

Cost containment in the pharmaceutical sector: the Maltese scenario

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1. Brief description of the current situation in Malta

The Government Health Services (GHS) in Malta, funded through taxation, provides free service to entitled patients. The provision of pharmaceuticals to such entitled patients is 100% reimbursable (i.e. there is no co-payment). Non-entitled patients purchase pharmaceuticals fully out-of-pocket through privately owned pharmacies.

Medicines placed on the local market are required to be authorised by the Maltese Medicines Authority (MA), which is also responsible for the control and assurance of quality, safety and efficacy of locally available pharmaceuticals.

The procurement, storage and distribution of pharmaceuticals required within the GHS are carried out by the Government Health Procurement Services (GHPS) which operates in terms of an annual budget allocated by the central government. Procurement is conducted through tendering procedures governed by the Public Service (Procurement) and Public Contracts regulations¹.

The provision of pharmaceuticals by the GHPS is made in line with the requirements of the GHS, both in terms of the different pharmaceutical products required, as well as in terms of the quantities required. The different pharmaceuticals approved for GHS patients are available on a list – the National Formulary List – which is maintained by the Health Department. Depending on the level of entitlement, GHS patients are given access to the different pharmaceutical products available through this list.

Entitlement to the GHS pharmaceutical supply is determined through the following systems:

- The Schedule II card (characterised by the issue of a pink card) is mainly provided to entitled patients after an assessment of the total household income level; and is regulated through the Medical Aids grant under the Social Security Act²;
- The Schedule V card (characterised by the issue of a yellow card) is granted on the basis of a list of chronic conditions (such as hypertension, CVS conditions) that appear in the fifth schedule in the Social Security Act. This type of entitlement is granted irrespective of the financial position of the patient;
- Other persons – that include members of the police and armed forces, inmates of correctional facilities, and persons injured on duty – are also entitled to GHS pharmaceuticals which are fully reimbursable.

¹ Public Service (Procurement) Regulations (S.L. 174.02) and Public Contracts Regulations (S.L. 174.04) - <http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/174/02.PDF> and <http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/174/04.PDF>

² Social Security Act (Cap. 318) - http://docs.justice.gov.mt/lom/legislation/english/leg/vol_7/chapt318.pdf

The private pharmaceutical sector is made up of a number of pharmacies situated all around the islands of Malta and Gozo, which supply pharmaceuticals in accordance with the local Medicines Act³, against payment. In the main, these pharmacies are owned by either a non-pharmacist who employs a managing pharmacist, or by a pharmacist. Supplies of pharmaceuticals are obtained through licensed pharmaceutical wholesalers.

Locally licensed pharmaceutical wholesalers obtain their supplies through importation mainly from EU countries; or through local manufacturers. In the last few years the number of local pharmaceutical manufacturers has increased.

In line with an important administrative and political decision, which was taken after years of debate and discussions, the Government has initiated the process for the implementation of the Pharmacy of Your Choice (POYC) scheme. The initial stages of this scheme do not envisage any change in the reimbursement system. This means that patients entitled to pharmaceuticals through the GHS will continue not to pay for the pharmaceuticals supplied through the GHS – i.e. there is no co-payment. Through the POYC scheme GHS patients choose a private pharmacy in their locality, through which they will be able to collect the pharmaceuticals which their doctor prescribes. The pharmaceuticals, procured by the GHPS, are provided to the private pharmacies through the POYC unit.

2. Cost containment mechanisms utilised in the provision of pharmaceuticals within the GHS

The maintenance of the list of pharmaceuticals available under the GHS is the concern of the Pharmaceutical Policy and Monitoring Directorate within the Strategy and Sustainability Division of the Health Department. Any changes in this list⁴ – inclusions and/or exclusions – are carried out after due consideration is given, amongst other issues, to the clinical efficacy and safety of the pharmaceutical; together with the cost-effectiveness of the product, and a comparison with other products within the same therapeutic class.

There has been an incremental increase in the number of pharmaceutical products registered with the local MA, after a period of time where there was a seemingly sluggish interest from local and foreign pharmaceutical wholesalers/manufacturers in registering pharmaceutical products in terms of the local regulatory legislation. This has obviously had a positive impact both in the public, as well as in the private pharmaceutical sector, in terms of the availability of different products of the same therapeutic classes as well as of different classes.

