

**Unclassified**

**DAF/COMP/WD(2014)72**

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

**28-May-2014**

**English - Or. English**

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

**GENERIC PHARMACEUTICALS**

**-- Note by the Delegation of India --**

**18-19 June 2014**

*This document reproduces a written contribution from the Delegation of India submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.*

*More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.*

**JT03358330**

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## ROUNDTABLE ON GENERIC PHARMACEUTICALS II\*

### 1. Introduction

1. The pharmaceutical industry constitutes the core of the public health system of a country due to its direct impact on the health of the people. Access to good healthcare has a key role in the growth and development of any country. Therefore, the pharmaceutical sector is among one of those regulated sectors across the globe where the role of the competition agencies becomes too crucial in maintaining competition in the pharmaceutical market.

2. The Indian pharmaceutical industry is one of the largest and most advanced among the developing countries where the role of the generic medicines is very crucial in reducing total healthcare bill not only for an individual but also for the economy as a whole as these are sold at a fraction of the price of the innovator product. The generic entry after the expiry of the patent is a major reason for drastic fall in prices of the medicines.

### 2. Recent Developments in Competition Enforcement

3. The provisions of the Competition Act, 2002 (Act) related to anti-competitive agreements and abuse of dominance came into force with effect from 20.05.2009 and those related to mergers and acquisitions from 01.06.2011. Since then the Competition Commission of India (Commission) has also dealt with some cases relating to the pharmaceutical industry. Most of these cases related to anti-competitive practices prevailing in the distribution chain wherein the Commission found violation of Section 3(3) and Section 3(4) of the Act by the trade associations of the chemists and druggists. The Commission has also dealt with some merger and acquisition notifications filed under the provisions of the Act.

4. As is generally understood, in the pharmaceutical sector, the determination of the relevant product market starts from the therapeutic classification of medicines where the molecules, classified under one therapeutic category, are generally considered to be similar or substitutable to each other and are used to treat the same indication and may, therefore, constitute a separate relevant product market. However, in some cases the prescribing doctors may prefer one molecule over the other or may not consider all the molecules within the same therapeutic category/group as substitutes to each other, depending upon various factors including the condition of the patient, mode of administration of the dosage form, frequency of dosage, mechanism of action, molecular composition etc.

5. A unique feature of the pharmaceutical market which may also be important from the point of view of assessment of the competition is that the choice of medicine as well its brand is generally

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\* The document is submitted in response to a call for papers contribution for a committee roundtable on 'Generic Pharmaceuticals II' at the forthcoming OECD Competition Committee meeting in June, 2014. The views expressed in the document have been researched and analyzed by the officers of the Competition Commission of India and do not represent the views of Government of India.

determined by the physicians who may have particular interest in prescribing one brand of medicine over the other. In India, the majority of the population may be unaware of the substitutes which could be the bioequivalent of the prescribed drugs but may be available in the market at a cheaper rate. It restricts the ability of the ultimate consumer to exercise choice in selection of a product which he has to buy. This information asymmetry also at times may result in creating an artificial demand for the brands prescribed by the doctors despite the availability of other cheaper substitutes available in the market. In this scenario, there is a probability that the manufacturers of the generic drugs/ lesser known branded generics which do not have strong marketing among the doctors could be forced out of the market.

6. Recently, another major development in India is the issue of the National Pharmaceutical Pricing Policy, 2012 (NPPP) and the Drug Price Control Order 2013, by the Government with the objective of promulgating principles for pricing of the essential drugs as laid down in the National List of Essential Medicines, 2011 (NLEM), issued by the Government. The current policy of the Government has not only reduced the leeway available to the pharmaceutical manufacturers to price their products as per their choice but at the same time provided motivation to the manufacturers to compete not only on the basis of the price but also on the basis of quality of drugs. NPPP, 2012 introduced two major changes in the pricing of the drugs to the effect that the regulation of prices of drugs under NPPP is none on the basis of regulating the prices of the formulations through the market based pricing, as compared to the principle of regulating the prices of specified bulk drugs and their formulations through cost based pricing as adopted in the previous policy. Under the new Drug Price Control Order, the price regulation would be on the basis of 'essentiality' of the drug as laid down in the National List of Essential Medicines, 2011 (NLEM), which could be modified from time to time, in public interest. The revision of NLEM for the purpose of price control is a dynamic process and any drug can be added in NLEM in public interest, under the new Drug Price Control Order, on the recommendation of the respective ministry in the Government.

