Reference Pricing for Pharmaceuticals: A Policy Perspective

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Abstract

Objective To analyse the introduction of reference pricing systems for pharmaceuticals in Malta, their effectiveness and adequacy to-date, and to propose possible improvements.

Method A study on 18 interviewees associated with pharmaceutical and economical pricing policies was performed. A literature review analysis of the local published media regarding the subject was also undertaken to confirm personal interpretations given and to bridge information gaps.

Key Findings There are two separate reference pricing systems in place; one for the private and another for the public health sector, operating via different economic mechanisms. Reasons for resorting to such systems centred around the lack of access and affordability of medicines. This situation had emanated from an inefficient business environment, lack of proper government regulation and management and an imbalance of power between medicines' suppliers, consumers and patients. A total of 18 respondents participated in the study. Two out of the 18 respondents considered the system successful, 6 deemed it unsuccessful and 7 thought the system had limited success. Results show that reference pricing may be regarded as a fair and simple means of monitoring and comparing local medicine prices with those of other countries. Reference pricing systems do not cater for many of the problems associated with such pricing.

Conclusions Reference pricing cannot be taken out of context in an integrated pharmaceutical system. The situation must be tackled holistically to address the real issues hindering the establishment of fair prices of medicines for Maltese consumers. Policy systems should be constructed in accordance with Malta's particular political, economic and cultural requirements in line with local and European Union (EU) legislation.

Keywords pharmacoeconomics, reference pricing, pharmaceutical pricing policy.

Introduction

Health policy systems represent a challenge for every government due to existing competing interests. Governments must safeguard public health, secure patient access to safe and effective medicines and contain the health expenditure within the required limits. Industrial policy obligations must also be considered.

Economic sustainability measures can be directed towards one or more of the four stakeholders in the health system, the four 'P's, namely the pharmaceutical industry, physicians, pharmacists and patients. Reference pricing is one such measure aimed at the pharmaceutical industry where a maximum level of financing is established for a drug in comparison with a group of drugs that are considered therapeutically equivalent.[1]

The aims of this study were to explore circumstances that led to the introduction of reference pricing for pharmaceuticals in Malta, to observe systems used locally and to observe how these compare with mechanisms in other EU countries. The level of effectiveness and adequacy of these systems since their implementation and possible ways of how they may be improved were also noted.

Method

Although pricing of medicines in Malta is a much discussed topic locally, documented information in the context of the local scenario is very scarce. To this effect, a qualitative study was carried out to obtain a detailed description of the subject matter. Data was then complemented with thematic frameworks, charting and mapping data to make it as illustratable as possible.

A study on 18 interviewees associated with pharmaceutical and economical policies was performed. The population considered consisted of relevant local and European politicians, high public service officials in their respective government departments, local pharmaceutical industry representatives, academics and experts in pharmacy and economics and relevant opinionists.

A literature review of 66 articles from the local online published media on the subject matter was additionally carried out to confirm personal interpretations given by such interviewees and fill any information gaps.

The research aims were translated into 7 interview questions, piloted and asked to each respondent. Similar opinions and arguments in different interviews were grouped together and quantified. Newspaper articles were printed, classified and important events were listed in chronological order. These were then discussed in relation to the relevant interview questions. Data from both studies was then analysed.

The number of countries used for referencing ranged from 4 to 27 Member States. Malta uses 12 reference countries from the EU and the European Economic Area (EEA) for the private sector medicines and in the public sector system eleven EU countries are used.
Choice of reference countries was based either on geopolitical factors, including similar size, population and geographical positions and historical, political and trade links or on economical factors such as similar Gross Domestic Product (GDP) values or baskets of reference countries from low-priced, medium-priced and high-priced countries. Malta uses 2 different economical systems. A group of countries within 20% points of Malta's GDP per capita in Purchasing Power Standards is used for the public reference pricing system whilst a basket of reference pricing mechanism of high, medium and low-priced countries is used for the private sector system with the selected countries being those where most medicines are imported from and the relevant price databases were available.
The price set varied between ex-factory, wholesale and retail prices. In Malta the two systems use different pricing policies. The private sector system reference price is the average retail price excluding VAT calculated by first taking the average retail price of each category then taking an average of these averages. The public sector reference price is taken as the lowest price from the average wholesale price of the basket of eleven countries, the UK NHS price, Government Health Procurement Services price, where applicable, and the Marketing Authorisation Holder price.