The GHPS follows current public procurement tendering systems to acquire pharmaceuticals for the GHS. The employment of tendering procedures will be sustained and developed: as such procedures have continuously encouraged significant competitive submission of offers, mainly from local and foreign pharmaceutical wholesalers. The following table, for example, illustrates the decreasing cost per Omeprazole 20mg capsule as procured by GHPS through open competition tendering procedures for the GHS:

³ Medicines Act, 2003 (Cap. 458) - http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_14/Chapt458.PDF

⁴ Available on line at http://www.sahha.gov.mt/showdoc.aspx?id=740&filesource=4&file=FormularyList_%2027508.pdf

Table 1: Average price per capsule for Omeprazole 20mg (GHPs data)

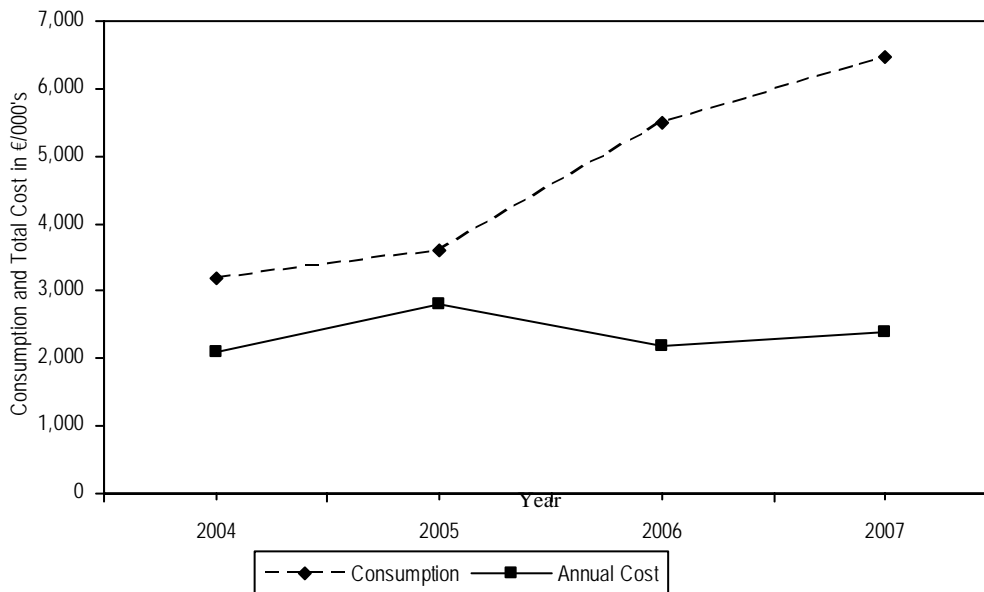
Year	Average purchased price per capsule in €
2006	0.059
2007	0.054
2008	0.042

In the case of newer drugs, due to intellectual property (IP) restrictions, the competitiveness when purchasing drugs for the GHS, is somewhat reduced when compared to other unpatented medicines. The use of tendering procedures however assists in ensuring that interested pharmaceutical wholesalers are allowed to submit financial packages in competition with each other. The need to continue to enhance competition in the local pharmaceutical market is a recognised channel towards financial sustainability of a health system which is a constant strain on the nation's economic status.

The role of the local Office for Fair Competition (OFC), through its price monitoring section, appears to require more development in terms of effective enforcement within the local pharmaceutical market; which is a small market and which is also characterised by a concentrated oligopolistic structure. Negotiated procedures are presently not carried out however this may need to be explored.

The spiralling costs of pharmaceuticals, coupled with the increasing use of pharmaceuticals and the introduction of new services, has intensified the difficulties in the sustainability of the public health system. Once again cost containment in the face of unprecedented increases in the use of some pharmaceuticals has been provided through the utilisation of tendering procedures by GHPs, as is shown in the following graph concerned with the use and cost of statins within the GHS over a four year period:

Graph 1: Annual consumption and cost of statins within the GHS (GHPS data)



As in other EU countries the question of financial sustainability of the local health system, as well as a lack of appropriate human resources, is an important and actively debated issue. The political implications of any changes to the current GHS will be a significant challenge to the new legislature.

3. Key issues and main questions proposed for debate at the review meeting

- The document explores the various means of cost containment measures that can be implemented, whilst at the same time assuring fair access for patients to drugs. In practice, for a small country such as Malta which depends almost exclusively on imports of pharmaceuticals, what would be the optimum interventions other than those already in place, that could be used to attain a balance between patient access and financial sustainability?
- The document contemplates the choice of either having a single European price or multiple national prices. In the face of the different economies and health systems of the EU MS, and the difficulties being experienced with, amongst other issues, soaring oil prices (and the consequent effect on the economies of the EU MS), the impact of a single European price within the small Maltese pharmaceutical sector would not aid financial sustainability.

- Considering the limited pharmaceutical market in Malta when compared to other EU MS, how can the pharmaceutical industry be encouraged in offering more cost-effective packages, possibly through innovative means within the present structure of the local GHS?