Transitioning to a national health system in Cyprus: a stakeholder analysis of pharmaceutical policy reform
Olivier J Wouters* & Panos G Kanavos†

Objective To review the pharmaceutical sector in Cyprus in terms of the availability and affordability of medicines and to explore pharmaceutical policy options for the national health system finance reform expected to be introduced in 2016.

Methods We conducted semi-structured interviews in April 2014 with senior representatives from seven key national organizations involved in pharmaceutical care. The captured data were coded and analysed using the predetermined themes of pricing, reimbursement, prescribing, dispensing and cost sharing. We also examined secondary data provided by the Cypriot Ministry of Health; these data included the prices and volumes of prescription medicines in 2013.

Findings We identified several key issues, including high medicine prices, underuse of generic medicines and high out-of-pocket drug spending. Most stakeholders recommended that the national government review existing pricing policies to ensure medicines within the forthcoming national health system are affordable and available, introduce a national reimbursement system and incentivize the prescribing and dispensing of generic medicines. There were disagreements over how to (i) allocate responsibilities to governmental agencies in the national health system, (ii) reconcile differences in opinion between stakeholders and (iii) raise awareness among patients, physicians and pharmacists about the benefits of greater generic drug use.

Conclusion In Cyprus, if the national health system is going to provide universal health coverage in a sustainable fashion, then the national government must address the current issues in the pharmaceutical sector. Importantly, the country will need to increase the market share of generic medicines to contain drug spending.

Abstracts in العربية, Français, Русский и Español at the end of each article.

Introduction
In 2013, Cyprus had a population of about 858 000 and a gross domestic product (GDP) of about 16 500 euros (€) per capita.1,2 The country’s health system consists of a public and a private sector. Individuals with annual incomes of no more than €15 400, the chronically ill and civil servants – together representing about 83% of the population – are eligible for public-sector coverage.3 The government pays for public-sector health care while patients and private health insurers pay for private-sector health care. Total health expenditure is about 7.3% of GDP.4 About 43% and 57% of health spending is publicly and privately funded, respectively.5 In 2010, pharmaceutical expenditure – €322 per capita – accounted for 19.8% of total health expenditure in Cyprus.6

In 2013, Cyprus agreed to a memorandum of understanding with creditors from the European Commission, European Central Bank and International Monetary Fund and introduced an economic adjustment programme to address the country’s financial, fiscal and structural challenges.5 The memorandum calls for the introduction of a national health system finance reform by mid-2016 to allow free choice of provider, social equality and solidarity, financial sustainability, and universal coverage of a minimum benefit basket.7 In the forthcoming system, the government will pay for all health-care services in the benefit basket – subject to cost sharing – and supplement current tax revenues with other sources of funding, including taxes on employers, employees and pensioners.2 The reform will bring major changes in financing, coverage, provider payment and data collection and monitoring.7 The government still needs to decide which drugs to cover, which pricing and reimbursement policies to apply and what type of cost sharing to introduce.

Given the lack of research on the Cypriot pharmaceutical system,6-12 the aim of this study was to review the current system of pharmaceutical care in the private and public sectors in terms of the availability and affordability of medicines. We also wanted to explore how the public and private markets could be efficiently merged in the national health system and to assess the key barriers to the implementation of the new system.

Methods
To collect primary data, we conducted interviews in April 2014 with senior representatives from seven national organizations (Box 1).13 The interviewees represented all but one of the organizations involved in pharmaceutical care in Cyprus. The exception was the Cyprus Medical Association, whose representatives were unavailable to meet. The interviewees were jointly selected by the researchers, the World Health Organization Regional Office for Europe and the Cypriot Ministry of Health. We met with the representatives from each organization separately over three days and each interview lasted between 30 minutes and two hours. All interviews were held at the headquarters of the health ministry’s Department of Pharmaceutical Services, in Nicosia. At least three members of this department were present at each interview.

The interviews were semi-structured (Box 2) but the discussions varied based on the roles of each organization. One of the researchers and a ministry of health employee took notes during each interview, and these notes were discussed with health ministry officials after each meeting, to confirm our understanding of the data. We followed the consolidated criteria for

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Table 1 summariz...part of the national health system reforms.

