

Pharmaceutical Care in Malta

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Abstract: The pharmaceutical sector in Malta is fully regulated in line with European Union legislation. There are about 230 community pharmacies in Malta and Gozo. Each town or village can have at least two pharmacies irrespective of its size. Medicines in Malta can only be sold from the licensed community pharmacies or from the hospital pharmacies. There are two categories of patients that are entitled to free medicines provided by the state. In 2009, Government started introducing the Pharmacy of Your Choice scheme (POYC) locality by locality.

1 Introduction

The pharmaceutical sector in Malta is fully regulated in line with European Union legislation. The Licensing Authority through the Medicines Authority inspects, monitors and regulates all medicinal products and pharmaceutical activities on the island. Medicines are available to the general public through a number of privately owned and run pharmacies. There are also pharmacies in Mater Dei Hospital and Gozo General Hospital which offer a twenty four hour service to the public during times when the community pharmacies are not open. There are about 230 community pharmacies in Malta and Gozo. Each town or village can have at least two pharmacies irrespective of its size. The number of additional pharmacies in the larger towns or villages is proportional to the size of the population of the town or village.

Malta has also a sizeable pharmaceutical industry. The production of pharmaceutical products is mainly of generic medicines and medicinal gases. Some manufacturers also have units where research and development of new pharmaceuticals also takes place. There are also two manufacturers of medicinal gases. Although some of the medicinal products produced are consumed locally, the vast proportion of manufactured pharmaceuticals is exported to other European and non-European countries. The local industry provides for only a small proportion of the pharmaceutical needs of the country and therefore the vast majority of medicines available on the local market are imported from overseas. There are thus many private Maltese pharmaceutical importers representing the international pharmaceutical companies. These importers act as purchasers and distributors of medicines both to the state and to private pharmacies or clinics. The State also has its own licensed importation facility. For imported medicines to be placed on the market they have to comply with all the licensing requirements.

2 Two Categories of Patients to Free Medicines

Medicines in Malta can only be sold from the licensed community pharmacies or from the hospital pharmacies. Some medicines can be sold directly to the patient by the pharmacist but the vast majority of medicines can only be dispensed (sold) upon presentation by the patient of a prescription issued by a doctor. All medicines issued to patients entitled to receive them free of charge require a doctor's prescription.

There are two categories of patients that are entitled to free medicines provided by the state. The first category includes those patients who have a low income. The income threshold is determined by law and changes from one year to the other depending on the rise of the cost of living in the country. This category of patients is entitled to receive all the medicines they need for free irrespective of whether it is for an acute condition (short term use) or a chronic condition (long term use). Thus these patients will be entitled to free antibiotics in the case of for example an acute

infection and will also be entitled to free medicines for the long term treatment of for example their arthritis.

The second category includes those patients who suffer from specific chronic conditions. All patients suffering from one of the listed chronic conditions will be entitled to free medicines irrespective of their level of income. The list of chronic conditions which makes patients entitled to free medicines is also determined by law and is also reviewed from time to time. The last review took place in 2012 when the list of chronic conditions was revised from 38 conditions to now include 79 chronic conditions. These patients will receive free of charge only the treatment that is medically used for the treatment of the particular chronic condition or conditions they suffer from but have to pay for all their other medicines. Thus these patients will receive free treatment for their for example high blood pressure (on the list) or asthma (on the list) or both but will not receive free treatment for their chest infection or arthritis (not on the list).

3 The list of medicines and the Pharmacy of Your Choice scheme (POYC)

The list of medicines available within the Government pharmaceutical system and therefore provided for free to patients both within and outside the hospital does not include all the medicines that are available on the local market from the private community pharmacies. The Government list (formulary) includes about 1300 medicines which are considered to provide a sufficient range to cover the effective management of all conditions that one encounters in and outside hospital. If patients who are entitled to free medicines want to make use of a medicine that is not on the Government list but is available on the local market, they will have to pay for it out of their own pocket

The formulary is being constantly reviewed such that medicines that are considered outdated are removed and more modern and effective medicines introduced. Evaluations of requests for the entry of a new medicine to the Government list are carried out by means of a Health Technology Assessment. The evaluation relies heavily on other centres in Europe, mostly the National Institute for Clinical Excellence (NICE) in the United Kingdom for the technical evaluation and applying local epidemiology and costs to carry out the budgetary impact analysis. The result of the assessment is presented to the Government Formulary List Advisory Committee (GFLAC). The GFLAC is responsible for coming up with a recommendation as to whether to add a new medicine to the Government Formulary List or not. The GFLAC submits recommendations to the Superintendent of Public Health who makes the final decision. With newer medicines generally being more expensive than their older counterparts and in the current financial and economic climate, the acceptance rate for introduction of new medicines on the government list seems set to go lower. New mechanisms to target new medicines for those patients who need them most are being tried out through for example the setting up of clinical review committees for approving very expensive new medicines.

Up to a few years ago patients entitled to free medicines had to go specific pharmacies in the health centres around the island to collect their free medicines. This caused substantial inconvenience for the patients as these pharmacies opened only between 08.00hrs and 13.00 hours. In view of the fact that there were a limited number of pharmacies and the restricted opening times, there used to be long waiting queues for patients to be served. Some patients used to collect their medicines from the village dispensaries which also had restricted opening times and required repeated attendances. In order to facilitate the collection of these medicines, in 2009 Government started introducing the Pharmacy of Your Choice scheme (POYC) locality by locality. By 2013 all localities in Malta were covered by the scheme. The POYC scheme aimed to increase accessibility to prescribed medicines and decrease the need for public pharmacies. Through the POYC, medicines bought by Government are supplied to patients through all the licensed private community pharmacies. The community pharmacies are remunerated by Government for the service they provide through an annual fee payable for each patient they provide a service to. Overall the aims have been reached as patients eligible for free medicines can now collect their

medicines from any pharmacy of their choice, greatly facilitating access and all the pharmacies in health centres have now been closed down.

4 Diseases And Conditions In Respect Of Which Free Medicines May Be Provided

- (1) Malignant Diseases
- (2) Cardiovascular Diseases:
 - (a) Chronic Heart Failure
 - (b) Hypertension
 - (c) Ischaemic Heart Disease
 - (d) Cardiac Arrhythmias
 - (e) Peripheral Vascular Disease
 - (f) Cerebrovascular disease
 - (g) Genetic Dyslipidaemia
- (3) Respiratory Diseases:
 - (a) Chronic Respiratory Failure
 - (b) Cystic Fibrosis
 - (c) Chronic Obstructive Pulmonary Disease
 - (d) Chronic Asthma
- (4) Digestive system diseases:
 - (a) Gastro - Oesophageal Reflux Disease
 - (b) Gastric/Duodenal Ulcers
 - (c) Inflammatory Bowel Disease
 - (d) Coeliac Disease
 - (e) Diverticular Disease requiring Stoma Care
 - (f) Hirschprung's Disease
 - (g) Imperforate Anus
 - (h) Small Intestinal Failure

Conclusion

The cost of medicines in Malta is not considered to be low. The price is regulated by a law which dates back to 1982. It allows a 15% profit margin after cost, insurance and freight to the importer/wholesaler. The pharmacist is allowed a further 20% profit. Although the system regulates the profit margins, it does not impose price controls. Expenditure on pharmaceuticals has been steadily increasing and now accounts for over 20% of government recurrent expenditure on health care. There are currently no mechanisms to influence doctors' prescribing practices, to promote cost-effective treatments or to analyse prescribing patterns of doctors. Information exists about drugs purchased by the state and where they are being used but no prescription monitoring occurs.

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