

Pharma & Healthcare Update

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PHARMA MANUFACTURERS BREATHE EASY: COMPETITION REGULATOR TREATS OLD AILMENT AFFECTING THE INDUSTRY

INTRODUCTION

On February 19, 2013, the Competition Commission of India (“**CCI**”) passed a significant order, which has the potential of re- defining the way drug manufacturers and importers in India (“**Drug Manufacturers**”) market their products domestically. In the reasoned order, the CCI has held certain practices of All India Organization of Chemists and Druggists (“**AIOCD**”) to be violative of the Competition Act, 2002 (“**Competition Act**”) and inter-alia ordered the organization to cease and desist from engaging in those practices. It was recently reported that the AIOCD has issued a circular to all its members to comply with the CCI order.¹

Considering the importance of the judgment on distribution of drugs in India, in this hotline with have analysed the judgement and the consequences arising therefrom.

BACKGROUND

The case was instituted on the complaint of Santuka Associates Pvt. Ltd. (“**Informant**”), being a clearing and forwarding agent (a key player in the distribution chain) of various pharmaceutical companies at Cuttack, including USV Ltd. (“**USV**”). The Informant was member of the Cuttack District Chemists and Druggists Association (“**CDDCA**”). The Informant was aggrieved by a development surrounding the potential revocation of its arrangement with USV by virtue of directions of the AIOCD. Consequently the Informant approached the CCI with a prayer to restrain AIOCD from abusing its dominant position to threaten and coerce any drug manufacturer in India, including USV, to terminate its arrangements with Informant.

The CCI found a prima facie case in the complaint to investigate the matter further and ordered the Director General (“**DG**”) to investigate the activities of the AIOCD and its affiliates. Interestingly, in the course of hearing of the matter, the Informant applied to the CCI to withdraw its complaint. The Commission held that once an investigation has been ordered by CCI, then withdrawal of complaint will neither affect the inquiry of the DG nor disable the CCI from hearing the matter based on the report of the DG.

The opposite parties to the Informant in this proceeding were AIOCD, Organisation of Pharmaceutical Producers of India (“**OPPI**”) and Indian Drug Manufacturers’ Association (“**IDMA**”). The OPPI and IDMA are associations of drug manufacturers, and were made parties to this proceeding because of an allegation of the Informant that OPPI and IDMA had entered into Memorandum of Understanding (“**MoU**”) with AIOCD which enabled AIOCD to carry out anti-competitive practices.

The controversial practices of the AIOCD relevant from the point of view of competition law are discussed next.

AIOCD AND ITS PRACTICES

The AIOCD is a national level association of chemists and druggists, active since 1975 and registered under the Societies Registration Act, 1909. It functions in an established hierarchy of chemists and druggist association, which works as follows:

At the bottom of the pyramid are ‘district- level chemists and druggists association’ (“**DLA**”) which have chemists and druggists of district as its members. The middle of the pyramid comprises of ‘state- level chemists and druggists association’ (“**SLA**”) to which all district- level chemists and druggists associations in that state are affiliated. Finally, at the top of the pyramid is AIOCD, to which all SLAs are affiliated. The decisions of the AIOCD percolate the pyramid and are enforced through SLAs and DLAs.

As per the AIOCD website, the association has over 750,000 chemists and is the “only true representative body of the pharmaceutical trade in India”.

Over the years, AIOCD has functioned as a single- window for distribution- related negotiations between Drug Manufacturers and chemists and druggists throughout India. The following practices of AIOCD, now on record of CCI, are worth discussing:

1. **Requirement of NOC or LOC from SLAs** Before appointment of any clearing & forwarding agent, super-distributor, distributor or stockist in a state, the drug manufacturer has to apply to SLA of that State requesting for a “No Objection Certificate” (“**NoC**”) or “Letter of Consent / Co- operation” (“**LoC**”) from it. In other words, a drug manufacturer cannot appoint any person for distribution of its drugs at any level in the distribution chain unless the said person has a NoC or LoC from the SLA of the State. The SLA issues NoC / LoC as per its discretion or

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based on the recommendation of the DLA (depending upon the level of the distribution). Such NoC / LoC is usually issued to only one person at a particular level in the distribution chain and that person is required to be appointed by the drug manufacturer. Needless to say, it is a pre- requisite to be a member of the DLA to be considered as a choice for NoC or LoC.

Until the end of 2011, this arrangement held water by virtue of MoU entered by AIOCD with OPPI and IDMA to that effect ("**Controversial MoU**"). In 2011, both OPPI and IDMA discontinued their Controversial MoU with AIOCD but the practice continues as an industry standard owing to threat of all- India boycott by AIOCD.

