Cyprus in crisis: Recent changes in the pharmaceutical market and options for further reforms without sacrificing access or quality of treatment

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Abstract

The pharmaceutical market in Cyprus has been characterised by high volume and a steep increase in per-capita expenditure over the past decade. Most importantly, the market is fragmented due to the absence of universal health insurance, and the uninsured have to rely exclusively on the private market. The objective of this study is to examine the weaknesses of the Cypriot pharmaceutical market before the financial crisis; to discuss the measures recently introduced after recommendations by the Troika; and to propose interventions that can improve access to pharmaceuticals and efficiency without compromising health outcomes. Apart from the introduction of new pharmaceutical policies, we also recommend the swift implementation of universal health insurance.

Keywords: Pharmaceutical policy; Reform; Cyprus
1. Introduction

In 2013 Cyprus became the fourth Euro zone country to resort to IMF, EC and ECB (the so-called Troika) funding as a result of the financial crisis. The Troika recommended the implementation of reforms, in (among others) the pharmaceutical market.

What makes the pharmaceutical market in Cyprus unique is that there is no universal health insurance scheme (NHIS). While employees in the public sector, people with an annual income below a certain threshold and patients suffering from certain chronic diseases are covered by public health insurance (85% of the population [Petrou 2009]), anyone who does not fall within these groups has to rely on the private sector. Cyprus is also the only EU country where out-of-pocket expenditure is higher than public health expenditure (Figure 1) (OECD 2012).

Therefore, it is important to include the private health sector in Cyprus in the discussion, because part of the population relies exclusively on this. In addition, patients who are covered by public health insurance often have to resort to the private market and pay out-of-pocket, as a result of unsatisfactory waiting times (Andreou, Pashardes et al 2010).

Figure 1. Pharmaceutical Sales in Cyprus, by sector (private or public) in million Euros

Regardless of the macroeconomic environment, governments should always seek to increase efficiency and reduce waste in health markets, in order to increase access to care without sacrificing outcomes. This means that either the same level of treatment can be achieved at a lower cost (thus releasing funds for other needs), or additional services can be provided at the same cost. Especially in a country like Cyprus, reducing waste can help fund the expansion of health insurance to the entire population. In this context, a country in crisis can implement measures that increase
efficiency, rather than simply resorting to -potentially hazardous for public health-
bullent cuts (Stuckler, Basu et al 2010; McKee, Karanikolos et al 2012; Quaglio,
Karapiperis et al 2013).

2. The Cypriot Pharmaceutical Market before the Crisis

Cypriot pharmaceutical market differs significantly compared to other EU
countries, with regards to lack of a universal health system and exclusive procurement
of drugs for public sector via tenders.

Patients covered by public health insurance can receive pharmaceuticals for
free from public pharmacies. Prior to the crisis there were no volume-control
measures in place, resulting in overprescribing and overconsumption of drugs(ECDC
2011). 39% of all prescriptions included more than five products (CPA 2011) while
patients could also receive OTC drugs and vitamins for free. Apart from costs, drug
overconsumption has been associated with adverse drug reactions and increased risk
of hospitalization (Köberlein 2013). The complete absence of demand-side measures
exacerbated this phenomenon: Intergraded prescribing guidelines for physicians were
limited, and there were no physician budgets nor any prescribing monitoring; in
addition there were no incentives for rational prescribing, or user charges as in other
countries (PPRI 2011).

While tenders are popular for the procurement of medicines in most hospital
markets in the EU, these are only used for a limited number of products in few
outpatient markets, such as the Netherlands and Germany. In Cyprus, however, the
procurement of all drugs in out-patients and hospital markets for the public system is
done via tenders, whereas the bidder offering the lowest price wins the right to supply
the entire market for two years (Petrou and Talias 2014a). In general, when there is no
monopoly power at the molecule or therapeutic level, tendering leads to lower prices
than reference pricing or price caps, and shifts in market shares (Blankart and
Stargardt 2012; Kanavos, Seeley et al 2004), meaning that for such markets in the
public sector, the Cypriot authorities have taken advantage of all possibilities for price
reductions. However, this is not always the case, as some drugs are on patent, which
may lead the government to purchase drugs at the therapeutic class level, whereas one
drug per class is purchased. If the product is the only drug in a therapeutic class, the
provider has additional market power, and the tender will not lead to any significant
price cuts, due to monopoly power. In any case, public expenditure on
pharmaceuticals in Cyprus appears to be mainly volume rather than price-driven (Petrou 2014a).

