Panos Kanavos, Olivier Wouters

# Competition issues in the distribution of pharmaceuticals

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## Global Forum on Competition

# COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

**Contribution from Mr Panos Kanavos**

**-- Session III --**

*This note is submitted by Mr Panos Kanavos and Olivier Wouters (London School of Economics) under Session III of the Global Forum on Competition to be held on 27-28 February 2014.*

Ms Cristiana Vitale, Senior Competition Expert, OECD Competition Division
Tel: +33 1 45 24 85 30, Email: cristiana.vitale@oecd.org

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# COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

**-- Contribution from Panos Kanavos and Olivier Wouters [*] --**

1. The pharmaceutical distribution chain is composed of manufacturers, distributors (wholesalers and importers), and retailers (public and private pharmacies, drugstores, online sellers, supermarkets, and dispensing doctors). In most developed countries, the various stakeholders in the supply chain are regulated extensively to improve the affordability and availability of medicines as well as maintain levels of service. In many low- and middle-income countries, the distribution chain is neither regulated nor subject to any formal oversight and, as a result contributes to problems of availability and affordability of medicines. In the sections that follow, we outline some of the key developments in the distribution chain in both developed and developing countries and highlight competition issues. The focus is on prescription-only pharmaceuticals (POM), as opposed to those that are available over-the-counter (OTC). Much of what is outlined below for developed countries is based on the evidence available from the European Union (EU).

## 1. Distribution issues in developed economies

### *1.1 Market structure of pharmaceutical wholesaling and retailing*

2. In many developed countries, the supply chains are characterized by fragmentation, especially at the retail level. The retail and wholesale sectors are more fragmented in Europe than in North America. Still, even with Europe, significant variation continues to exist in the density of wholesale and retail outlets, largely due to differences in regulation, historical patterns, and service requirements (*e.g.* the public service obligation for wholesaling). For example, in 2005 there was one pharmacy per 1,250 persons in Greece compared to one pharmacy per 20,000 persons in Denmark. The proliferation of retail outlets in some cases also seems to be a predictor of concentration observed in other types of services, such as the availability of OTCs and the types of outlets these are available from.

3. There is a trend towards the horizontal and vertical consolidation of retailers and wholesaler to encourage economies of scale and scope in procurement and distribution. Horizontal integration refers to the fusion of entities that pursue the same line of business (*e.g.* mergers among retailers or among wholesalers), while vertical integration is the fusion of entities that have complementary business interests (*e.g.* acquisition of a pharmacy or pharmacy chain by a wholesaler or vice versa).

4. Alternative models of wholesale and retail distribution, such as Direct-To-Pharmacy and Reduced Wholesaler Models, have appeared in certain cases over the past 5 years. This trend can alter the rules of the game, particularly in settings where wholesaling does not operate under the public service obligation. Through a variety of schemes manufacturers are in a position to bypass wholesalers and sell directly to pharmacies. However, these models are either limited to special products only or apply in specific circumstances when the regulatory environment allows.

[*] This paper was written by Panos Kanavos and Olivier Wouters, London School of Economics.

5. Elements of diversification, particularly in connection with services expansion, by both wholesalers and pharmacies have been shown to exist as a response to some of the pressures on margins.

### *1.2 Remuneration and incentives*

6. The mark-ups or margins charged by wholesalers and retailers can significantly increase the cost of drugs for insurers. Unlike the US or Canada, most EU member states implement margin controls to curb the pecuniary benefits captured by the distribution chains for reimbursable medicines; the distribution chain for non-reimbursable medicines is usually not regulated.

7. Pharmacy margins are classified as progressive, regressive, or fixed (percentage or fee-based). The type of remuneration strategy will influence whether the pharmacists dispenses the lowest-priced option, which is usually a generic drug. Countries increasingly also legally require pharmacists to dispense the generic version of a medicine when it is available (*i.e.* generic substitution). Most wholesale margins in the EU range between 2% and 8% of the pharmacy retail price, although markups of as high as 24% have been observed in some cases and relating to a small number of medicines. The average pharmacy margins in the EU are less transparent, although a recent analysis of 15 countries estimated that the margins ranged from 12% to as high as 50% of wholesale prices. In North America, distribution margins are less transparent and are included in the list prices negotiated between manufacturers and insurers; additionally, they are thought to be lower, on aggregate, compared with margins in EU countries, although the trend over the past decade is for margins to decline in most EU countries. Pecuniary motivations may influence the behaviour of distributors and may lead to lower availability of certain medicines (*e.g.* generics, where the payoffs can be lower) in certain regions or countries.