Table 2 summarizes the drug expenditure in the public sector for the year 2013; the 10 and 50 highest-selling products accounted for 17.6% and 44.0% of expenditure, respectively. In the same year, there were 18 foreign research-based manufacturers that each had over €1 million in public-sector drug sales in Cyprus – together representing 56.0% of all such sales. All foreign manufacturers sell their drugs in Cyprus via about 45 importers. These importers serve as wholesalers and handle national pharmacovigilance requirements. There are three Cypriot generic drug manufacturers, which export as much as 93% of their output to foreign markets.

All drugs sold in the Cypriot public sector are listed in a national formulary, which included 1767 products in 2013. Nearly all of the drugs used in Cyprus for the treatment of cancer, haemophilia, hepatitis B, hepatitis C and human immunodeficiency virus are sold exclusively in public pharmacies because all patients with these illnesses are eligible for public coverage. There is a co-payment plan, with an annual budget of €600,000, that allows public-sector patients to buy medicines only available in the private sector.

**Private sector**

Private-sector drug prices are set by the health ministry based on the recommendations of a pricing committee. For on-patent products, this committee bases the Cypriot wholesale price on the mean of the wholesale prices in one high-price country – i.e. Sweden, two medium-price countries – i.e. Austria and France, and one low-price country – i.e. Greece. If a medicine is not available in one of these countries, the committee uses the price in a pre-selected alternate country. To account for the cost of importing the drug into Cyprus, the committee adds a 3% mark-up to the derived mean price. The committee recalculates the prices of most drugs every two years. It revises the price of each newly launched product annually for the first two years. The private-sector prices in Cyprus are among the highest in Europe, largely because this pricing system captures the official prices in the reference countries.
and does not take into account confidential discounts.

After patent expiry, originator brand drugs continue to be priced through international price referencing. Generic drugs must be priced at least 20% below the price of the originator brand drugs for any originator brand drugs prescribed by physicians (Box 3).

In 2013 there were 481 private pharmacies in Cyprus – i.e. about one for every 300 private-sector patients. The consumption of generic drugs in the private sector is low, partly because pharmacists are forbidden by law to substitute such drugs for any originator brand drugs prescribed by physicians (Box 3).

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The consensus was that reviewing the current pricing policies to facilitate the transition to the national health system was important. To decrease the prices of on-patent drugs in the public sector, the association representing research-based manufacturers recommended the ministry of health keep price discounts confidential – thus limiting the spillover effect on markets that use Cypriot prices for reference. The health ministry representatives agreed to investigate legal options that could be followed to strike confidential agreements on drug prices. To reduce private-sector prices, the ministry of health offered to adjust its system of international price referencing – e.g. it could apply the lowest price paid in the reference countries.

Table 2 summarizes the 2013 drug expenditure in the private sector. The 10 and 50 highest-selling products accounted for 11.5% and 34.5% of private drug spending, respectively. About 87% of the total health expenditure within the Cypriot private sector was out-of-pocket while private health insurers paid the rest. Only 2054 of the 5241 products registered for sale in the private sector were available in 2013 – mostly because of insufficient demand for the other products.

Policy options

We investigated pharmaceutical policy options for the national health system, dividing the main feedback and suggestions of the stakeholders into the categories of pricing, reimbursement, prescribing, dispensing and cost sharing. Below, to contextualize the stakeholders’ statements, we have added references to relevant studies.

Pricing

The consensus was that reviewing the current pricing policies to facilitate the transition to the national health system was important. To decrease the prices of on-patent drugs in the public sector, the association representing research-based manufacturers recommended the ministry of health keep price discounts confidential – thus limiting the spillover effect on markets that use Cypriot prices for reference. The health ministry representatives agreed to investigate legal options that could be followed to strike confidential agreements on drug prices. To reduce private-sector prices, the ministry of health offered to adjust its system of international price referencing – e.g. it could apply the lowest price paid in the reference countries.

Stakeholders held differing views about which pricing policy to follow. The national associations for drug importers, local generic drug manufacturers, pharmacists and research-based manufacturers each noted that there is a possible trade-off between low prices and the availability of medicines. As Cyprus is a

