking after them. This is particularly true of the mentally ill. Drugs now play a much bigger role in psychiatric treatment but they require careful handling by patients, some of whom may find this difficult without help. The transfer of patients into social care within the community means that they could be deprived of the support that was available to them in a hospital. Many of these patients require continuous medication.

Commercial context

The pharmacy profession is not alone in engaging in commercial activities. Members of all professions do so. Any professional in private practice is also a businessman. What distinguishes community pharmacy from other professions is the divorce that exists between the professional service given by its members and the way they are remunerated. Advice brings no return: the sale of a medicine does. A serious criticism of the way in which the community pharmacist is at present remunerated is that it acts counter to, rather than in support of, the exercise of a professional role. This criticism, we would stress, is a reflection on the system and not on the individual pharmacist. It is the system that needs to be changed.

Remuneration

The ways in which the NHS services provided by a community pharmacy are paid for act counter to, rather than in support of, the exercise by pharmacists of their professional role.

Professional activities which should be specifically remunerated might include:

a. Work done in collaboration with doctors, either in individual practices or at health centres, to improve the effectiveness and reduce the cost of prescribing. This would also cover work done as a member of a drug and therapeutics committee.
b. Advice to patients on response to symptoms, which may or may not then lead to the sale of a medicine. It would be preferable to make a standard payment in respect of this work. (It would hardly be sensible to charge the individual for a consultation with a pharmacist when he could visit his doctor free.) There is a variety of ways in which it would be possible to define the work for which payment is to be made and to monitor that it has been done. These include specifying the facilities that have to be provided to qualify for various levels of payment, and the keeping of simple records. We consider it quite wrong that payment for this important work should be hid-

den in a general sum, the amount of which depends on the quite irrelevant consideration of the number of NHS prescriptions dispensed.

c. Services provided to individual patients on long-term or complicated medication. These might include the elderly, the mentally handicapped and the mentally ill. One possibility would be for payment to take the form of a capitation fee for patients opting to register at a single pharmacy.
d. Domiciliary activities and attendance at clinics.
e. The supply of an appropriate range of pharmaceutical services to NHS and other publicly owned residential establishments.
f. Health education.

Appendix II

6.2 *Quality of Drugs*

6.2a *Drug Adulteration and Dumping* [15]

During the Commonwealth Pharmaceutical Association Conference held in Nairobi in March 1987, Sam Agboifo, the representative from Nigeria touched on a very sore point which made all delegates stop and think.

It appears that in his country it is very common practice that drugs arrive at patients in an identically packed but adulterated form. He showed us two identical packs of Ambaxin and asked everyone to try and identify any differences between them. This was impossible to do since they were absolutely identical with the expiry date, batch no., designation etc. on both. In actual fact one was the genuine drug, the other had its capsules filled with talc! This seems to be rampant practice in Nigeria with, naturally, the fake drug selling at a cheaper price and the public complaining about the price of the actual drug. He did mention the suspicions of his Association as to which countries are responsible for such an unprofessional and criminal practice. These countries seem to be luckily quite far off from our Island. But can we be absolutely sure that no such adulterated drugs are touching our shores? We have had in Malta instances of pirate importation at cheaper prices.

Sam Agboifo explained that if his country was plagued with this problem of drug adulteration one had to try and imagine the magnitude of the drug dumping problem in his country. If completely 'faked' drugs were available freely, was it so difficult to have medicinals with faked dates? And what about generics? Was it so difficult to have generics which have been discarded by other countries for being sub-standard or expired?

What about the quality control measures taken in Malta?

The examples reported in the Chamber's memorandum make us doubtful as to the sufficiency of import controls.

6.2b *Equivalence of Generic Topical Glucocorticoids*

Trade name glucocorticoid formulations, triamcinolone acetonide, fluocinolone acetonide, and betamethasone valerate were compared with the irgeneric equivalents because of increasing substitutions of generic formulations for trade name formulations. The vasoconstrictor assay was the method used for these comparisons. Large differences were found between generic and trade name formulations containing the same steroid in the same concentration in both cream and ointment vehicles. If generic substitutions are to be used for trade name formulations, the physician must be aware that significant differences in therapeutic effectiveness may be expected[16].

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(1) Gatt M., B.Pharm. Thesis, 1985, page 55.
(2) ibid, page 58.
(3) Formulary Government Pharmaceutical Services — Introduction.
(4) Gatt M., B.Pharm. Thesis, 1985, page 83, page 85.
(5) ibid.
(6) Walker R and Wright S.E.: Patient compliance and the pharmacist — Pharmaceutical Journal Feb. 2, 1985.
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(9) Prof. B. Abel Smith: The Economics of Drug Consumption in Malta, Malta 1981.
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