8. To obtain a competitive advantage, many distribution chain actors provide price discounts. Commercial discounts exist in many countries (offered by manufacturers to wholesalers, by wholesalers to pharmacies, by manufacturers to pharmacies, and in some cases by pharmacies to patients) but can be limited by regulation in some cases. While there are often legislated limits on the discounts wholesalers and manufacturers may offer pharmacies, the level and scope of discounts are kept confidential. This prevents policymakers to easily calculate the payoffs to different distribution chain actors. For generic drugs, the discounts can be high and are important predictors of market shares. If health insurers are aware of the approximate level of discounts awarded to pharmacies, they can try to recover some of these savings through clawbacks on pharmacy reimbursement. This is used in the UK and the Netherlands, while in other countries wholesalers and pharmacies are legally required to grant rebates to public insurers.

### *1.3 Impact of distribution on prices of prescription medicines*

9. Analyses have shown that the price charged by the manufacturer (ex-manufacturer, ex-factory or list), wholesaler (trade or wholesale), and pharmacy (retail or public) varies substantially across Europe and across type of medicine (*e.g.* generic, originator, or OTC). The wide price spread at each level suggests that the effectiveness of various regulatory mechanisms differ. This price spread is more pronounced for generic medicines than originator products, and far more apparent for less expensive medicines where distribution chain markups represent a higher proportion of the price. In extreme cases, distribution costs and taxes can account for over 90% of the total price that insurers face.

10. Several regulatory options are employed in high-income countries to enhance the efficiency of the distribution chain. Of particular importance are the remuneration schemes for the distribution chain players. As mentioned in the last section, distribution chain mark-ups and margins are often regulated. The financial incentives are likely to have a significant impact on the efficiency and extent of competition of the distribution chain. Ex-manufacturer prices are not always a good predictor of the final gross pharmacy

retail price, which is the price the payer faces. Therefore, more focus on the distribution chain and the make-up of drug prices is needed to ensure that appropriate regulation is implemented.

### *1.4 The changing market structure and its impact*

11. The distribution sector is essential to guarantee sustainable access to high-quality medicines. However, it is important to ensure that the cost of distribution is commensurate to the added benefit of that these distribution entities provide to the general public and payers. As logistics and stock management is increasingly controlled remotely through IT, it is important for the distribution chain actors to innovate and continue to add value.

12. Manufacturers are in principle interested in a supply chain that guarantees the efficient distribution of their products for the intended markets at a reasonable cost. As previously mentioned, manufacturers are experimenting with different distribution arrangements to lower drug prices. Manufacturers are increasingly attempting to bypass wholesalers and distribute directly to pharmacies where possible, or only collaborate with a small number of wholesalers whose behavior they can monitor and influence more effectively (reduced wholesaler model).

13. Increasing competition and pressure on the wholesale and retail businesses are catalyzing a change in the market dynamics, with the number of mergers and acquisitions growing, including the establishment of vertical links with the retail business. In addition, the retail business is reconsidering its traditional role and services and is increasingly looking to diversify and expand the services provided. For example, pharmacies could engage in health promotion campaigns, monitoring, or clinical governance. However, it may be difficult to measure the additional value of these services. Pharmacies are also trying to engage more actively and directly with patients, for example by providing health information and advice (*e.g.* prevention, disease management, etc.). These trends are likely to continue as payers increasingly demand lower prices and that the most cost-effective options among equally therapeutic alternatives are dispensed. However, the willingness of health authorities to encourage the provision of these supplementary services these endeavors remains sluggish.

## 2. Low- and middle-income countries: background and issues

14. In many low- and middle-income countries, access to essential medicines is reduced due to high prices, low quality, and irregular supply. Even though the average patient in these countries usually experiences low financial protection due to the deficiency or lack insurance, drugs are sometimes more expensive than in high-income countries. The issue of quality is also very pertinent. Interpol recently estimated that 30% of all medicines in Africa are counterfeit or of inferior quality.

15. These availability and affordability issues are often the result of inefficient procurement mechanisms, weak or absent safety regulation, lack of infrastructure, bottlenecks in the distribution chains, little political and operational leadership by ministries of health, corruption, import duties and value-added taxes, excessive mark-ups, and inefficient or old national drug policies. A lack of coordination of capabilities generates significant waste of resources and reduces access. For example, procurement in China and India is carried out by public sector hospitals, private sector retail pharmacies and some governmental bodies. The resulting lack of coordination has led to inefficiencies, including the duplicate procurement of drugs. These inefficiencies are exacerbated by insufficient government investment, limited human resources capacity and financial support, irregular policy enforcement in the private sector, lack of stakeholder accountability, fragmented and discordant supply systems at regional level, poor information availability, a weak regulatory framework, and inadequate or non-existent transportation networks.