### Table 1. Anonymized tender results for three selected medicines, Cyprus, 2013

| Product, condition, bid | Quantity, packs | Bid price, €/pack | Budget impact, €* | Private-sector wholesale price, €/pack |
|-------------------------|----------------|------------------|------------------|-------------------------------------|
| **Product A (hypertension)** | | | | |
| Bid 1 (winner) | 36 000 000 | 0.0189 | 678 857 | 0.35 |
| Bid 2 | | | 804 000 | |
| Bid 3 | | | 801 000 | |
| Bid 4 | | | 861 428 | |
| Bid 5 | | | 936 000 | |
| Bid 6 | | | 1 200 000 | |
| Bid 7 | | | 1 478 571 | |
| Bid 8 | | | 1 668 215 | |
| Bid 9 | | | 5 399 999 | |
| **Product B (osteoporosis and other bone disease)** | | | | |
| Bid 1 (winner) | 5 000 | 12.00 | 60 000 | 208.02 |
| Bid 2 | | | 146 450 | |
| Bid 3 | | | 147 500 | |
| Bid 4 | | | 149 250 | |
| Bid 5 | | | 169 850 | |
| Bid 6 | | | 194 500 | |
| Bid 7 | | | 250 439 | |
| Bid 8 | | | 525 000 | |
| Bid 9 | | | 645 000 | |
| **Product C (colorectal cancer)** | | | | |
| Bid 1 (winner) | 2 800 | 9.12 | 25 336 | 50.00 |
| Bid 2 | | | 33 600 | |

*€: euros.

* Actual budget impact may vary due to rounding.

Source: Data provided by the Department of Pharmaceutical Services, Ministry of Health, Nicosia, Cyprus.

### Table 2. Drug expenditure in the public and private sectors, Cyprus, 2013

| Category | Expenditure (millions of euros)a | Public sector | Private sector |
|----------|----------------------------------|---------------|---------------|
| **Prescription drugs** | | | |
| Inpatient | 98.5 | 80.6 |
| Outpatient | 59.5 | 9.7 |
| On-patent originator brand | 39.0 | 70.9 |
| Off-patent originator brand | 7.7 | 8.4 |
| Generic | 10.8 | 46.6 |
| Vaccines and others | 19.3 | 11.4 |
| **Over-the-counter drugs** | 1.2 | 4.5 |
| **Total drug expenditure** | 103.5 | 94.9 |

* Excluding value added tax.

* Inpatient and outpatient drugs are sold in hospital and retail pharmacies, respectively.

Source: Data provided by the Department of Pharmaceutical Services, Ministry of Health, Nicosia, Cyprus.
small market, these groups posited that, if prices drop too low, the manufacturers of originator brand and generic drugs might not sell their products in Cyprus – because it would produce insufficient returns on the manufacturers’ investments and/or adversely affect prices in other markets that use Cypriot prices for reference. The same groups urged the Cypriot government to use international price referencing in any future national health system and to apply a reimbursement system to receive confidential discounts. Other things being equal, however, a small population size does not appear to be associated with a relatively low market penetration by generic drugs.16

The ministry of health claimed the current wholesale prices of drugs in the private sector would be unaffordable in a national health system and that tendering could be used more widely. The Health Insurance Organization suggested the prices of drugs in the national health system should be set somewhere between the current public- and private-sector prices, but did not elaborate further.

Reimbursement

All stakeholders were in favour of introducing a national reimbursement system. The Health Insurance Organization intends to create a new national formulary and a reimbursement committee to manage it. Formularies can be used to specify the medicines eligible for reimbursement and – alongside prescribing guidelines – encourage the rational use of medicines.17

The Health Insurance Organization and ministry of health are working independently on criteria for the admission of new products to a future formulary. The ministry of health suggested that, to guide the inclusion or non-inclusion of drugs in a national formulary, the government should monitor, collect and analyse all relevant clinical and economic evidence from health technology assessment bodies in other countries. The government could ask manufacturers to adapt foreign data on the cost–effectiveness of drugs to local conditions.

The association for research-based manufacturers favoured the use of risk-sharing schemes in the national health system. Such schemes could be applied to hedge against uncertainties – at the time of a drug’s entry to the Cypriot market – regarding the drug’s budget impact, clinical effectiveness and cost–effectiveness. These schemes grant manufacturers favourable reimbursement rates in return for achieving financial or outcome targets. The Health Insurance Organization is considering the use of risk-sharing schemes. Although such schemes are widely used in Europe, they require appropriate performance measurement and enforcement.19,20

Finally, the Health Insurance Organization noted that widespread tendering in a unified national market could create supply disruptions, drive some generic drug manufacturers out of business and lead to higher generic drug prices over time. The organization proposed instead to use internal reference pricing and to tender selectively if such pricing does not achieve adequate price reductions for some products. Internal reference pricing sets a reimbursement ceiling based on the prices in a basket of drugs – e.g. the mean price of all drugs with the same active ingredient. If the price of a drug exceeds the reference price, the patient usually has to pay the difference. Systematic reviews have consistently found that such a policy can reduce drug prices and generate savings.20–22 The federation representing patients supported offering patients the choice between a generic drug and an originator brand version at a higher price.