Table 1: Differences in calculating reference price between local system and other EU countries[2,3]

Results

The eventuality of an increase in the price of medicines had been discussed prior to Malta's accession to the EU but no mechanism was in place to prevent excessive increases in prices or to curtail increases once they occurred, resulting in reports of medicines' prices to be considerably higher than other EU Member States' a few years down the line.[4]

The situation could not be contained owing to several factors emanating from the three stakeholders in the economic system namely inefficient business environment and lack of proper regulation and management on the part of government; market failure due to uncompetitive practices by medicine importers and lack of a well informed and empowered consumer society. Reference pricing was introduced as a solution to this problem.

There are essentially 2 systems of reference pricing in Malta; one for the private market, on a voluntary basis, introduced in February 2008 and another for the public sector medicines that is obligatory, established in January 2010. The private sector mechanism applies to all medicines on the private market whilst the public service system is applicable only to new medicines introduced on the government formulary.

Both systems use external reference pricing where prices of the drug manufactured by the same company are compared across a number of countries, also called 'cross-country referencing'. There is however also some degree of internal reference pricing within the government health system where new medicines introduced on the government formulary are compared to others within the same therapeutic group already on the formulary.

Comparing these systems together and to those in different EU countries showed that the mechanism of calculating the reference price differed in three main aspects (Table 1).

Out of the 18 respondents interviewed 2 thought the system was a success, 6 thought it was not successful and 7 stated that it had limited success (Figure 1).

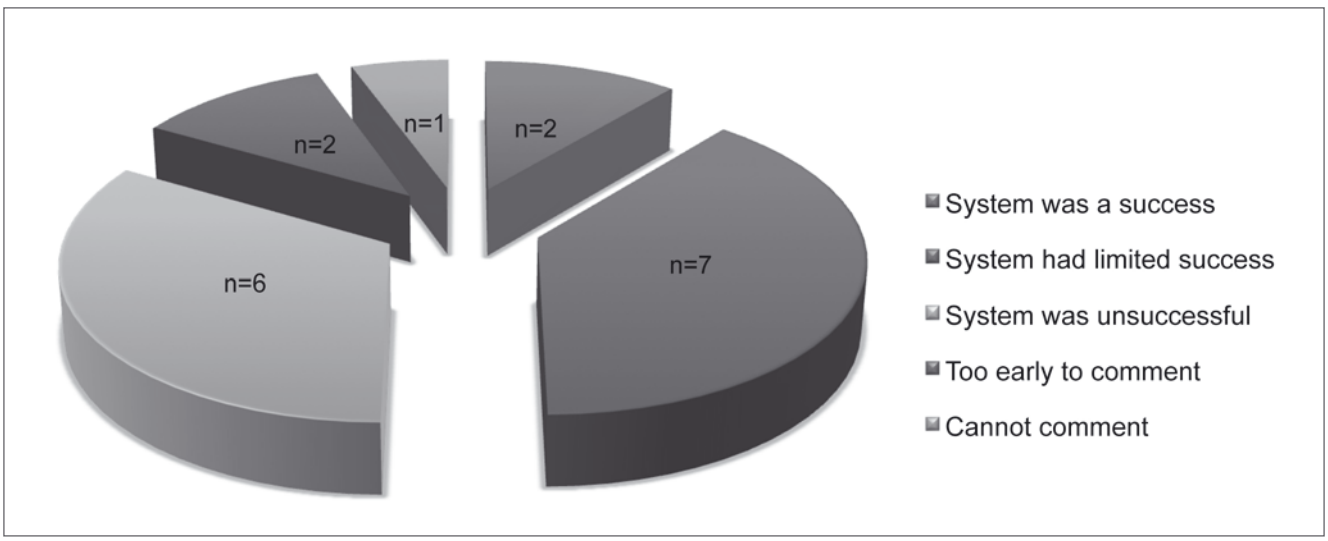

Figure 1: Success of local reference pricing system (N=18)

