COMPETITION COMMISSION OF INDIA

Case No. 30 of 2011

In Re:

M/s Peeveear Medical Agencies, Kerala

Informant

And

All India Organization of Chemists and Druggists

Janssen Cilag Pharmaceuticals, (A Division of M/s Johnson & Johnson Ltd.), Mumbai

All Kerala Chemists & Druggists Association

All Kerala Chemists & Druggists Association (Affiliated to AIOCD)

Organization of Pharmaceutical Producers of India

Indian Drug Manufacturers Association

Opposite Parties

CORAM:

Shri Ashok Chawla
Chairperson

Dr. Geeta Gouri
Member

Shri Anurag Goel
Member

Shri M.L. Tayal
Member

Shri Justice (Retd.) S.N. Dhingra
Member

Shri S.L. Bunker
Member

Appearances:

1. Shri Amit Gupta, Advocate for the informant
2. Shri Yusuf Iqbal Yusuf, Advocate for All India Organization of Chemists and Druggists
3. Shri Aditya Narain, Advocate for Janssen Cilag Pharmaceuticals, (A Division of M/s Johnson & Johnson Ltd.), Mumbai
4. Shri Antony Tharian, Advocate for All Kerala Chemists & Druggists Association (Affiliated to AIOCD)
5. Shri Samir Gandhi, Advocate for Organization of Pharmaceutical Producer of India)
6. Shri D. B. Patil, Secretary General & Shri S. K. Arya, Jt. Director for Indian Drug Manufacturers Association

Majority order u/s 27 of the Competition Act, 2002 by Shri Ashok Chawla, Shri Anurag Goel, Shri M.L. Tayal and Shri S.L. Bunker

1. Factual Background

1.1 The present information has been filed by M/s. Peeveear Agencies, a partnership firm through its Managing Partner Shri P. R. Sreeram (the 'Informant') under Section 19 of the Competition Act, 2002 (the 'Act') alleging that the All India Organization of Chemists & Druggists ('AIOCD' or 'Opposite Party No. 1') and Janssen- Cilag Pharmaceuticals ('Janssen' or 'Opposite Party No. 2') are limiting and restricting the supply of pharmaceutical drugs in India in contravention of the provisions of the Act.

1.2 The facts and allegations as stated in the information, in brief, are as under:-

1.2.1 The Informant M/s. Peeveear Agencies is a registered partnership firm, constituted in the year 1980 and is in the business of stocking, exhibiting, selling and distribution of wholesale drugs. As per the Informant, it is a distributor of 47 companies, manufacturing different pharmaceutical products.

1.2.2 The AIOCD is an all India body registered under the Societies Registration Act having one of its objectives to promote and protect the interest of drug trade industry and allied lines in India and of the persons engaged therein. As per the information, AIOCD, as the All India body, exercises complete and absolute control over stockists of drugs and medicines in the country and various State Associations are affiliated to it. The Opposite Party No. 2 i.e. Janssen- Cilag Pharmaceuticals is a company engaged in manufacturing of various medicines and pharmaceutical products in India.

1.2.3 As per the information, under the guise of protecting interests of its members, the AIOCD has been abusing its dominant position and is regularly involved in anti competitive agreements which have the result of limiting and controlling the supply and markets, and directly influencing the sale and purchase price of the drugs and pharmaceutical products in India. The AIOCD has been controlling the trading policies of different manufacturing companies, controlling the profit margins, regulating the stockists / distributor agreement of each and every manufacturing company, recommending to all its members and stockists all over the country, the profit margins, collecting Rs. 2,000/- per product (described as Product Information Service, "PIS") from every manufacture in each state for permitting to launch their new medicines.

1.2.4 In pursuance of the above said objectives, AIOCD has been issuing dictates to stockists all over India not to deal with the stocks of different medicine manufacturers. As per the Informant, AIOCD is able to pressurize and prevail up on the manufacturers to abide by its directions in the appointment of stockists and its terms and condition because of its total control over stockists. If a manufacturer does not abide by the instructions of AIOCD, it is not allowed to market its products anywhere in the country.

1.2.5 AIOCD has entered into various Memorandum of Understandings and Agreements with various associations of pharmaceutical manufacturers such as IDMA (Indian Drugs Manufacturers Association) and OPPI (The Pharmaceuticals & Allied manufacturers & Distributors Association Ltd.) in terms of which a drug manufacturing company can appoint stockists only in consultation with the concerned State/District Chemists & Druggists Association and as per the guidelines laid down by the State Associations. Furthermore, where there is only one stockist of the company in the district, the second stockist can be appointed only in consultation with the concerned State/District Association and even the second stockist should be a bonafide member of the associations affiliated with the AIOCD. It is alleged that the AIOCD not only formulates guidelines for appointment of wholesalers/agents/ distributors by pharma companies but also fixes price margins.