Prescribing

Prescribing guidelines can have a beneficial impact on prescribing, when enforced appropriately.23,24 The Cypriot Ministry of Health plans to develop such guidelines for conditions with a high budget impact. When appropriate, the ministry might adapt guidelines published in other countries.

The interviewed representatives of the ministry of health, the Health Insurance Organization and pharmacy association suggested the government enforce the prescribing of generic drugs in the national health system. The Health Insurance Organization aims to introduce an electronic prescribing system to examine prescribing patterns and to improve the quality of medicine use. The organization is reviewing other options to encourage cost–effective prescribing, such as pay-for-performance schemes. It remains unclear, from the evidence collected in other countries, whether pay-for-performance schemes often achieve their intended goals.25

The Cypriot Ministry of Health believes there should be appropriate limits on drug advertising and on the gifts and contributions given to physicians by drug manufacturers. One survey has found that, for Cypriot physicians, pharmaceutical sales representatives are one of the most important sources of information on the safety and efficacy of medicines.26

Dispensing

In some countries, if a physician prescribes an originator brand drug despite the availability of a cheaper generic equivalent, pharmacists can override the physician’s decision and dispense the generic drug instead. Depending on the country, such generic substitution can be mandatory, voluntary27 or, as in Cyprus, forbidden. In our interviews, both the ministry of health and the Health Insurance Organization favoured mandatory generic substitution, which can speed up the market entry of ge-
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Generic drugs and reduce pharmaceutical spending. The federation representing patients opposed such substitution, however, and stated that all treatment decisions should be made by physicians. Most (81.3%) sales in the Cypriot private sector in 2013 were for drug packs with a wholesale price of no more than €50 per pack – these packs were subject to one of the highest pharmacy mark-ups in Europe, of 37%. The ministry of health and the Health Insurance Organization stressed that pharmacy mark-ups needed to be reduced and revised in Cyprus to encourage the dispensing of generic drugs. However, the interviewees from the association representing pharmacists expressed concern about the poor macroeconomic conditions in Cyprus and, consequently, the financial viability of pharmacies if the remuneration system were to change in any way that would reduce the income of pharmacists.

Cost sharing

The Health Insurance Organization is exploring various cost-sharing options – i.e. deductibles, co-insurance or cost-sharing caps to protect patients financially. It may remove co-payments for conditions where compliance is an issue, such as some psychiatric conditions. The interviewees from the federation representing patients stressed the importance of limits on cost sharing to protect vulnerable groups like the chronically ill. The interviewees from the ministry of health stated that the current out-of-pocket burden on private-sector patients was too high and that this burden needed to be reduced in the national health system.

Barriers

We identified four key barriers to the successful implementation of a comprehensive drug-benefit plan in the forthcoming national health system reforms. First, it appeared difficult to obtain the buy-in of all stakeholders for the health-care reform. Notably, there was disagreement over whether the prices of prescription medicines in the future system should be the current private-sector or public-sector prices or lie somewhere between the two. Other disputes might arise, such as physicians resisting the monitoring of prescribing habits. To resolve such disputes, it is important to involve all stakeholders in the reform process.

Second, the governmental stakeholders – i.e. the Health Insurance Organization and ministry of health – need to clarify their roles in the forthcoming system, particularly regarding who will be in charge of reimbursement. Clear and transparent rules are needed to allocate responsibilities. Since its inception, the Cypriot Ministry of Health has been solely in charge of national pharmaceutical policies. Although the Health Insurance Organization was established in 2001, it has only been actively engaged in discussions with the ministry of health for the last few years.

Third, most of the proposed policy changes would need to be accompanied by legislative changes, which may be time-consuming. Although the memorandum of understanding provided a broad timeline for the implementation of a national health system – including deadlines for key legislative changes – it allowed little time for consensus-building and preparation.

Finally, the Pancyprian Federation of Patients Associations and Friends stated that many patients – especially in the private sector – do not perceive generic drugs to be as good as the originator brand drugs in terms of safety and efficacy. It is possible that in Cyprus some physicians and pharmacists also exhibit loyalty to originator brand medicines. Such perceptions and brand loyalty have been observed elsewhere and may explain why generic substitution has been forbidden in the Cypriot private sector. The government could launch a public education campaign to promote the use of generic drugs.

