PHARMACEUTICAL MARKET REFORMS IN PORTUGAL UNDER THE MEMORANDUM OF UNDERSTANDING

By: Pedro Pita Barros

Summary: The Portuguese pharmaceutical market has seen permanent and intense government intervention over the last decade. The financial assistance programme given to Portugal in 2011 and the associated Memorandum of Understanding (MoU) impose further changes in the market. The main objective of the more recent measures is to lower government expenditure and a mix of instruments is being employed: tougher pricing rules; promotion of a framework more conducive to competition from generics; reduction of distribution margins and more rational prescription patterns by doctors. Most of the measures set in the MoU have been adopted.

Keywords: Pharmaceutical Policy, Distribution Margins, Rational Prescribing, Portugal

The Portuguese pharmaceutical market has been subject to a large number of policy measures over the last decade. These included the introduction of a reference price system whenever competition from generics was possible (since 2003) and changes in the way the reference price is defined; administrative price reductions (2005, 2007 and 2010); several changes in co-payment rules and values; and the increased use of economic evaluation as a hurdle to the introduction of new products, both in ambulatory care and hospitals. Most of these measures were largely ineffective over the medium term, although since 2010 the package of measures seems to have had a noticeable impact on public expenditure, with a reduction in public expenditures on pharmaceutical products in ambulatory care and a slight slowdown in the increase of hospital expenditures (see Figure 1). The administrative price reductions, introduced in 2010, included changes in the setting of maximum prices for pharmaceutical products and changes to co-payment rules for products included under National Health Service (NHS) coverage.

The MoU, signed in May 2011 under the financial assistance programme for Portugal, brought important changes to pharmaceutical policy. First, it set targets for public pharmaceutical expenditure. Second, it required changes
Figure 1: Public expenditure on pharmaceuticals

% GDP

Public expenditure on pharmaceuticals

Public retail pharmaceutical expenditure

Hospital pharmaceutical expenditure


Source: Author’s elaboration based on Infarmed data

To the structure of distribution margins. These two demands constitute new approaches to containing high public pharmaceutical expenditure growth. Additional requirements of the MoU include: the promotion of generics, use of clinical guidelines and the redefinition of the international referencing rules that establish prices of new pharmaceutical products. The latter is now focused on the prices of three countries with the lowest prices in Europe, but which have some broad similarities with the Portuguese economy.

Public pharmaceutical expenditure

Public pharmaceutical expenditure has clear targets set under the MoU: the Portuguese government should decrease such expenditure in both the hospital sector as well as in ambulatory care. The target is 1.25% of Gross Domestic Product (GDP) by the end of 2012 and 1% by the end of 2013. These targets were defined in line with European Union (EU) average values, according to the wording in the initial version of the MoU. The revised version (as of 9 December 2011) drops the reference to EU average values, but keeps the target unchanged.

Estimates for Portugal’s total public pharmaceutical expenditure at the end of 2011 are circa 1.34% of GDP, down from its highest value of 1.55% in mid-2010. Therefore, despite the considerable effort expended so far, there is still an important reduction to be achieved in 2012 and 2013 to meet the target. Moreover, as illustrated in Figure 1, cost containment occurred only in ambulatory care, as hospital pharmaceutical expenditure is still rising.

Pharmaceutical prices

In Portugal, following market authorisation, an international reference pricing (IRP) system is applied to define the maximum market price. After this price is set, the pharmaceutical company can apply for the new product to be included in the positive list for reimbursement by the NHS. This price cannot be higher than the initially approved price.