Prices for in-patent drugs are determined based on an international reference
pricing system. The price is determined as the average of available prices in Austria,
Sweden, France and Greece, plus 3 percent to cover importing costs, on top of which
a 37% pharmacist mark-up applies. As price revisions occur at longer intervals,
compared to other EU countries (Dylst, Vulto et al 2011) private sector prices in
Cyprus remain relatively high.

For off-patent markets, generic drugs are 20 percent cheaper than the
originator price. This directly translates to relatively high prices, given that in other
EU countries reference prices push generic prices down (Stargardt 2011; Kanavos, Costa-Font et al 2008), while price caps limit prices directly to a lower
fraction of the originator price than 80 percent (e.g. 50 percent in France; 52% in
Austria [Vogler 2012]).
3. Policy Changes recommended by the Troika

The Troika recommended the development of clinical guidelines as an important tool for rational prescribing (Woolf et al 1999; Grimshaw and Hutchinson 1995). As a result, guidelines for ten health conditions have been delivered and ten more are currently being developed (Clinical Pathways 2013). The implementation of guidelines is in accordance with Troika’s recommendation to render GPs as gatekeepers (Starfield, 1994).

There was little room for further price reductions in the public sector as a result of tendering, at least for products with substitutes. Consequently, the Troika focused on the implementation of adjacent policies that can enhance the efficiency of the system through the implementation of cost effectiveness analysis for the ten most costly products and some conditions with expensive treatments. While cost effectiveness analysis is a prerequisite in assessment of pharmaceuticals for inclusion in the formulary in the majority of EU countries (PHIS 2010), HTA, (Drummond et al. 2011; Garrido 2008) was only recently introduced in Cyprus.

As a way to address volume, the Troika requested the introduction of demand side control measure in the public sector. A 0.50-Euro co-payment fee per prescription was implemented to tackle moral hazard and overprescribing. User charges are not a preferred option during economic downturns because they provide barriers to healthcare. However, the 0.5-euro prescription fee is low, and in any case much lower than other EU countries. Given the low cost, this co-payment works more as a way to address moral hazard, rather than a way to actually finance the health budget. It is worth noting that a number of patient categories are already exempt from co-payments (Hynd, Roughhead et al. 2008) and this exemption should be expanded further to vulnerable socio-economic groups, as also suggested by Cylus et al (2012).

The Troika recommended new income criteria for public health care beneficiaries, reducing health insurance coverage even further. Uninsured people will have to pay for their healthcare entirely out of pocket (Petrou 2014b).

With regards to the private sector, the Ministry of Health introduced price reductions in order to reduce the financial burden (although this was not explicitly demanded by the Troika). We found only a modest 5.8% weighted reduction in total expenditure when we compared 1,691 commonly prescribed products under the old and new pricing system. Moreover, prices below 10 Euros were frozen. This is of major importance since 47% of total private wholesale pharmaceutical expenditure falls in this category. In addition, OTC products will be priced freely.

In this context, pharmacists’ remuneration in the private sector changed from a flat percentage to a regressive margin, which may remove the incentive to dispense more expensive medicines (37% for EPR below 50 euros, 33% for EPR between 50 and 250 and 25 % for EPR over 250 Euros). A prescription fee of 1 Euro was also implemented, cancelling out part of the benefit of the new pricing scheme. This has a negative impact on private sector patients, without being combined with any new activities of pharmacists such as cognitive services and management of chronic conditions (Farris 2008).

The introduction of the regressive pharmacy profit margin has a limited effect on the profitability of private pharmacists, since the lowest profit margin tier (25%) pertains to medicines which are mainly dispensed by public sector pharmacies.
Consequently, private sector pharmacists also reacted positively, and the one-Euro prescription fee may have contributed to a positive reception of the measures.