Discussion

Pharmaceutical policies should reflect national priorities for health and industrial policy, including cost containment, employment, innovation and trade promotion. In many countries, the main objectives of pharmaceutical policies are to ensure equitable access to – and the good quality and rational use of – effective drugs. The findings of this study are meant to inform the ongoing policy deliberations in Cyprus. They can also be used to inform discussions in other countries aiming to establish a comprehensive drug-benefit plan under universal health coverage.

This study has some limitations. First, personal bias is unavoidable in interviews. To minimize the risk of such bias, both interviewers closely followed an interview template. Second, no representatives of the Cyprus Medical Association were available for an interview during the study visit. Members of this association could have provided valuable input on the prescribing environment. Finally, although this study looked at reform in the pharmaceutical sector, a holistic analysis is needed to understand the full impact of national health system reforms in Cyprus.

Over the next few years, there is a need to update the legislative and institutional framework in Cyprus and to acquire data, through pilot studies and simulations, on how health care might operate under the new system. There is a further need to build capacity and to address issues before and after reforms are introduced. The government should work to eliminate each of the four barriers identified. The Cypriot authorities should also prepare for unforeseen problems that inevitably accompany large-scale changes to health systems. Once new policies are implemented, the government should continue to monitor the results.

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Abstract

The transition to a national health system in Cyprus: an analysis of the policy makers' perspective on pharmaceutical policy reform

Objective

To examine the pharmaceutical sector in Cyprus as regards the availability and affordability of medicines, and the options for pharmaceutical policy reform envisaged for the financing of the national health system, planned for 2016.

Methods

We conducted a semi-structured interview in April 2014 with key representatives from seven national organisations involved in pharmaceutical care in Cyprus. The data were coded and analysed using the predefined themes: pricing, reimbursement, prescription, dispensing and cost-sharing.

Results

We identified several key issues, including the high prices, the underutilisation of generic medicines and direct costs. Most stakeholders recommended that the national government should review the existing pricing policies to ensure that medicines are available and affordable in the new national health system.

Conclusion

If Cyprus wants to ensure that the new national health system will offer national coverage in a sustainable way, it will have to address the current issues in the pharmaceutical sector. An important element will be to increase the market share of generic medicines in order to contain expenditure on medicines.
Резюме
Переход к национальной системе здравоохранения на Кипре: партнерский анализ реформы фармацевтической политики

Цель: Рассмотреть состояние фармацевтического сектора на Кипре с точки зрения доступности медикаментов по ассортименту и цене и изучить возможности фармацевтической политики в плане реформирования национальной системы здравоохранения, которая, как ожидается, будет проведена в 2016 г.

Методы: В апреле 2014 г. были проведены частично структурированные опросы представителей высшего руководства семи основных национальных организаций, вовлеченных в оказание лекарственной помощи населению. Собранные данные были переведены в цифровой формат и проанализированы с точки зрения заранее определенных аспектов: ценобразования, возмещения, выдачи рецептов, отпуска и распределения препаратов. Мы также изучили вторичные данные, предоставленные Министерством здравоохранения Кипра, которые включали сведения о цене и количестве рецептурных препаратов, выписанных в 2013 г.

Результаты: Были выявлены несколько основных проблем, включая высокие цены на лекарства, недостаточное использование дженериков и слишком частое использование собственных средств на оплату лекарств. Большинство партнеров предложили национальному правительству пересмотреть существующую политику ценобразования, чтобы в будущей системе здравоохранения лекарства были более доступны по цене и ассортименту, ввести национальную систему возмещения затрат на медикаменты и поощрить назначение и отпуск дженериков. Имелись разногласия по поводу того, как (i) распределить ответственность между правительственными органами в национальной системе здравоохранения, (ii) привить разногласия во мнениях между партнерами и (iii) предоставить пациентам, врачам и фармацевтам больше информации о пользе дженериков.

Вывод: Если национальная система здравоохранения на Кипре намерена стабильно предоставлять населению общедоступные услуги по охране здоровья, национальному правительству следует обратить внимание на текущие проблемы фармацевтического сектора. Важно, что страна должна будет увеличить рыночную долю дженериков, чтобы уменьшить затраты на медицинские препараты.

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