Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

10-Feb-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/GF/WD(2014)46
Unclassified

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Pakistan

-- Session III --

This contribution is submitted by Pakistan 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

JT03352199

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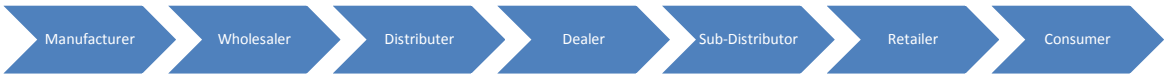
COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Pakistan --

1. The various stages of the distribution chain, how each one is structured and how this structure is changing

1. For marketing and sales promotion of the pharmaceuticals, the manufacturers appoint distributors. A particular territory is assigned by allocating the market/zones/areas for the distribution of products. The distribution chain of the products from the manufacturer to the end consumers is as under:

Supply Chain-I for out of pocket purchases



Supply Chain-II for provision of drugs through public sector hospitals

2. Generally, the rate running contract procedure is adopted for purchase of drugs from the selected firms for a specified period (mostly three years). Tenders are invited and opened by a 'Drug Committee', comprising the senior most doctors, specialists, consultants, etc. The Committee recommends the brand names of products for procurement.

3. The hospitals that purchase medicines in bulk, follow the Public Procurement Regulatory Authority Rules of the respective province where the hospital is located. Prequalification is conducted through a formal procedure for the screening of potential bidders prior to invitation of bids by the procuring agencies. Sealed tenders are invited on prescribed proforma from well-reputed firms registered with income tax and sales tax departments having experience for the supply of drugs.

4. In Pakistan, the pharmaceutical industry developed over time responding to indigenous demand. The sector contributed about 5% to the total manufacturing output - greater than automobile or fertilizer. In 2012, medicines worth $400 million were exported. Notwithstanding that the sector underwent robust growth, 13% until recently, Pakistan is still amongst lowest per capita medicine users (US$ 9/annum). Medicines are hardly accessible to half of the population - reflecting industry's growth potential as well as incapability to develop and generate market clearing supplies.

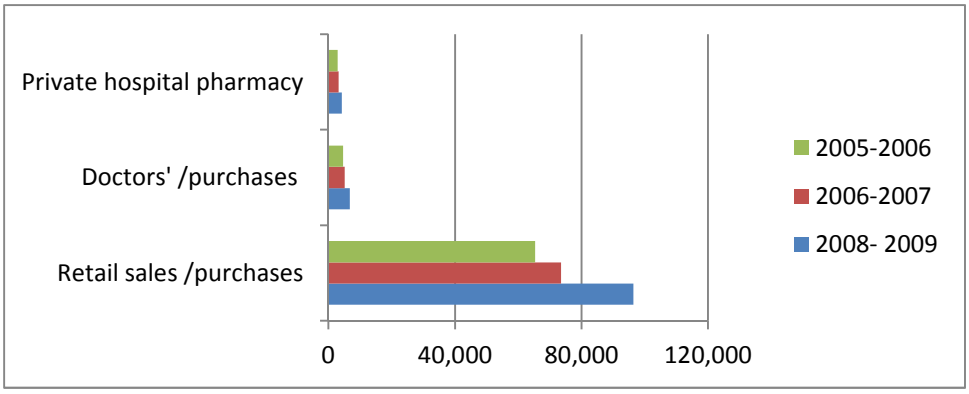
5. The industry has more than 400 licensed pharmaceutical manufacturing units producing about 50,000 products. Twenty-five multinational companies comprise about 53 to 55% of the market and more

than four hundred national companies share the remaining. This is indicative of openness of the sector for FDI as well as cautions on low level of national capacity development. Size matters a lot in the pharmaceutical sector; bigger units are better able to face risks, afford expensive/sophisticated machinery, conduct R&D, clinical trials, and undertake product liability. The sector employs more than 100,000 people.[1]

6. The operational environment for drug makers in Pakistan faced a number of challenges during recent past including the following:

- The dissolution of the Ministry of Health (MoH) and the subsequent decentralization of drug regulation. Provinces are in the process of instituting a mechanism for drug regulation.
- Incidence of deceptive marketing and counterfeit medicines are reported more frequently due to media activism. This reflects the need for strengthening of monitoring system for supply of quality drugs.
- The granting of Most Favoured Nation (MFN) trading status to India is expected to exert competitive pressure on the local pharmaceutical industry.