7. As per the new policy, the prices of the drugs not covered under the NLEM would be monitored on regular basis, and where such price increase is at a rate of above 10 percent per annum, the Government would be empowered to have the price of these drugs reduced to below this limit for the next 12 months.

### **3. Pharmaceutical Companies under the Competition Scrutiny**

#### **3.1 Patent:**

8. The protection of the patents is an essential feature of the pharmaceutical industry. Since the innovation of pharmaceuticals is a high-risk and high-cost business and imitation, on the contrary, is a low-risk and low cost business, it is universally accepted principle that protection against imitation must be provided in order for the innovation to exist. It is often argued that if no protection is provided against imitation, the high cost of R&D would discourage companies from investing money in innovation, with the consequence that certain medicines would never be able to reach the market. Thus, the function of a pharmaceutical patent is to provide a sufficient degree of protection to ensure that the new drugs are developed, however, without making it difficult for the competitors to enter the market.

9. The grant of patent may also create a monopoly in the form of exclusive rights. In the long run, however, the IPR monopoly is not considered to be in conflict with the competition law, as the object of both is to promote innovation and competition. It is in the overall interest of the society that the innovation is protected, however, any abuse of this protection by the innovator company for gaining undue benefit to the detriment of the patients, needs to be addressed both under the patent laws and the antitrust laws of any country.

### **3.2 Unilateral Practices and Abuse of Patents:**

10. The unilateral anti-competitive practices generally result from the abuse of its dominant position by an enterprise. As discussed above, the determination and analysis of relevant market in a case involving pharmaceutical sector is a complex process. Although the abuse of patents could be addressed under the ambit of the Competition Act, 2002, (Act), however, the Commission is yet to receive any case involving abuse of patents for restricting competition in the pharmaceutical market. In this context it is also noticed that evergreening of patents could at times be considered as one such abuse which may be resorted by the companies to extend the term of protection of their products shortly before the patent is about to expire. The evergreening of patents also results in delay of introduction of generic medicines as substitute of the patented product, thus restricting competition. The effect is to 'reset the clock' on the patentee's protection period, excluding the potential competitors from the marketplace for another full term, thus affecting public health by way of delaying entry of the cheap generics.

11. The Supreme Court of India has also recently held with respect to the application of Section 3(d) of the Patents Act, 1970 that mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance is not an invention and thus not patentable. In this case, the appeal case filed by Novartis against the rejection of patent for its anti-cancer drug sold under brand name "Gleevac" was rejected by the Hon'ble Supreme Court. The judgement of the Supreme Court of India, therefore, left the door open for the true and genuine inventions but at the same time, aimed to check an attempt at repetitive patenting or extension of the patent term on spurious grounds.

12. Another important tool for addressing the problem of abuse of patents in the pharmaceutical industry is issue of the compulsory license by the Government without the consent of the patentee. The Indian Patent Act has provisions regarding issue of the compulsory license to a third party. Generally, the grounds on which a compulsory license can be requested by an interested person after the expiry of three years of granting of the patent are: (a) reasonable requirements of the public have not been satisfied; (b) patented invention is not available to the public at a reasonably affordable price and (c) the invention has not worked in the territory of India. The compulsory license is a legal instrument designed to force the intellectual property owners to license out their statutorily granted right to the interested third parties, capable of manufacturing the patented product, at a cheaper prices. The main objective behind the compulsory licensing is that the Government ensures that the public in general are not denied drugs due to their pricing being too high. In March 2012, the Indian Patens Office had granted its first compulsory license, for the manufacture and sale of Bayer's patented drug Nexavar to Natco Pharma Limited.

