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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from India

-- Session III --

This contribution is submitted by India 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

-- India (Competition Commission) *--

1. CCI's involvement in the Indian Pharmaceutical Industry

1. The pharmaceutical sector is one of the vital sectors of the economy due its linkages with the provisioning of healthcare to people. Access to good healthcare has a key role in the growth and development of any country. Regulating and managing health care markets is, therefore, of utmost importance in most countries, for providing safe and affordable health care to people. The pharmaceutical sector is among the highly regulated sectors across the globe, regulated especially with respect to the prices, quality, availability and affordability of medicines, health insurance etc.

2. India is one of the biggest emerging markets of pharmaceuticals and therefore, the application of Indian competition law to the pharmaceutical industry is important, to deal with the competition issues concerning working of the pharmaceutical industry, both from the horizontal and vertical point of view.

3. The issues concerning competition in the pharmaceutical sector should be seen in the overall perspective of the regulation of the sector as a whole. There is no denying the fact that patents are a major source of market power. The patent system is at the core of the competition related issues between the branded and generic drugs. The TRIPS Agreement (1995), which set a common binding cornerstone agreement, mandated for the availability of both product and process patents. Hence, the 2005 Amendment to the Patents Act, 1970 reintroduced product patents for pharmaceuticals in India. As regards the public health safeguards, the provisions regarding the prevention of 'ever-greening' of pharmaceutical inventions and those for compulsory licensing under the Patent Act, 1970 are also of specific significance.

4. Many countries regulate drug prices directly or indirectly, and it is generally agreed that some form of price regulation is necessary as a public policy imperative and therefore, many countries also effectively regulate the prices, quality and availability of the drugs, including the patented drugs, through different means. In India, the Drug Prices Control Order issued under the Essential Commodities Act, 1955 has been in place since the 1970s and has been revised periodically. The prices are controlled both for the bulk drugs as well as for formulations by the National Pharmaceutical Pricing Authority (NPPA). The NPPA also monitors the prices of non-scheduled drugs, including the patented drugs. The Drugs and Cosmetics Act, 1940 is also one of the major regulatory norms based framework which regulate the sale, manufacture, distribution of drugs in India. The quality standards prescribed by various authorities also play an important role in the sale of pharmaceuticals.

5. The supply chain of pharmaceutical drugs is complex and includes a web of intricate practices followed by various agents involved in the chain, which at times may appear to be unfair and anti-competitive. For example, the absence of any statutory framework except the code of ethics of the Medical

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Council of India, to check the malpractice of giving gifts/financial benefits etc. by some pharmaceutical companies to health care professionals as an inducement to prescribe a particular type of medicine. Some of the existing legislations may also not have an adequate and fool proof mechanism regarding the regulation of some of the advertising/promotional material of drugs.

6. The pharmaceutical markets in India are growing at a rapid rate. The industry has also witnessed a high level of FDI as well as consolidation in the recent past, aided by the FDI policy of the Government.

7. The Indian pharmaceutical market has three types of substitutable drugs being sold. The first category includes drugs which are patented and have a brand name. The second category is of branded generic drugs which includes generics sold under a brand name. The third category is of generic – generic drugs, which are generics sold without a brand name.

8. The different kinds of agreements between enterprises would usually form a significant part of the competition assessment in any sector. It is generally agreed that not all agreements can be termed as anti-competitive and there are only certain agreements between the competing firms or between firms in the supply chain, which may constitute a violation of the competition law. The agreements can either be horizontal or vertical. The mergers and acquisitions happening in an economy may also, at times, raise anti-competitive concerns, which, therefore, are examined on an ex-ante basis.

9. The Competition Commission of India (CCI) has, in the past, dealt with a few cases of market distortions pertaining to the pharmaceutical sector and had also commissioned a sector specific study to examine competition related issues in the pharmaceutical sector [through the Centre for Trade and Development (CENTAD), in the year 2010]. The report submitted by CENTAD to the CCI on “Competition law and Indian Pharmaceutical Industry” is available on the CCI website¹.

10. The relevant legislation for enforcing competition in India is the Competition Act, 2002 (Act). The CCI has been established with the objectives of (a) promoting and sustaining competition in the market, (b) preventing practices having adverse effect on competition, (c) protecting the interest of consumers and (d) ensuring freedom of trade. The Act prohibits/regulates three type of activities i.e. anti-competitive agreements (section 3), abuse of dominant position (section 4) and regulation of combinations (sections 5 and 6).

11. *Section 3 of the Act deals with the anti-competitive agreements.* According to the Act, an agreement includes any arrangement, understanding or concerted action entered into between parties. An anti-competitive agreement is an agreement having appreciable adverse effect on competition (AAEC). Anti-competitive agreements as per the provisions of Section 3(3) of the Act, include agreement to limit production and /or supply; agreement to allocate markets; agreement to fix prices and bid rigging or collusive bidding. Depending on the facts of the case, the agreements which also fall under the category of anti-competitive agreements as per the provisions of Section 3(4) of the Act include conditional purchase/sale i.e. tie-in arrangement; exclusive supply/distribution agreements; resale price maintenance; and refusal to deal.

