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**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Session III --

Call for country contributions

This document is a call for country contributions for Session III of the Global Forum on Competition to be held on 27-28 February 2014. GFC participants are invited to submit their contributions by 6 January 2014 at the latest.

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TO ALL GLOBAL FORUM PARTICIPANTS

Re: Competition Issues in the Distribution of Pharmaceuticals

Global Forum on Competition (27 and 28 February 2014)

Dear GFC Participant,

The OECD Global Forum on Competition will hold a Roundtable on competition issues in the distribution of pharmaceuticals on the second day of the meeting, Friday 28 February 2014. You are invited to make a written contribution to this session by **Monday 6 January 2014** at the latest.

A well-functioning health system requires final users to be able to rely on an adequate and reliable supply of affordable drugs of an acceptable quality (*i.e.* that are safe and effective). However, adequate levels of availability, affordability and quality of pharmaceuticals are attained in different degrees around the world for a number of reasons, ranging from lack of infrastructures, obstructive regulation and insufficient competition, to import duties, corruption and financial constraints.

The Roundtable on the distribution of pharmaceuticals will explore the role competition policy can play in helping to better achieve this outcome.

The supply chain of pharmaceuticals is composed of a complex network of private and public players, some of which are directly involved in the production and the distribution, while others have a role because they directly or indirectly shape the demand. Once pharmaceuticals are produced by manufacturers, they pass through the hands of importers, wholesalers or distributors, and retailers (*e.g.* public and private pharmacies, drugstores, online sellers, supermarkets, dispensing doctors) before arriving to the final consumers (individual patients and hospitals). To a large extent consumers' demand for drugs is affected by doctors¹, sometimes pharmacists, and private and public insurers. The relationships between the various players in this chain are subject to extensive regulation in order to ensure affordability and availability. This shapes their incentives and, hence, affects their behaviour and the final outcome for the patients. However, this does not mean that competition has no role to play, especially since more and more countries are reforming their health system so as to rely to greater extent on market forces rather than on intrusive regulation.

This session will explore the role that competition can play in improving the distribution of drugs and thus ensuring an adequate supply of affordable and safe drugs to final users. It will examine the kind of anticompetitive behaviours that may arise in the distribution chain, but it will also focus on more general policy questions and regulatory design. However, it will not consider any issue related to Intellectual Property Rights, their uses and abuses and their reform. The focus will be on distribution - manufacturers will be of interest only as producers of pharmaceuticals that enter the distribution chain. Further the focus will mostly be on prescription drugs, though some attention will also be devoted to the distribution of non-prescription drugs.

¹ Doctor prescribe the medicines and hence have a strong power to influence the choice of final consumers, in some countries doctors can also dispense pharmaceuticals, in which case they play an active role in the distribution chain.

More specifically the roundtable will consider:

- the various stages of the distribution chain, how each one is structured and how this structure is changing,
- how the players in the distribution chain are regulated and whether this regulation can introduce distortions to competition and can hinder, rather foster, the objective of ensuring an adequate and affordable supply of drugs,
- what kind of competition enforcement problems can arise along the distribution chain, and
- in general, how can the objective of ensuring an adequate and affordable supply of drugs be better achieved using competition.

This roundtable will last a full day. The morning will be dedicated to a plenary discussion of how distribution is regulated to achieve an adequate and reliable supply of affordable drugs of an acceptable quality and what role competition could play in ensuring that this objective is met and to an introductory discussion of the antitrust issues that may arise in the distribution of pharmaceuticals. The afternoon, in which three smaller parallel sessions will be held, will instead focus mostly on antitrust issues. The Secretariat will allocate delegations in the three break-out sessions according to the topics discussed in their contribution. The roundtable will terminate with a wrap-up plenary session, in which the outcome of the parallel sessions will be summarised and discussed.

This roundtable will extensively discuss policy questions and regulatory design, and not just competition law issues. This is an area where the responsibility of competition agencies overlaps with those of Health Departments, which design and administer the regulatory framework. Hence we would suggest that you invited your colleagues from this Department to take part in the Roundtable. This will ensure an informed and fruitful discussion.

The quality and utility of this roundtable will be greatly strengthened by written contributions. In order to assist you with the preparation of your contribution, we have included a detailed list of the issues in the attachment. This is not an exhaustive list, and participants are encouraged to raise and address other issues in their submissions related to competition in the distribution of pharmaceuticals.

Please advise the Secretariat by 13 December 2013 if you will be making a written contribution. As noted above, **written contributions are due by 6 January 2014**. This deadline applies to both members and non-members. It is important to meet the deadline in order to allow the Secretariat to best organise the break-out sessions. Failure to meet this deadline may result in your delegation being assigned to a break-out session, whose content may not be relevant to your contribution. In addition, late contributions may not be distributed via the Global Forum website (www.oecd.org/competition/globalforum) in advance of the meeting.

All communications regarding documentation for this roundtable should be sent to Ms Erica Agostinho (Email: erica.agostinho@oecd.org). All substantive queries relating to this roundtable should instead be sent to Ms Cristiana Vitale (Email: cristiana.vitale@oecd.org) and to Mr Gianpiero Mattera (Email: gianpiero.mattera@oecd.org).

SUGGESTED QUESTIONS AND POINTS FOR CONSIDERATION

Countries are invited to answer the questions listed below, bearing in mind that both the issues and the questions are intended to be illustrative rather than exhaustive. You should feel free to discuss other pertinent topics that are not mentioned here. Moreover some of the questions may overlap or may not apply to you; hence we do not expect you to answer all the questions listed below. They are meant as guidance in preparing your contribution. Wherever possible, please demonstrate the points you raise by referring to specific cases and examples.