4. Options for further Policy Changes towards Efficiency

4.1 Public sector

The special nature of the Cypriot pharmaceutical market leaves little room for many of the available supply-side drug policies that are implemented in other EU countries. Cyprus optimised tendering system, so interventions must be sought elsewhere. However, new drugs can achieve higher prices due to the lack of direct substitutes with comparable clinical outcomes, which makes the tendering process ineffective. In this case there may be room for alternative pricing policies, such as risk-sharing and managed entry agreements, in which case coverage depends on clinical evidence and the available budget. These have been applied “where risk and uncertainty about value are very high in relation to the cost of the treatment, and the result is a very high cost per unit of health gain, which is deemed unaffordable by health insurers” (Kanavos, Ferrario et al. 2013). Via this mechanism, manufacturers may have to lower their prices, provide discounts or adjust the cost-effectiveness ratio (Willis, Persson et al. 2010; Ferrario and Kanavos 2013). In Italy, current outcome related risk sharing schemes generated savings up to 50% for innovative products (Espín, Rovira et al. 2011) while in the UK a non outcome coverage decision provides that NHS will cover the cost of first 14 injections, and any subsequent costs burden the supplier (Walker et al 2012). In the same context, a value based pricing scheme, according to which the price should be aligned to the clinical value of the product, could be selectively implemented, as some authors propose (Petrou and Talias 2014b).

To address overprescribing (Köberlein 2013), health authorities can introduce interventions at the demand side. These can include financial incentives for physicians to encourage rational prescribing, such as budgets (PPRI; Kanavos, Vandroos et al. 2011). Although budgets can reduce overprescribing (Busse, Schreyögg et al. 2005), if they are not carefully designed and adjusted for each physicians’ patients’ demographic and other characteristics, they may provide a barrier to access to care. In addition, information campaigns can inform patients of the dangers of overconsumption of drugs, as overprescribing may be driven by demanding patients (Kravitz, Richard et al. 2005). Of course the preparation of clinical guidelines for all major diseases must go forward as planned and, once ready, carefully followed by physicians, as these can also prevent a switch in prescribing from off-patent towards in-patent medicines (Vandosos 2013). It is also essential that e-prescribing is implemented across the country, so that prescribing is monitored and appropriate feedback is sent to physicians. Finally, appropriate detailing and marketing regulation must be adopted: Pharmaceutical Marketing activities have not been regulated apart from an ethics code agreed among seven R&D Companies and there is some evidence that aggressive promotion of some products may accelerate their early uptake and induce supply-side demand (Gagnon and Lexchin 2008; Kesselehim 2011; Vinod and Rao 2000).

Further implementation of HTA seems challenging for a small country but a combination proposed by Vandroos and Stargardt (2013), which limits external price referencing to countries that already apply HTA and then adjusts for the local market
needs and characteristics could be a rational starting point. An alternative could be the introduction of two versions of HTA with regards to Budget Impact Analysis of products: (a) Full version for estimated sales above a certain threshold; and (b) rapid (light) version for estimated sales below this threshold (Petrou and Talias 2013).

4.2 Private sector

While the public sector appears to demonstrate relatively low prices in most cases, things are totally different in the private sector. Given that these patients have no other option, this part of the market also deserves attention, until NHIS is implemented. First, setting generic prices at the 80% level of originators is relatively high and the potential for further savings for private-sector patients is foregone. Different generic policies can be adopted, such as lower price caps or internal reference pricing. Both these mechanisms also work as a price floor apart from a price ceiling, but they normally lead to lower prices than 80% of the originator price, which is the case in Cyprus (Kanavos, Cost-Font et al. 2008). Free generic pricing has resulted in even lower generic prices in the UK and US (Kanavos, Cost-Font et al. 2008; Kanavos and Vandoros 2011) but this is not recommended for Cyprus’ small market. For in-patent markets, external reference pricing can work well, as long as prices are updated frequently and adjusted for local market characteristics.