12. *Sections 5 and 6 of the Act deal with regulation of combinations (mergers and acquisitions).* Broadly, combination includes acquisition of control, shares, voting rights or assets, acquisition of control by a person over an enterprises where such person has control over another enterprises engaged in competing business, and mergers or amalgamations, between or amongst enterprises where these exceed the thresholds of assets or turnover as specified in the Act. If the combination causes or is likely to cause

¹ CENTAD (2010), “Competition Law and Indian Pharmaceutical Industry” Report submitted to the CCI, available at <http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf>

AAEC within the relevant market in India, it is prohibited or can be modified by the Commission. Further, for the purpose of determining whether a combination would have the effect of or is likely to have an AAEC in the relevant market, the Commission has to consider the factors provided under Section 20(4) of the Act.

2. Vertical Restraints

13. It is observed that in its application to the pharmaceutical sector, section 3(3) of the Act may prove to be useful in dealing with cartel like agreements or cases of bid-rigging and more specifically with respect to the supply chain. The vertical restraints could be the agreements under section 3(4) of the Act. As regard its application to the pharmaceutical sector, the pharmaceutical supply chain may include practices that could be regarded as vertical restraints. Section 3(4) of the Act states that “any agreement amongst enterprises or persons at different stages or levels of the production chain in different markets, in respect of production, supply, distribution, storage, sale or price of, or trade in goods or provision of services, including –

- Tie-in arrangement;
- Exclusive supply agreement;
- Exclusive distribution agreement;
- Refusal to deal;
- Resale price maintenance;

14. shall be an agreement in contravention of sub-section (1) if such agreement causes or is likely to cause an appreciable adverse effect on competition in India.”

15. Reasonable conditions as may be necessary for protecting intellectual property rights (IPRs), as prescribed under section 3 (5) of the Act, would not constitute anti-competitive agreements.

16. In the case of pharmaceuticals, the questions regarding the relevant market may also be pertinent, like the physical characteristics test as to whether the drugs have the same dosage and delivery forms, such as injectable, liquid, capsule, tablets; the end use test, like if the drugs have the same frequency or strength of dosage; distinction between the prescriptions and the OTC drugs; whether the drugs are currently marketed or in the development stage; whether the drugs have same specific chemical compounds which treat a disease with the same mechanism of action on the body etc. The factors for defining the relevant market have been provided under section 19(6) and 19(7) of the Act.

3. Vertical links in the Pharmaceuticals Sector in India

17. As per report of the Department of Pharmaceuticals, Government of India, a majority of the Indian pharmaceutical companies are engaged in the production of formulations. The sector is also dominated by small scale firms in terms of the number of units. It is observed that the Indian pharmaceutical industry broadly functions under a three tier structure. The large MNCs operate as originator drug companies and generic companies, along with the large Indian generic companies. In the second tier, the medium and small scale industries are also engaged in the production of branded generics and contract manufacturing related activities. In the third tier, most of the units in the small scale sector are engaged in production of generic-generic medicines.

18. The anti-competitive practices, both horizontal and vertical, in the supply chain of pharmaceutical drugs, unethical behaviour as practiced by doctors, hospitals, pharmacies as well as by the pharmaceutical firms can take the form of exclusive supply and distribution agreements, market allocation

and cartelisation etc., which can adversely affect the consumer. The existence of competition issues along with the nature of the pharmaceutical sector makes it imperative for the sector regulators to remain vigilant. The CENTAD Report and other studies also point out that the pharmaceutical companies not only approach doctors but also agencies such as hospitals, pharmacies and their associations, to expand their sales. The blurring boundaries of what constitutes fair practice on issues involving the drugs promotion may also be a subject of debate. The pharmaceutical industry also spends heavily on advertising of their drugs in widely circulated journals meant for clinical specialists or general practitioners. The doctors in medical institutions may also be influenced by the pharmaceutical companies as they are in a position to further influence several new entrants in the field. The pharmaceutical companies may also be pressurised at times to sponsor/finance the programmes/conferences for doctors. A link between the doctors and the medical laboratories is also at times established. The CENTAD report points out that though there could be various voluntary resolutions passed from time to time by the industry associations for ethical drug promotion, such measures currently, have largely remained ineffective to deal with the anti-competitive practices in the pharmaceutical market in India. There could also be a possible link between hospitals, especially the private hospitals and drug manufacturers, which may affect the patients adversely as most of the hospitals in the private sector are seen to have their own pharmacies. Sometimes, the pharmaceutical companies may also agree to finance the setting up of small hospitals in return for the sole right to set up the hospital pharmacy.