2. Requirement of payment for Product Information Service

All SLAs publish a Product Information Services ("**PIS**") bulletin in periodic intervals, which contains description of new medicines to be launched in market. The drug manufacturers are charged a one- time fee for publication of an entry containing description of their medicine in the bulletin. It is an unwritten by- law of the AIOCD that a medicine which is not described in a PIS bulletin published by a SLA will not be sold in the market of the State to which the SLA belongs. Consequently, all drug manufacturers are stretched to ensure an entry into every SLA's PIS bulletin before a product launch. Many a times, drug manufacturers face difficulty in launching a product if a SLA demands exorbitant sum for publication of to- be launched medicines in its PIS bulletin.

The requirement for payment of fees for publication in PIS bulletins was also agreed upon as a term in the Controversial MoU. It continues to survive today as an industry practices for reasons same as that for survival of requirement of NoC / LoC stated above.

3. Fixation of Trade Margins

There exists a uniform whole sale and retail margin ("**Trade Margin**") for sale of all drugs in India. The Trade Margin for drugs whose prices are controlled by the Central Government through Drug Price Control Order, 1995 ("**DPCO**") are fixed by law. The Trade Margins of uncontrolled drugs are, however, fixed by AIOCD. It has become industry practice for drug manufacturers to offer 10 % margin to whole- sellers and 20% margin to retailers for sale of their drugs. No whole- seller or retailer will offer to settle for a margin lesser than the fixed margin.

The fixation of Trade Margins for uncontrolled drugs was also agreed upon in the Controversial MoU. As is true with practices above, the Trade Margins continue to be fixed post expiry of the MoU for the same reasons as are applicable to other controversial practices.

4. Boycott from sale of medicines at regional, district, state or national level

In the past, AIOCD and its affiliate associations have boycotted Drug Manufacturers to ensure that the requirements of NoC, publication in PIS bulletin and uniform Trade Margins are adhered to. Many a times, AIOCD and its affiliates have issued letters to Drug Manufacturers directing them to call back the goods dispatched to certain stockists, who are not members of the association or who have indulged in anti- associational activities.

COMPETITION LAW ANALYSIS

Applicable Law: Any agreement that restricts or is likely to restrict the competition will attract provisions of Section 3 of the Competition Act. Section 3(3) of the Act is attracted when, inter alia, enterprises or association of enterprises, engaged in identical or similar trade of goods and provisions of services, enter into an agreement, or carry on a practice, or take a decision, for the purpose of directly or indirectly fixing prices, limiting output or sales, or sharing markets or customers. All such agreements, practices and decisions are presumed to be anti- competitive. Where after inquiry the CCI finds that any such agreement is in contravention of the provisions of the Competition Act, it has the power under section 27 of the Competition Act to inter-alia to direct the defendant to desist from carrying such act and impose a penalty on the defendant up to 10 % of the average of its annual turn- over for the last three financial years.

AIOCD as an Association of Enterprises: The CCI noted that the controversial practices of the AIOCD can be tested for violation of Section 3(3) of the Competition Act since AIOCD is an association of enterprises engaged in identical or similar trade of goods or provision of services. All SLAs are affiliated to AIOCD and all DLAs are affiliated to respective SLAs and union territory associations. The CCI observed "It can be inferred that that members / constituents of AIOCD (though indirectly) are stockist and retailers of pharmaceutical companies who are engaged in the supply of Pharma products to the consumers. Therefore, such members / constituents fall squarely within the definition of 'enterprise' provided in the Act". CCI goes on to hold that "AIOCD, being association of constituent enterprises, is taking decisions relating to distribution and supply of pharma products on behalf of its members who are engaged in similar or identical trade of goods and that such practices carried on, or decisions taken by AIOCD as an association of enterprises are covered within the scope of Section 3(3)."

Whether requirement of NOC or LoC from SLAs is anti- competitive : DG's submission: The requirement of NoC or LoC clearly limits the market / supply and thus the conduct of AIOCD and its affiliates, is anti- competitive.

AIOCD's response: The practice of obtaining NoC from the SLAs was evolved to curb the proliferation of large number of stockist and whole sellers at the cost of small retailers. Such NoC has led to a balanced relationship between the large pharmaceutical companies and small retailers.

CCI's judgement: The CCI found overwhelming evidence which proved that normally, without obtaining NoC from AIOCD (acting through respective State and District Associations) no stockist can be appointed. Therefore, it held that the requirement of NoC attracts Section 3(3) of the Act as AIOCD and its affiliates create restraint on freedom of trade on account of NoC, which has the effect of limiting or controlling market supply.

Whether requirement for payment for Product Information Service is anti- competitive DG's submission: Any attempt on part of the members of AIOCD and / or its affiliates to delay or withhold any PIS publication (also understood as PIS approval) on any ground which limits or controls supply or market thereof has to be treated as kind of boycott, thus attracting the provisions of Section 3(3) of the Competition Act.

AIOCD's response: The requirement of PIS publication is actually to prevent entry of spurious / doubtful drugs of those purchased from unauthorized sources. This in consonance with the Mashelkar Committee's recommendation for chemists and pharmacists to act as "watch dogs" through their Associations.