16. In countries with nascent regulatory infrastructures and/or weaker organisational capacities, inefficiencies in the procurement model and supply chain system contribute to higher pharmaceutical prices, inferior product quality, and distribution issues (*e.g.* stock-outs or only branded medicines sold instead of generics). Table 1 highlights the variability in mark-ups across settings, which are subject to significant variation across regions and private/public outlets. It is important to note that even where there are formal mark-up limits, actual mark-ups may exceed permitted levels due to corruption or lack of monitoring and/or enforcement. This has been documented in Ghana and several other low and middle income countries.

17. Exceptionally high mark-ups can result in medicines prices in that are often much more expensive than international reference prices (IRPs) (Tables 2 and 3). For example, in Yemen, the private sector patient prices have been as high as 129 times the IRP. Oversight and regulation on margins across different market segments should therefore significantly reduce prices and promote more equitable access. Even moderate efficiency gains are expected to have substantial cost and access implications. Fuel Africa, a medical products distribution company, conservatively estimated that improvements to logistics and inventory management system could reduce total pharmaceutical expenditure by $162-324 million annually in Sub-Saharan Africa.

18. To evaluate the performance of the supply chain and correct some of the aforementioned shortcomings, robust IT systems and data platforms are necessary. Better information availability would allow policymakers to examine determinants of the variation in availability/prices in public and private sector outlets across regions to correct inequitable access to services. Procurement models in low and middle income countries often exclude pricing or needs assessment, which is often not possible due the lack of IT. It is therefore advisable for governments to invest in data platforms to collect micro-level data to monitor the behaviour of the distribution system players.

## 3. Issues that merit further discussion and reflection

19. A sound procurement and distribution system needs to guarantee a steady and timely supply of medicines, maintain affordability of retail prices of prescription drugs, safeguard quality standards, and ensure supplier accountability for the quality and reliability of their services. A number of issues arise in both developed and low and middle-income countries relating to the strengthening of regulatory systems, public procurement mechanisms, and public supply chain management:

- **Market structure and concentration levels**: spatial monopolies are common and hard-to-reach populations usually experience diminished availability (*i.e.* inequitable distribution patterns, especially to rural areas). On the other hand, sources of fragmentation of distribution chains need to be analysed and their implications evaluated. It is also important to consider the regulations relating to wholesale and retail licenses, as well as who is allowed to operate pharmacies.

- **Vertical and/or horizontal integration at retail and wholesale level**: wholesalers and pharmacies may accumulate substantial market power with unknown consequences for patients. While achieving economies of scale is desirable in a sector characterised by significant changes in IT and logistics, availability of medicines and sufficient levels of service should be maintained.

- **Remuneration and mark-ups**: significant variation exists within the OECD area concerning approaches to remuneration (*i.e.* regulatory vs. market-oriented); by contrast, absence of any sound intervention or regulation may result in arbitrarily high mark-ups for essential medicines particularly in low and middle income countries.

- **Safety and quality assurance**: This is an important element considering the advent of e-pharmacies and their sourcing of product.

- **Product quality assurance programs**: quality control measures and labelling standards should be stringently enforced; quality control is often used to inform the selection of suppliers based on past performance (*i.e.* certified or preferred manufacturers).

- **Regulatory framework**: policymakers need to define and implement more effective and context-specific policies. For example, to discourage local monopolies and other distribution bottlenecks, including inefficiencies in storage, transport, and dispensary facilities.

- **Transparency**: written procedures and annual audits with published results may be necessary as is regular reporting on procurement performance. This requires reliable systems of data collection and management to enable timely and evidence-based decisions.

- **Public or private models of procurement**: mobilization of resources and collection of funds, pooling of available funds, and purchasing. This should be coupled with formal supplier qualification and monitoring.

- **Future role of distribution:** many countries are entering phases of out-patient tendering; in these circumstances, the wholesale distribution chain may become a pure logistics provider rather than adhere to specific levels of service.

- **Discount practices**: explore the extent to which these are competition-enhancing or competition-reducing in a variety of settings.

- **Low and middle income countries**: a greater body of evidence is needed to assess the performance of distribution chains and networks in different geographical settings, as well as study the extent to which policies or practices in OECD settings are transferable or generalizable.