Figure 1 Purchase of pharmaceuticals in PKRs (million)[2]



7. The sale of medicines over the counter (OTC) is prevalent in Pakistan, private out of pocket (OOP) expenses have about 66% share in the health expenditure whereas the public sector provides about 14%. These factors provide an explanation of Figure 1, which shows that the share of retail sale/purchase of medicines is the highest. During the period 2005-2009, for which the national health accounts are available, the shares of purchases by various categories have remained stable.

2. 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

8. In Pakistan, the distribution chain is regulated at each stage i.e. from manufacturing of drugs to the opening of pharmacies/ medical stores. Below an overview of the regulatory system is provided.

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1 Mohammad Aamir and Khalid Zaman, 'Review of Pakistan Pharmaceutical Industry: SWOT Analysis, International Journal of Business and Information Technology, (June 2011), Vol. 1, Issue 1, pp. 114-117.

2 *Source*: Pakistan National Health Accounts, 2007.

9. The pharmaceutical industry has grown in an environment where at the federal level, the ministry of health (MoH) used to regulate drug manufacturing and pricing.[3] The companies were not allowed to revise prices rather the MoH addressed the drug price revision on a case-to-case basis, and only 'hardship cases' were allowed an increase. A manufacturer/ importer initially had to registere a pharmaceutical product, and the MoH ascertained whether the product is an 'original' one or a 'me-too'. An original product was usually introduced by multinational companies. The MoH granted these 'new' products a 'leader price'. Any 'me-too' introduced after the original product was granted prices lower than the leader price, and in some cases equal to the leader price. This assigned price was the maximum retail price (MRP), but the manufacturer/importer was allowed to offer the product at any price below that and may increase it up to the MRP without prior intimation. The medicine price revisions were not allowed as and when required, which distorted investment incentives.

10. This system of governance underwent a fundamental change. The Constitution (Eighteenth Amendment) Act, 2010 was promulgated on 20 April 2010. A as a result, MoH was abolished and a number of Federal Health responsibilities were placed under the jurisdiction of seven other ministries/Division.[4] According to the constitutional requirements, all the departments under the Federal Health ministry were to be absorbed gradually in the Provincial Health administration. This Included the Registration and Regulation of medicines.

11. After the decentralisation of the Health Ministry on June 30, 2011, there was no drug regulatory authority in the country until DRAP came into being in December 2012. DRAP consists of Chief Executive and seven members including member Registration, Medicines, Licensing, Pharmacy, Prices determination, Manpower and Legal Affairs. All matters relating to medicines e.g. preparations of medicines and issuance of license, price determination, issuance of quota, etc. are now being dealt with by the DRAP.

12. DRAP faced several problems in its effective functioning due to the late appointment of its head and delayed funding. This created problems for the pharmaceutical trade and industry, as their concerns could only be addressed through functioning of the drugs' registration board, licensing board and pricing committee. As a result, their applications remained pending at various levels. The impact is not quantified but as reported by the pharma industry, this created difficulty in exports. Now, the DRAP is functioning and the approval's process is going on smoothly but the increased fees and charges for various services are likely to affect drug prices.