### **3.3 Anticompetitive Agreements:**

13. The Competition Act 2002 (Act) recognises the importance of IPR, including the patents. While Section 3 of the Act prohibits anti-competitive agreements, sub-section (5) of Section 3 states that nothing contained in this section shall restrict "the right of any person to restrain any infringement of or to impose reasonable conditions, as may be necessary for protecting any of his rights, which have been or may be conferred upon him inter-alia under the Copyright Act, 1957 and the Patents Act, 1970. The unreasonable conditions such as 'pay-for-delay' imposed by an originator, in order to protect his patent may, therefore, appear to be anti-competitive under the Competition Act 2002. An unfair or discriminatory condition, when imposed by a dominant player i.e. the originator, may also amount to abuse of dominant position under Section 4 of the Competition Act, 2002. As the manufacturers of the patented drugs can have a downside due to the generic entry, it can greatly impact their market share and profits. Hence, there is a strong motivation to prevent the market entry of the generics by the originator. There is a likelihood that the patentee can respond conventionally or conduct itself in an anti-competitive fashion in such a condition.

14. Though the Competition Commission of India has not yet received any complaint in relation to pay for delay agreements or any other anticompetitive agreement of such nature, however, the Commission is empowered to take cognizance of any such matter *suo-moto*, if anything comes across to its knowledge.

15. Till date, the Competition Commission of India has dealt with few cases involving anti-competitive practices of the trade associations in the pharmaceutical sector and has found violation of the provisions related to anti-competitive agreements under the Competition Act, in some of these cases. The primary allegations involved in these cases were generally related to the appointment of stockists or wholesalers from amongst the non-members of the respective trade association; requirement of 'no objection certificate' from the associations for appointment of a stockist or a wholesaler; trade margins fixed by the associations, below which the stockists were not allowed to sell; discounts to customers; requirement for routing bids for supply of drugs to the government and the government hospitals through authorized stockist only, etc. The Competition Commission of India in most of these cases held that the said practices of the associations were anti-competitive in nature and, therefore, ordered the respective associations to cease and desist from engaging in such practices and also file an undertaking to the effect that such practices have been discontinued. The Commission also imposed penalty in some of these cases.

#### **3.4 Mergers and Acquisitions (Combinations):**

16. Since the enforcement of the provisions of the combinations under the Competition Act, 2002 with effect from 1<sup>st</sup> June, 2011, the Competition Commission of India has also dealt with few cases of mergers and acquisitions in the pharmaceutical sector. These pre-merger notifications which involved companies engaged in manufacturing of pharmaceutical products were approved by the Commission within a period of 30 days in phase I itself.

17. In some of these combination notices pertaining to the pharmaceutical sector, the Commission also gave its observation with respect to the incorporation of non-compete clause in the agreement(s) and noted that non-compete obligations should be reasonable particularly in respect to the duration over which such restraint is enforceable and 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 agreement to reduce the period as well as the scope of the obligation so that the restrictions imposed were reasonable.

18. Recently, the Commission approved the acquisition of branded domestic formulations of one company by the other wherein both these Indian companies were engaged in the business of manufacturing, distribution and sale of branded generic medicines. For the purpose of the competition analysis of the proposed combination, various pharma products of these companies were classified on the basis of their therapeutic category i.e. the intended use of the drugs/formulations, as prescribed by AIOCD (All India Organisation for Chemists and Druggists). The horizontal overlap between the products of the two companies was assessed both at the therapeutic category and molecule level and it was noted that the proposed combination is not likely to result in any appreciable adverse effect on the competition in India.

#### **4. Looking forward:**

19. The provisions of the Competition Act, 2002, thus can deal with the anti-competitive practices prevailing in the pharmaceutical market both in the product as well as the distribution side. However, there is a need for greater awareness among the market participants including not only the generic and innovator pharmaceutical companies but also the distributors, doctors, consumers and the regulatory agencies, etc about the importance of competition in the market and the requirement of the Act.

20. Empowering the end consumers who are the patients by increasing their awareness about the availability of equally effective but cheaper generic medicines in the market will increase choices available to the consumers, reduce their total healthcare bills and will also promote competition between the generic companies.

21. Under the provisions of the Competition Act, 2002 the Commission is required to take suitable measures for the promotion of competition advocacy, creating awareness and imparting training about the competition issues. The Commission therefore, also give due importance to the role of advocacy in the pharmaceutical sector for creating awareness among the market participants about the competition related issues. This will not only create awareness among the market participants including the consumers about their rights as well as about the bodies for enforcement of their rights.

22. The architecture of the Act also allows the Commission to take up the matter suo-moto as and when any possible violation of the provisions of the Act is reported to the Commission.