CCI's judgement: The CCI found overwhelming evidence which proved that payment of prescribed charges for

publication in the PIS bulletin was a sine qua non (without which nothing), in absence of which new products were not allowed to be introduced in the distribution channel. Therefore, it held that actions of AIOCD and its affiliates delaying or withholding PIS approval is in violation of Section 3(3).

Whether fixation of Trader Margin is anti- competitive : DG's submission: The fact that trade margins have been decided for the whole sellers and retailers operating in pharmaceutical market would mean that the prices of the drugs are not getting fixed by the interplay of market forces. The minimum trade margins are part of horizontal agreements amongst the members of the trade and industry because of the Controversial MoU. There is hardly any competition between one retailer and the other, resulting in drugs being generally sold on MRP. Thus, fixation of Trade Margins has directly or indirectly led to the determination of the purchase or sale prices of drugs in market, which is violative of the Competition Act.

AIOCD's submission: The Trade Margin of decontrolled formulations has been specified in law itself. The DPCO paragraph which describes the Trade Margin for controlled drugs also mentions Trade Margin for decontrolled drugs.

CCI's judgement: The CCI found overwhelming evidence which proved that the Trade Margins were fixed and followed as a practice. It observed that Trade Margin of unregulated drugs was not specified in DPCO as claimed by AIOCD. It further observed that in a scenario where Trade Margin is not fixed, competition amongst the retailers will force them to reduce their trade margins resulting into sale of drugs at prices even below the MRP. Therefore, it upheld the DG's view that fixation of Trade Margins had the effect of directly or indirectly determining the purchase or sale price of drugs in market and such a practice was in violation of Section 3(3).

Whether boycott from sale of medicines at regional, state and or national level was anti- competitive : DG's submission: The act of boycott has the effect of limiting or controlling the supplies, distribution, availability of drugs which causes appreciable adverse effect on competition for pharma companies and non- availability to the consumers.

AIOCD's response: AIOCD had no response to DG's submission.

CCI's judgement: The CCI found overwhelming evidence which proved that AIOCD and its affiliates threatened pharma companies of boycott and, at times, actually boycotted them, to enforce its decision connected to various controversial practices described above. It held that such boycott results in denial of market access to pharma companies and non- availability of drugs to customers. Therefore, the act of boycott by AIOCD and its affiliates violated Section 3(3) of the Act.

In its final order, the CCI ordered AIOCD to:

1. (along with its affiliates) Cease and desist from the controversial practices found to be anti- competitive by the CCI.
2. File an undertaking that the practices carried on by it and its members regarding grant of NOC for appointment of stockist, fixation of trade margins, collection of PIS charges and boycott of products of pharmaceutical companies have been discontinued within 60 days from the date of receipt of the order by it.
3. Issue a letter to OPPI, IDMA and USV that there is no requirement of obtaining an NOC for appointment of stockist and the pharma companies, stockist, whole sellers were at liberty to give discounts to the customers.
4. Issue a circular / letter to all chemists and druggist associations that they are free to give discounts to the customers.
5. Issue circular that PIS charges were not mandatory and PIS services could be availed by manufacturers / pharmaceuticals firms on voluntary basis.
6. Pay a penalty of INR 47,40,613 within 60 days from the date of receipt of copy of the order by it.

It is worth mentioning here that the DG had accused the OPPI and IDMA of collaborating with AIOCD by entering into the Controversial MoU. On examination of this issue by CCI, it came to the conclusion that the OPPI and IDMA would not have entered into an agreement to restrict or limit supply of products of its own members unless it was a victim of exploitative tactics of the AIOCD. Further, it found that the OPPI and IDMA do not satisfy the basic test of being an 'enterprise' in order to examine the vertical agreement (Controversial MoU) entered by each one of them with AIOCD for anti- competitive characteristics. Hence, it judged that OPPI and IDMA were not parties to anti- competitive practices carried out by AIOCD.

IMPACT

The order of CCI described above is bound to have a deep impact on the distribution of medicines in India as well as prices charged to the customers. Effective February 19, 2013, a Drug Manufacturer may appoint any person or agency, and any number of persons and agencies, at any level in its distribution chain as it may deem fit without any fear of repercussions from the traders' body. It may also set up an exclusive distribution channel managed by itself for distribution and sale of its medicines. In cases of appointment for distributor, a Drug Manufacturer now has the option to negotiate the Trade Margin. Further, Drug Manufacturers can launch and distribute their new products without publishing information of their products in PIS bulletins.

The players in the distribution chain such stockist, distributors and retailers can offer discounts to the consumer without fear of boycott from AIOCD and its affiliates.

In case any Drug Manufacturer or concerned party is victim of any anti- competitive practice described above, it may notify the CCI who will take appropriate action as required, usually amounting to criminal proceedings against the guilty associations and its office- bearers, and imposition of heavy monetary penalty.

¹ See "AIOCD issues circular to members, state assns urging strict compliance of CCI order", published in pharabiz.com on Friday, May 17, 2013. Available at <http://www.pharabiz.com/PrintArticle.aspx?aid=75384&sid=1> (last checked May 17, 2013).

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