1. Supply conditions

- Do you consider that in your country there is an adequate and reliable supply of affordable drugs of an acceptable quality?
- If not, can you describe the extent of the problem and possibly quantify it?
- What are the main reasons for these problems? What solutions have you attempted?
- What role can competition policy play to improve the situation (both through competition law enforcement and competition advocacy)?

2. Manufacturing level

- What kind of regulation, if any, exists on ex-factory prices of originator drugs?
- What kind of regulation, if any, exists on ex-factory prices of generic drugs?
- Are you concerned that this regulation may be stifling price competition or innovation?
- Have you ever performed a market study that has looked at this regulation?
- Do you rely mostly on local manufacturers of drugs or on foreign ones?
- Are there barriers to trade and import that constraint the availability of drugs in your country?

3. Wholesale distribution

- How is wholesale distribution organised in your country? Are wholesalers buying drugs from manufacturers and selling them downstream or are they simply distribute of manufacturers? Is this changing and if so in what ways?
- How many players are involved in wholesale distribution? Is it a very concentrated sector? Are there many layers (*e.g.* large national wholesalers who supply smaller local wholesalers)? Do retailers usually stock themselves from one wholesaler or do they rely on more than one?

- Are there vertical agreements in place between wholesalers and manufacturers (*e.g.* exclusive distribution, and exclusive territories)? What are the main characteristics of these agreements? Do you have concern that these agreements may reduce inter and intra brand competition?
- Are wholesalers vertically integrated with retailers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?
- Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?
- Are there special provisions or regulation in place to ensure that rural and sparsely populated areas are served by wholesalers?
- Are wholesalers subject to regulation on prices, profits or margins?
- Are they subject to any other type of regulation that may affect the prices paid by final consumers or the availability of drugs to final consumers?
- Does the existing regulation of wholesalers cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?
- Have you ever performed a market study that has looked at this regulation?
- Do wholesalers/importers source drugs in countries that have lower prices (often referred to as parallel imports)?

4. Retail distribution

- How is retail distribution organised in your country?
 - Who can sell prescription drugs and who can sell over-the-counter drugs?
 - Are there separate retail outlets for paying out of their pocket patients and for reimbursed/non-paying patients?
 - Are there publicly owned pharmacies and what is their role?
 - Are doctors allowed to sell the medicines they prescribe?
 - Can hospital pharmacies also sell to external patients?
 - Are on-line pharmacies allowed?
 - Is it possible to locate pharmacies in supermarkets?
 - Are chains allowed? What percentage of all existing pharmacies are chains?
- Are their restrictions imposed on opening hours of pharmacies?

- Are there restrictions on the number and locations of pharmacies? And other retail outlets of drugs?
- How is it ensured that a sufficient number of retailers are located rural and sparsely populated areas?
- Do NGOs run retail outlets in your country? What impact does it have on affordability and availability? Does their presence spur price competition?
- Are retail outlets vertically integrated with wholesalers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?
- Have retailers tried to obtain some buyer power through the creation of chains or by creating buyers groups?
- Have you had cases of abuse of dominance or collusion? Are market conditions conducive to these types of infringements?
- Are retailers subject to regulation on prices, profits or margins?
- If so does this type of regulation cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?
- Have you ever performed a market study that has looked at this regulation?
- Is there price competition between retail outlets? And service competition?

5. International Donors

- Are international donors of medicines active in your country?
- How they distribute medicines? Do they use the traditional distribution chain (local distributors and local pharmacies) or do they have their own channel?
- Does their presence create any pressure on the prices of the medicines not provided by donors?

6. Public and private insurers

- Do public insurers try to exert control over the distribution chain in order to contain the price of drugs (*e.g.* do they run tenders to buy medicines)?
- Do private insurers, if present, play a role in trying to exert control over the distribution chain in order to contain the price of drugs (*e.g.* do they run tenders to buy medicines)?

7. Generics competition

- How extensively are generics used in your country? Has their usage increased in the last few years? Do you think it has had an effect on prices of originators?
- Are generics subject to the same quality and safety controls as originator drugs?

- Does price or margin regulation at manufacturing, at wholesale and at retail level encourage the production and sale of generics? If so how? Could it be improved?
- To what extent you consider that manufacturers affect the above incentives by providing wholesalers and retailers with financial incentives when they sell originators rather than generics?
- Does any other type of regulation favour/foster the sale and use of generics? For example are doctors required or incentivised to prescribe generics? Do doctors have maximum dispensing budgets? Are pharmacists required to substitute originators with generics whenever possible? Are there other types of financial incentives for doctors or pharmacists aimed at favouring the prescription and dispensation of generic drugs?
- Are there financial incentives on consumers to request generics rather originator drugs?
- To what extent you consider that manufacturers affect the above incentives by providing doctors with financial incentives when they sell originators rather than generics?
- Do consumers perceive generics as safe and effective drugs, or does the suspicion that these drugs may be sub-standard or counterfeit encourage consumers to require/buy originators? How aware are they of the price difference between generics and originators?

SUGGESTED READINGS

Competition Bureau Canada (2007), Canadian Generic Drug Sector Study.

Kremer (2002), Pharmaceuticals and the Developing World, Journal of Economic Perspectives Vol. 16, No. 4.

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WHO/EURO (2003), Dukes, Haaijer-Ruskamp, de Joncheere and Rietveld (Editors), Drugs and Money, Seventh Edition, WHO Publications.

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<http://www.haiweb.org/medicineprices/05062011/Mark-ups%20final%20May2011.pdf>

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<http://www.haiweb.org/medicineprices/24072012/CompetitionFinalMay2011.pdf>