The way prices are set also subject to change. The IRP system prevailing before the MoU used the average price of the same product in four reference countries (Greece, Spain, Italy and France). The MoU required a redefinition of the system to use the lowest price of a set of three countries to be chosen based on the level of prices prevailing in their markets (“lowest prices within Europe” as stated in the MoU) and which have a comparable GDP to Portugal. The countries selected were France, Spain and Slovenia. The option of including countries within the Euro-zone seems to constitute a good decision, as it avoids confusion introduced by exchange rate changes and how such variations should be accommodated. The change does not constitute as radical a departure from the previous set of countries as might have been expected from the wording of the MoU. Nonetheless, it is expected that some prices will be lowered due to the new rules and no price can increase, even if the mean value over the reference countries is higher.
Table 1: Wholesale and retail distribution margins of pharmaceutical products

<table>
<thead>
<tr>
<th></th>
<th>Wholesalers</th>
<th>Retailers</th>
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<tbody>
<tr>
<td></td>
<td>Mark-up (%)</td>
<td>Fixed fee</td>
</tr>
<tr>
<td>≤€5</td>
<td>11.20</td>
<td>–</td>
</tr>
<tr>
<td>€5.01–€7</td>
<td>10.85</td>
<td>–</td>
</tr>
<tr>
<td>€7.01–€10</td>
<td>10.60</td>
<td>–</td>
</tr>
<tr>
<td>€10.01–€20</td>
<td>10.00</td>
<td>–</td>
</tr>
<tr>
<td>€20.01–€50</td>
<td>9.20</td>
<td>–</td>
</tr>
<tr>
<td>&gt;€50</td>
<td>–</td>
<td>€4.60</td>
</tr>
</tbody>
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Source: Legislative Decree 112/2011 of 29th November.

Competition from generic pharmaceutical products

Several measures included in the MoU aim to increase competition from generics. Many of these measures are to be adopted within the first year of signing the MoU. The focus is on the price regulation of the market, administratively forcing lower prices. The measures already enacted include: a) setting the maximum price of the first generic to enter the market in its class at 60% lower than the price of the originator product (initially, it was set at 50% but later changed); b) automatic reduction of the price of the originator pharmaceutical product when the patent expires; c) resolving the legal dispute over intellectual property to ensure speedier entry of generics; and d) allowing substitution at the pharmacy of prescribed products by generics under certain conditions; the substitution may be refused by the physician, who has to provide a justification in the prescription; and refusal is also an option for the patient (Law 11/2012, of March 8). Moreover, pharmacies are forced by law to carry at least three of the five lowest-price generics in each class defined by a branded product.

Dealing with intellectual property disputes

A common strategy used by pharmaceutical companies to delay the entry of generic products in the Portuguese market was to initiate a challenge in the courts alleging infringement of intellectual property rights. Given the long time that the Portuguese courts take to produce a decision, the legal process itself worked as a delaying tactic. This issue was tackled in the MoU with the requirement that administrative and legal hurdles to the entry of generics had to be removed by the end of 2011. In November 2011, a new law was enacted that requires the resolution of intellectual property disputes through arbitration, taking the problem out of the courts. Moreover, specific time limits are defined for these procedures to be completed.

The MoU aims to increase competition from generics

One of the stated aims of this change is to save €50 million in distribution costs. The savings target is reinforced by the requirement for wholesalers and retail pharmacies to pay a special contribution (clawback) if not enough savings are generated (although pharmacies in remote areas with low turnover may be exempt from this pay-back mechanism). This requirement will be monitored and assessed by the third quarter of 2013. A second objective of the margins change is to increase the incentives to pharmacies to offer patients the option of purchasing generics. Under the previous system, where margins were defined by constant percentual mark-ups over the final price, pharmacies had the incentive to favour the dispensing of products with higher prices. Thus, the new rules mitigate this relative incentive to dispense more expensive products (by not carrying generics products).

Distribution of pharmaceutical products

The wholesale and retail distribution of pharmaceutical products was also addressed in the MoU. Historically, retail pharmacies and wholesale distributors earned a margin over the consumers’ price. The MoU stipulates that a new structure of margins, using a combination of fixed fees and regressive margins over the wholesale price must be defined (see Table 1). Before the new legislation package enacted for this purpose, the pharmaceutical wholesale margin was 8% and the retail pharmacy margin was 20%, both over the final price (at the consumer). These margins had been the subject of much discussion over the years and by the end of 2010 and early 2011, the possibility of moving to a different system of margins was mooted. Therefore, the MoU proposal to combine regressive margins and fixed fees did not come as a surprise.