Discussion

The advantages of reference pricing are that it constitutes a comparative mechanism where prices of medicines in Malta could be compared to those in other EU countries, it does not require an intensive or elaborate infrastructure to operate, it is a good compromise between government and other stakeholders, it is in line with EU legislation, it has been in use for up to 20 years nearly all over Europe and in other non-European countries with some measure of success, it can reduce inflation and government expenditure and it is considered as being better that cost-plus pricing as well as bulk buying practices used in the past.

Reference pricing however also has its limitations such as it may be an arbitrary and artificial concept and cannot be considered a fair price. Many problems associated with pricing of medicines in Malta are not being catered for by this mechanism such as differential pricing policies set by mother companies abroad, doctors' prescribing habits and pro-British tendencies towards branded products, lack of reimbursement systems that are usually considered part and parcel with reference pricing, restricted medicinal entitlement and limited government formulary, inefficient and ineffective government purchasing systems, insufficient competition leading to manipulation in the private market, small volumes and low salaries compared to counterparts in other EU states, high government induced costs such as transport, utility, licensing fees and lack of legal back up, adequate regulation and enforcement, insufficient investment in innovation, limited local industry and high level of importation, inadequately informed and socially and politically disadvantaged consumers.

Regarding the future of reference pricing in Malta the way forward could be divided into short, medium and long-term measures. Short-term measures include acknowledgement of problems affecting the pharmaceutical field and addressing them in a responsible manner to benefit all parties concerned. Through consultation processes and tools available such as government departments and authorities, fora are created for objective information dissemination about important matters such as medicines that are expensive yet essential to the most vulnerable groups of society. Reengineering of procurement procedures to become efficient and effective, curtailing of abuses in the system such as medicinal entitlement, pilfering and expired goods, serious investment in EU standard warehousing and IT systems, better management of the government formulary and more rational use of medicines ensured.

Government-induced costs are to be analysed and revised. Through competent authorities, barriers to trade such as cartels and price fixing and issues constituting such barriers should be tackled allowing true market forces to act in the longer term. Possible measures include liberalisation of pharmacies, sale of over-the-counter medications from other outlets, competition within retail pharmacies on non-medicinals, introduction of full-line wholesalers and therapeutic class referencing and tendering. Measures to actively promote free competition such as incentives to local industry, parallel importation and prescription and dispensing of generics could be also addressed.

Medium-term measures address future possible courses to follow and include fine-tuning the current system, introducing more comprehensive changes to address any unmet needs, adding more pricing policies or completely replacing the current system by a better one. Options should be studied by government and stakeholders and actions for implementation taken accordingly.

Long-term measures aim at considering equity, accessibility and sustainability of government health services. The current restricted system of entitlement to free medicines would have to be reviewed considering options such as introducing new chronic conditions in stages or opting for more drastic yet more sustainable measures such as reimbursement schemes considering also the most socially disadvantaged. Other wider perspective options include the application of cost-benefit analysis or the concept of pay-back mechanisms based on outcome success.

Conclusion

Reference pricing systems cannot be considered in a vacuum out of context of a holistic and integrated pharmaceutical system. Lessons must be learnt from the past where systems such as medicines registration and the Pharmacy of Your Choice Scheme could have benefited more from better planning prior to their implementation. Economic and social impact assessments should be resorted to and results used to set up the necessary legislation, clear strategies and relevant policies, guidelines and protocols in line with set priorities to benefit all those parties involved. The system should be in line with EU regulations and in the spirit of such EU directives, cater for the specific economical, social, and political factors of this country.

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