OTC drugs provide treatment for minor and frequent conditions and as such they constitute an important segment of pharmaceutical care. It appears that the fact that the market in Cyprus is small, and the presence of other market characteristics cannot enhance competition, as prices have recently been increasing.

In addition, the recent introduction of a pharmacist fee seems to have been unnecessary, since it was not substantiated by the introduction of additional pharmacist activities (Vogler 2012).

5. Discussion and Policy Implications

We have discussed the policy measures that have been adopted in the Cypriot pharmaceutical market and have recommended measures for further changes in order to increase efficiency without sacrificing access to care. Our recommendations for the public sector include risk-sharing for innovative drugs; restrictions on marketing and detailing; e-prescribing at the national level; and demand-side measures such as clinical guidelines, physician budgets, and prescription monitoring. For the private sector we recommend internal reference pricing or lower price caps for generic drugs, and more frequent revisions of prices under the external reference pricing scheme for in-patent originators (Table 1).

Table 1. The Troika’s main recommendations on pharmaceuticals
<table>
<thead>
<tr>
<th>Issue</th>
<th>Health Sector</th>
<th>Current state</th>
<th>Troika’s approach</th>
<th>Drawbacks/Barriers</th>
<th>Author’s Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricing</td>
<td>Private</td>
<td>External Reference Pricing</td>
<td>Not explicitly raised yet (although price reductions were implemented due to the crisis)</td>
<td>Low prices may lead to shortages of medicines due to reduced profitability of industry, which is aggravated by the fact that it is a small and unattractive market.</td>
<td>Significant reductions can be achieved under a unified market in the context of a National Health System. Frequent price revisions and lower generic prices.</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>Tendering (based on reference pricing)</td>
<td>Reduced agreed budget for public health expenditure is not exceeded</td>
<td>Limited room for further price reductions</td>
<td>Introduction of supplementary approaches to further enhance system such as risk sharing and managed entry agreements</td>
</tr>
<tr>
<td>Cost sharing</td>
<td>Public</td>
<td>Not applicable</td>
<td>Introduction of capped fixed co-payment fee to reduce medically unnecessary demand for pharmaceuticals</td>
<td>May restrict access to health care</td>
<td>Cost sharing can help address the problem of overusing medicines, which has been dominant in the public sector. Socioeconomic conditions must be taken into account so that it does not work as a barrier to treatment.</td>
</tr>
<tr>
<td>HTA</td>
<td>Public</td>
<td>Selectively</td>
<td>Introduction of intergraded HTA to selected pharmaceuticals and consumables</td>
<td>Economies of scale (human resources). A time-consuming process that requires resources and capacity.</td>
<td>Referencing countries that have HTA. Alternatively, two versions (rapid and full) based on Budget Impact Analysis (BIA).</td>
</tr>
</tbody>
</table>
Clinical Guidelines and medical audit

Public

Prescribing guidelines for high value products

Implementation of guidelines and medical audit for ten high volume and value diseases

Education, monitoring and audit are essential. It must be decided how divergence from guidelines will be addressed.

The private sector has been ignored in the effort to rationalise the pharmaceutical market. Nevertheless, the importance of this segment is underlined by the fact that a part of the population is not covered by public health insurance. The ultimate goal should be to swiftly shift towards a system of NHIS. The exclusion of patients from public health insurance, due to revision of eligibility criteria is in the exact opposite direction, and can only have a negative effect on the population’s health.

While the authorities work towards increasing efficiency with the implementation of (mainly) demand measures, it is crucial that any savings that occur are re-invested in the health sector as there is great need for additional funding elsewhere in the healthcare system (Gené-Badia, Gallo et al. 2012). Previous studies have shown that in other recession countries, the populations’ health deteriorated, either directly [Karanikolos, Mladovsky et al. 2013; Kentikelenis, Karanikolos et al. 2011; Vandoros, Hessel et al. 2013; Hessel, Vandoros et al. 2014] or indirectly (Vandoros, Kavetsos et al. 2013). In order to prevent a public health disaster, any interventions adopted must increase efficiency without sacrificing quality of or access to healthcare.
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