4. Cases Examined by the CCI

19. The Commission has also dealt with a few cases involving anti-competitive practices of the trade associations in the pharmaceutical sector and found violation of Section 3(3)/Section 3(4) of the Act in these cases². The main issues/allegations involved in these cases mostly related to:-

- Non appointment of a stockist or a wholesaler from amongst the non-members of the respective trade association;
- Requirement of a No Objection Certificate (NOC) from the association for appointment of stockist or wholesaler. These NOCs pertained to the following:
 - Associations formulated guidelines for its members to obtain permission/NOC before which they could become a stockist of a particular company;
 - Associations forced the stockists not to sell the products of a pharmaceutical company unless NOC was obtained by them from the existing stockists of that pharmaceutical company operating in that area.
- Associations fixed trade margins below which the stockists were not allowed to sell;

² The following are the major cases:

- Varca Druggist & Chemist & Ors. Vs. Chemists and Druggists Association, Goa – Case No. MRTPC 127/2009/DGIR4/28, decided on 11th June, 2012, available at: <http://cci.gov.in/May2011/OrderOfCommission/4-28%20Main%20Order.pdf>.
- Vedant Bio Sciences vs. Chemists & Druggists Association of Baroda – Case No. C-87/2009/DGIR, decided on 5th September, 2012, available at: <http://cci.gov.in/May2011/OrderOfCommission/c872009.pdf>.
- M/s Santuka Associates Pvt. Ltd. Vs. All India Organisation of Chemist and Druggist (AIOCD), Organisation of Pharmaceutical Producers of India (OPPI) and Indian Drug Manufacturers Association (IDMA) – Case No. 20/2011, decided on 19th February, 2013, available at: <http://cci.gov.in/May2011/OrderOfCommission/202011.pdf>
- M/s Sandhya Drug Agency Vs. ADDA, BDDA, AIOCD, IDMA, OPPI, Case No. 41/2011, decided on 9th December, 2013, available at: <http://cci.gov.in/May2011/OrderOfCommission/27/412011.pdf>.
- Peeveear Vs. AIOCD and Janssen, Case No. 30/2011 decided on 9th December, 2013, available at: <http://cci.gov.in/May2011/OrderOfCommission/27/302011.pdf>.

- The distributors/retailers were not allowed to give discounts to customers;
- Compulsory approval from association for introduction of drugs in the market- Product Information Service (PIS); and
- Requirement for routing bids for supply of drugs to the government and the hospitals through authorized stockist only.

20. The Commission, in these cases, held that the said practices of the associations were anti-competitive in nature and therefore, ordered the associations to cease and desist from engaging in such practices and file an undertaking to the effect that such practices have been discontinued. The Commission also imposed penalty/fines in some of these cases.

21. The CCI has also dealt with pre-merger notification(s) in the pharmaceutical sector, after the enforcement of the merger regime in India with effect from 1st June, 2011³, such as the acquisition of Agila Specialties Pvt. Ltd. by Mylan Inc., acquisition of Betalactum API business along with R&D facility of Orchid Chemicals and Pharmaceuticals Ltd by Hospira Healthcare India Pvt. Ltd etc. All these pre-merger notifications involved companies engaged in manufacturing of pharmaceutical products and were approved by the Commission within a period of 30 days as it was observed that the parties had either limited presence in domestic market in India or there was insignificant overlap between the products offered by combining parties in India. In two of the above notices, the Commission gave its observation with respect to incorporation of non-compete clause in the agreement(s) pertaining to combination and noted that, *“non-compete obligations, if deemed necessary to be incorporated, should be reasonable particularly in respect of (a) the duration over which such restraint is enforceable; and (b) the business activities geographical areas and person(s) subject to such restraint, so as to ensure that such obligations do not result in an appreciable adverse effect on competition.”* The Commission also accepted the proposal of the parties in these cases to modify the non-compete clause to reduce the period as well as scope of the non-compete obligation so that the restrictions imposed are reasonable.

22. Section 49(3) of the Act, which deals with Competition Advocacy states that “the Commission shall take suitable measures for the promotion of competition advocacy, creating awareness and imparting training about competition issues.” In light of the mandate of the Act, the Commission imparts great importance to the role of advocacy in the pharmaceutical sector for creating awareness and sensitizing the private and public agencies, including the medical practitioners and other actors in the supply chain, about the competition related issues.

³ Major combination cases are:

- Orchid Research Laboratories Ltd., Orchid Chemicals and Pharmaceuticals Ltd. Merger, Case No. C-2012/02/31, decided on, 29th February, 2012, available at: <http://cci.gov.in/May2011/OrderOfCommission/CombinationOrders/ORLfeb12.pdf>.
- Acquisition of shares in Arch by Mitsui Case No. C-2012/08/73, , decided on 19th September, 2012, available at: <http://cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2012-08-73.pdf>
- Acquisition of the Transferred Business by Hospira for Orchid, Case No. C-2012/09/79, decided on 21st December, 2012, available at: <http://cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2012-09-79.pdf>.
- Mylan’s acquisition of Unichem Laboratories Limited, Case No. C-2013/04/119, decided on 6th June, 2013, available at: <http://cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2013-04-119.pdf>.
- The acquisition of Agila Specialties Private Limited by Mylan, Case No. C-2013/04/116, decided on 20th July, 2013, available at: <http://cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2013-04-116.pdf>.