13. The devolution of the MoH to the provinces did cast severe impact on the health sector including pharmaceutical trade because the provinces did not have the administrative mechanism in place to provide such services including funds, facilities and personnel to run such a system. As a result, Pakistan's pharmaceutical industry operated in a legal vacuum since 2010, when a constitutional amendment dissolved the ministry of health and shifted the responsibility to the provincial governments. Afterwards, the Ministry of National Health Services, Regulation and Coordination was created at the Federal level. DRAP functions under this ministry as per Drug Regulatory Authority Act, 2012.[5]

14. The provincial governments also regulate the sale of drugs. For instance, there are Punjab Drug Rules, 2007, which bar the drug store not appointing the pharmacist to sell a total one hundred and forty

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[3] Ministry of Health was headed by the Health Minister on a democratic level, while controlled by the Federal Secretary as well as the Director General Health on a bureaucratic level.

[4] Previously, MoH was responsible for provision of health services and to frame health policies, and to implement the same at a national level.

[5] http://www.na.gov.pk/uploads/documents/1352964021_588.pdf

five life-saving controlled/ narcotics/ potent drugs. Such rules promote fairness in trade as these are in line with internationally accredited standards to provide quality health services to promote rational drug usage.

15. It is noted however, that the Punjab Drugs Rules 2007 were prepared under section 44 of the Drugs Act 1976. [6] The rules were revised after a gap of 19 years, and the period of renewal of drug sale license was reduced from two to one year. The licensing authority will conduct inspection of premises, business procedure and other legal requirements reported by the inspector of drug of that area of jurisprudence. These regulatory requirements also have implications for the distribution chain as well as for about 50,000 medical stores in Punjab. The role of wholesalers and distributors had also not explained in the rules.

16. In Pakistan, there are three categories of a pharmacist: a) a qualified pharmacist is the one who has completed all pre-requisites to become a graduate from any pharmacy school; b) a registered pharmacist is the one who is registered by the concerned council or board of pharmacy; and c) a licensed pharmacist is the one who is qualified and registered by the concerned board or council of pharmacy, and the very same council or board granting him permission to practice as a pharmacist. In Pakistan, as profession of pharmacy has not been developed, therefore licensed pharmacist here means a pharmacist who has been granted by pharmacy council to supervise the sale and distribution of drug at retail drug store or pharmacy; as well as to supervise the manufacturing of drugs in pharmaceutical industries. In Pakistan, the qualification of pharmacist is the purview of the Institutions of Pharmacy recognized by Pharmacy Council. Registration of Pharmacist is the duty of Provincial Pharmacy Council and Grant of License to sale of drugs is also the purview of Provincial Pharmacy Council.[7] Accordingly, the medical store/pharmacy/pharmaceutical distributors have to take a license.

17. Besides the above, the manufacture of drugs is also protected under the Intellectual Property law of Pakistan. As far as Competition Act, 2010 is concerned, the crucial aspect to be tested is whether the protection vested amounts to pharma companies assuming a monopoly situation in the market, leading to huge price margins and substantial market power. The other anti-competitive issues in the pharmaceutical sector are centered on anti-competitive agreements and collusive practices along the supply and distribution chains. The following are the examples of the anti-competitive behavior by the manufacturer undertakings for appointing distributors, suppliers and dealers.

2.1 Territorial restrictions

18. The manufacturer undertakings divide the market into various industry specific sectors and appoint distributor(s) or dealer (s) to the defined industries/areas of the market. They either appoint sole distributor for the whole territory of the Pakistan or may divide the territory and appoint more than one distributors.

19. The manufacturer undertakings also grant the right to its sole supplier or distributor for executing any sub-distributorship agreement with the approval of the manufacturer undertakings. In such type of sub-distributorship agreements, the distributor or supplier further allocate the areas/zones to its sub-distributor and restricts them to take the fixed quantity of the products of the undertaking. In some cases, the undertakings want their dealers/ distributors to sell the product of the undertaking only, and in case of non compliance, there is a conditionality that the agreement of the distributor will be terminated. This type of restriction is also unreasonable. The Competition Commission of Pakistan directs the manufacturer

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6 http://www.pcdapakistan.com/wp-content/uploads/2013/04/PUNJAB-DRUGS-RULES-2007.pdf

7 Established under the Pharmacy Act, 1967.

undertakings to amend the clause of the agreement regarding the fixation of the prices and file exemption application of the said agreement under Section 5 of the Competition Act, 2010.[8]

2.2 Competing products

20. The manufacturer imposes restrictions on their distributors/dealers to sell the product of other undertaking or not to sell the similar product of any competitors. Such type of non-competition clause also restrict the competition and undertakings are obliged to comply the provisions of Section 5 of the Competition Act, 2010.