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## ANNEX. TABLES AND FIGURES

**Table 1. Summary of distribution margins and taxes in a basket of LMICs**

| Country | Value (% of ex-manufacturer) | Stage/Purpose | Comments |
|---|---|---|---|
| Thailand | 33-2000% | Cumulative mark-ups | Figure is estimate and subject to substantial variation |
| | 28-41% | Public sector facility mark-up | Originator brand (OB) |
| | 20-285% | Public sector facility mark-up | Generics |
| | 37-900% | Private sector cumulative mark-up | Extreme variability noted |
| | 7-31% | Wholesale mark-up | Generics |
| | 0-2% | Wholesale mark-up | OB |
| | 20-150% | Pharmacy mark-up | Generics |
| | 13-40% | Pharmacy mark-up | OB |
| Philippines | 87-273% | Cumulative mark-up | Sector unspecified (public or private) |
| | 3-5% | National corporate taxes | |
| | 12% | Value-added tax (VAT) | |
| China | 4% | Duty tax on all imported medicines | |
| | 17% | VAT | Only for pharmacy medicines; excluding public health facilities or hospitals |
| Pakistan | 25% | Cumulative mark-ups | Ex-factory prices for locally produced generics |
| Morocco | 10% | Wholesale | Regulated |
| | 30% | Retail | Regulated |
| | 7% | VAT | Regulated |
| | 32% | Custom charges | EU imported medicines |
| | 40% | Custom charges | Non-EU medicines |
| Kyrgyzstan | 44-63% | Cumulative mark-ups | Sector unspecified |
| | 25-35% | Wholesale mark-up | Generics |
| | 15-25% | Wholesale mark-up | OB |
| | 15-25% | Retail mark-up | Generics |
| | 5-15% | Retail mark-up | OB |
| Yemen | 57.44% | Cumulative mark-ups | Sector unspecified |
| Ghana | 177.8-246.3% | Cumulative mark-ups | Public sector |
| | 27.35-387.6% | Cumulative mark-ups | Private sector |
| | 66.7-185.7% | Cumulative mark-ups | Mission sector |
| Nigeria | 123% | Cumulative mark-up | For imported medicines from the point of landing till dispensing |
| | 44% | Landing cost | |
| | 8% | Clearance fee | |
| | 12% | Inspection fee | |
| | 13% | Import mark-up | |
| | 23% | Wholesale mark-up | |
| | 23% | Retail mark-up | |
| Uganda | 48.5% | Import mark-up | |
| | 34.9% | Retail mark-up | |
| | 1.3% | Wholesale mark-up | |
| | 11.9% | Import fee | |
| | 1.5% | Clearing fee | |
| | 1.5% | Customs | |
| | 0.4% | National drug authority tax | |

***Source:*** Kanavos (2014, forthcoming). Author summarized the findings from the literature (primarily WHO/HAI evaluations of medicines prices).

**Table 2. Private sector patient prices in a basket of LMICs**

| Country | Prices | Comments |
|---|---|---|
| India | Median price < 2 * international reference price (IRP)* | Excluded OBs |
| | MPRs: 1.74-4.38 * IRP | OB |
| | 1.3-1.69 * IRP | Most-sold generics (MSGs) |
| | 1.3-1.84 * IRP | Lowest priced generics (LPGs) |
| Malaysia | OB 114% > Generics | |
| | Private sector OB 47% > Public sector OB | |
| | Private sector generics 60% > public sector generics | |
| China (Shanghai) | Median MPR: 8.76 * IRP | For 17 OBs surveyed |
| | Median MPR: 1.77 * IRP | For 20 LPGs surveyed |
| Jordan | 17 * IRP | OB |
| | 11- 51 * IRP | For 50% of the surveyed medicines |
| | 10.5 * IRP | LPGs |
| Pakistan | 3.36 * IRP | OB |
| | 2.26 * IRP | LPG |
| Yemen | 2- 129 * IRP | OB |
| | 0.26-18 * IRP | LPGs |
| Ghana | 18 * IRP | OB |
| | 2.04-7 * IRP | For 50% of the LPGs surveyed. |

***Source:*** Kanavos (2014, forthcoming). Author summarized the findings from the literature (primarily WHO/HAI evaluations of medicines prices).

* IRPs based on the Management Science for Health (MSH) calculations

**Table 3. Public sector patient prices in a basket of LMICs**

| Country | Prices | Comments |
|---|---|---|
| Malaysia | OB 33% more than Generics | |
| China (Shanghai) | MPR: 5.64 * IRP (OB) | 21 OB drugs surveyed |
| | MPR: 2.03 * IRP (Generics) | 29 Generics surveyed |
| Jordan | 5.95*IRP | OB |
| | 0.85*IRP | LPGs |
| Yemen | 0.64-2.33 MPR | 75% of MPRs < IRP |
| Ghana | 2.43 * IRP (LPG) | 50 Medicines surveyed |
| Nigeria | 2-64* IRP | Not specified whether OB or LPG |

***Source:*** Kanavos (2014, forthcoming). Author summarized the findings from the literature (primarily WHO/HAI evaluations of medicines prices).