While many of the other measures in the pharmaceutical sector aim to lower prices, some also act on volume; that is, the prescribing patterns of doctors. This is usually a delicate matter and previously has not been explicitly and directly addressed by the Portuguese authorities. The MoU requires a monitoring system that regularly provides information on both the volume and value of prescribing by individual doctors. The system has been in place since October 2011 and for the moment is used to provide feedback to doctors. This has been made possible by another MoU condition: the establishment of a mandatory electronic prescription system for pharmaceuticals covered by the NHS. The system has been operating since August 2011 (with a few temporary exceptions due to operational reasons). In addition, the MoU calls for the adoption of international prescription guidelines in Portugal, to provide clear rules for more rational prescribing patterns. These guidelines would complement the feedback mechanism provided to doctors on their own prescribing. By September 2011, the Ministry of Health and the Portuguese...
Medical Association had signed a protocol to compile clinical guidelines and to train auditors. The Directorate-General for Health is now making available an initial set of guidelines. The next step will be to ensure they enter current decisions in the NHS.

pharmaceutical arrears in the public health sector was estimated at €3 billion

Governance of the system

The first revision of the MoU, dated 9 December 2011, introduced a governance change, setting up a one-stop shop for the price setting of pharmaceutical products. This provision was included in a legislative package approved at the end of 2011. The pharmaceutical regulator, Infarmed, is defined as the single point of contact, although the prices of pharmaceutical products should result from a joint proposal by Infarmed and the government department in charge of price setting (Directorate-General of Economic Activities). Most companies did not see the one-stop-shop issue as critical. The more relevant delays apparently occur during the assessment process for inclusion in the NHS positive list.

Remaining issues

At the time of writing (March 2012), one relevant issue to be resolved, and which has important implications for the pharmaceutical market, is the existence of arrears. These are mainly, but not exclusively, delayed payments to the pharmaceutical industry by NHS hospitals. Resolving the issue has two steps: the government must first make funds available to NHS hospitals to pay these debts; and secondly, procedures must be put in place to avoid a future build-up of arrears. The first deadline for the government to present a solution to this problem was the end of September 2011, but the difficulties involved meant successive postponements of the deadline. The estimated value of arrears in the public health sector at the end of December 2011 was €3 billion (as reported in the government’s budget for 2012). To provide a sense of magnitude, the NHS budget for 2012 is circa €7.5 billion. Moreover, the importance of this issue is demonstrated by one pharmaceutical company’s recent decision to supply some NHS hospitals only under the condition of immediate payment.

Concluding remarks

For Portugal, the main challenge is to achieve the targeted reduction in public pharmaceutical expenditure and to this end a variety of instruments have been implemented: international reference pricing, changes to retail and wholesale distribution margins, monitoring of prescription patterns, promotion of generics entry and price competition. While the downward adjustment in public pharmaceutical expenditure had actually begun prior to the MoU, it is likely that the new set of measures will reinforce the trend.

References


New Health System Review – Denmark

Maria Olejaz, Annegrete Juul Nielsen, Andreas Rudkjæbing, Hans Okkels Birk, Allan Krasnik, Cristina Hernández-Quevedo

London: European Observatory on Health Systems and Policies, 2012

Number of pages: 192

The new Health Systems in Transition (HIT) review for Denmark reflects recent health trends and structural changes in the Danish health system. Lifestyle related risk factors and chronic illnesses are increasingly becoming major health issues which are still more challenging as a result of the ageing population.

This has pressed the health system towards a model of provision focused much more on the management of chronic care conditions. Although this report reveals a system that generally provides high quality services within each sector of the health system, the authors show that the fragmented structure of the Danish health system poses serious challenges in providing effectively coordinated care, Traditionally characterised as a decentralised system, several reforms from 2007 have strengthened coordination and centralised control.

The new HIT will be officially presented at a meeting of the Chief Medical Officers taking place in Copenhagen on 12 April in the context of the Danish EU Presidency.

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