2.3 Legal Provisions dealing with vertical agreements

21. Under Section 4 of the Competition Act, 2010 states that no undertaking or associated undertakings shall enter into any agreement or, in the case of an association of undertakings, shall make a decision in respect of the productions, supply, distribution, acquisition of control of goods or the provision of services which have the object or effect of preventing, restricting or reducing competition within the relevant market unless exempted under Section 5.

22. To comply with the Competition Act, the undertakings once they execute any agreement in vertical level, are obliged to inform to the Commission either to seek advice on the drafted agreement whether it falls under the ambit of Section 5 of the Competition Act or to apply for seeking exemption from the Competition Commission of Pakistan (CCP).

23. To facilitate businesses, the CCP has issued the Voluntary Compliance Code (VCC). The objective of the code is to ensure that undertakings achieve the overall purpose of the Competition Act by establishing a formal internal framework to ensure compliance with the competition law, and encourage the adoption of a self-correcting mechanism. Few of the multinational undertakings have made guidelines with respect to the behaviour in the competition or added the corporate responsibility as well. "Behaviour in Competition" is designed to provide each employee with enough information about the competition law to recognise situations that require legal advice and to obtain it. While those undertakings, having the knowledge about the Competition Act submit their vertical level agreements to the Commission for seeking advice on it.

3. What kind of competition enforcement problems can arise along the distribution chain.

24. As a result of rigorous advocacy efforts, the undertakings have become aware the mandate of the Commission as per Competition Act, 2010. Most of the multinational pharmaceutical companies voluntarily provide the copies of the vertical Standard Agreement to the Commission for seeking exemption of the said agreement in template form. While the other companies do resist providing copies of their agreements to the Commission due to the apprehension that the Commission will somehow impede their business. For such a situation, the CCP's officers meet the concerned officers of the undertakings to resolve their apprehension by informing them about the legal compulsions.

25. The other competition enforcement problem that arises along the distribution chain is the reluctance of the undertaking to submit their distribution agreements. In some cases, when an exemption certificate is issued to the undertaking for the distribution of a specific product in the market, and later on the same company launches another product and executes an agreement with the same distributor appointed for the distribution of the former product. The undertaking resists providing subsequent

[8] Competition Act is available at: http://cc.gov.pk/index.php?option=com_content&view=article&id=60&Itemid=110

agreement because they already have the exemption certificate granted by the CCP. In this regard, the Commission has either to do correspondence with them or to have meetings with the concerned officer.

26. The enforcement of Competition law with respect to the Prohibited agreements is problematic. The Commission's directives given in the letter to the undertakings with respect to their vertical type of agreements are presumed by the undertakings as they have been involved in Cartel activities and they get engaged their legal counsel for making correspondence with the Commission for resolving the issue. The legal counsels are highly paid by the undertakings on the presumptions that they may get rid of them from the Competition law's provisions. In fact, their own legal advisors come to the concerned officer of the Commission for having the understanding of the enforcement of the relevant provisions of the law on the distribution agreements. The CCP also held seminars and meetings with stakeholders, group of companies, sectoral regulators, etc to make them aware of the mandate of Competition law. In spite of this, the undertakings try to escape themselves from the compliance of legal liability. However, this situation will improve with the passage of time as awareness about competition issues will grow.

27. To identify the relevant situations, the CCP's staff thoroughly monitors the newspapers for advertisements on "Distributors are required". The undertaking is then contacted to provide a copy of the agreement. It is explained to the that the purpose to call for information is not related to fixation of prices, as this in not the mandate of the CCP.

28. Another example of the enforcement of the competition law in distribution agreements, the undertakings do execute a number of identical agreements with distributors and request the Commission to grant them block exemption instead of template form of exemption. In this regard, the Commission has to clarify that there is a distinction between the template and block exemptions. Once the exemption certificate is granted, the undertakings request the Commission for grant of perpetual exemption, which is never granted by any Competition Authority.

4. In general how can the objective of ensuring an adequate and affordable supply of drugs be better achieved using competition?

29. Under section 4 of the Competition Act, no undertaking or associated undertakings shall enter into any agreement or, in the case of an association of undertakings, shall make a decision in respect of the productions, supply, distribution, acquisition of control of goods or the provision of services which have the object or effect of preventing, restricting or reducing competition within the relevant market unless exempted under Section 5. At the time of seeking exemption application, the undertakings give justifications with respect to the each and every anti competitive clause of their vertical type of prohibited agreements to the Commission. Section 9 of the Competition Act provides the criteria for seeking exemption in respect to agreement, which substantially contributes to:

- improving production or distribution,
- promoting technical or economical progress, while allowing consumers a fair share of all resulting benefit, or
- the benefits of that clearly out weigh the adverse effect of absence or lessening of competition.

30. As far as the improving production or distribution is concerned, where the undertakings restrict their distributors or dealers to distribute their products within certain designated areas, they provide justification to the Commission that in view of the limited resources available to the distributor, it becomes important to ensure that the operations of the appointed distributors, suppliers are confined to defined industries/areas of the market so that they can focus on the efficient and timely supply of product to

retailers/wholesalers/consumer in their respective areas. These restrictions are indispensable for the attainment of the required objectives as they substantially contribute to the improvement of the distribution of the products in every industry. This makes it possible for the distributors to focus on their respective industries/areas of the market and to employ all their resources to distribute and make available the relevant products to customers in the concerned industry in a timely and efficient manner.

31. As far as the other justifications are concerned, like the restrictions on the sale of the competing products, it enables the distributors to channel all their resources and efforts into distributing the products of the manufacturer. This improves the efficiency of the distribution and availability of the relevant product in the assigned territory. If the distributors deal in competing products, their resources and efforts will be divided and they will not be able to efficiently distribute the products of the manufacturer in the concerned industries/area of the market.

- In case of granting the Exclusive Trademark License Agreement by the undertaking based abroad to the local manufacturer, it is imperative for the licensor to ensure quality control of the products. These types of vertical agreements enable local manufacturing of the product, which would otherwise be manufactured aboard. The local manufacturing activity contributes to the national economy by way of taxes, jobs, skill development and technological improvements. Furthermore, they also reduce cost of products as compared to products manufactured abroad.

- Distribution of quality products in a smooth manner is also the advantage of the consumer, who can rely on a quality controlled source of the product.

- The advantages of the agreement for the national economy in general and consumers in particular clearly outweigh the adverse effect.

32. In view of the above, it is important to mention that the enforcement of the Competition law and the compliance of the undertaking by way of giving the justification to the Commission substantially contributes towards improving the distribution of the products and are economically justifiable as they benefit the end consumer as well.

5. Concluding remarks

33. In Pakistan's pharmaceutical sector, the competition has never been allowed to thrive; Government has been regulating the sector since a long time, ostensibly to check prices on the grounds of public interest/social welfare. Absence or inadequate enforcement of regulations and exploitation of lacunas in rules related to drug manufacturing is one of the key challenges faced by genuine manufacturers who face unfair competition. According to the WHO the sale of counterfeit drugs is a very serious issue in Pakistan.

34. Reduction in regulatory barriers can also promote competition, for this purpose, streamlining of processes at the provincial level is a necessary pre-requisite. There is also incidence of smuggling of drugs across borders, which also has implications for competition.

35. The competition concerns in the distribution agreements are generally corrected through advocacy and advice. However, considering the importance of pharmaceutical industry, the CCP has just initiated a detailed sectoral study to identify competition concerns and take remedial measures.