1.2.6 As per the information, in the last quarter of 2010, Informant sought appointment as a distributor of the Janssen i.e. Opposite Party No. 2 and pursuant thereto the Opposite Party No. 2 had asked for complying various formalities which were done accordingly by the Informant. Being fully satisfied with the details supplied by the Informant, its credibility and track

record, Opposite Party No. 2 entered into distributor agreement with the Informant w.e.f. March 2011. Pursuant thereto, the Informant commenced sale of products of Opposite Party No. 2.

1.2.7 However, as per the Informant, the Opposite Party No. 2 by a cursory e-mail dated 26.04.2011 informed that supplies of medicines would not be made to the Informant, owing to the reason that the documents submitted by the Informant, with reference to distributorship appointment, were not authentic as per the AIOCD. The Informant was further informed by the Opposite Party No. 2 that till the dispute raised by the AIOCD is resolved, no supplies of drugs would be made to the Informant. Upon making enquiries with the Opposite Party No. 2, Informant was informed that the lack of "authenticity" referred to in the said e-mail dated 26-04-2011 meant that the Informant had not obtained "No Objection Certificate" (NOC) from a faction of All Kerala Chemists & Druggists Association (AKCDA), which had been propped up and supported by the President of the AIOCD Shri J.S. Shinde.

1.2.8 The Informant, thus, has alleged *inter alia* that AIOCD is abusing its dominant position by imposing unfair and discriminatory conditions which had the effect of limiting / denying market access to genuine distributors unless they submit to its dictates. The Informant has also submitted that various MOUs and agreements by AIOCD and its affiliated organizations either with the association of drug manufacturers or with individual drug manufacturers restricting the appointment of distributors is illegal and contrary to the provisions of the Act.

1.3 The Informant has prayed the following :

1.3.1 To inquire into the illegal action and activities of the Opposite Party No. 1 which are in direct contravention of the provisions of the Act.

1.3.2 To direct the Opposite Party No. 1 not to abuse its dominant position in limiting and restricting the supply of pharmaceutical drugs in India resulting in denial of market access.

1.3.3 To direct the Opposite Party No. 1 not to threaten and coerce any pharmaceutical drug manufacturer, indicating the Opposite Party No. 2 to terminate its distributor arrangement or contract with the Informant.

1.3.4 To pass such other order or orders as the Commission deem fit and proper in the facts and circumstances of the case.

1.4 Besides the above relief, the Informant has also sought the *interim* relief that pending inquiry into the facts as mentioned in the information, the Opposite Party No. 2 be restrained from giving effect to its e-mail dated 26.04.2011 and from discontinuing supplies of its products to the Informant and also from appointing any other distributor in the State of Kerala. Furthermore, the Informant requested that the Opposite Party No.1 be also restrained from issuing any directions / threats to the Opposite Party No. 2.

2. The Commission considered the matter in the meeting dated 23.06.2011 and after giving thoughtful consideration on the matter formed an opinion that there exists a *prima facie* case to direct the Director General (DG) under Section 26 (1) of the Act to cause an investigation.

3. The Commission also heard the parties on the prayer of the Informant for *interim* relief and vide its order dated 23.08.2011 granted *interim* relief restraining the Opposite Party No.2 from giving effect to its e-mail dated 26.04.2011 regarding termination of distributorship of the Informant. Further, AIOCD was also restrained from issuing any direction or threats to the Janssen to terminate the distributorship of the Informant.

4. The DG after receiving the directions from the Commission investigated the matter and submitted his report dated 29.12.2011 to the Commission.

5. Findings of DG

5.1 Issue of No Objection Certificate (NOC)

5.1.1 In the report, DG has concluded that NOC from the concerned Chemists & Druggists Association is a *sine qua non* for appointment of a stockist by any pharma company.

5.1.2 During investigation, DG has also noted that the requirement of NOC for being appointed as stockists or in appointing stockist from the trade association is neither provided in the licensing requirement nor required under any other law. Thus, no third party, such as the AIOCD or its affiliates had any mandate except perhaps through the MoUs, to decide the manner of appointment of a stockist by a pharma company. As such, as per DG, any restraint on freedom of trade on account of NOC, legitimized through the MOUs, which had the effect of limiting or controlling the market or supply falls within the mischief of Section 3(3) (b), read with Section 3(1) of the Act.

5.1.3 DG observed that the conduct of AIOCD, as well as that of OPPI and IDMA, being signatories to the agreements regarding the requirement of NOC for appointed of stockists as well as continuing to adhere to the same by their tacit and implied conduct, had to be presumed a *per se* contravention of the provisions of Section 3(3) (b) read with Section 3(1) of the Act. Thus, the DG has concluded that the conduct of the AIOCD or its affiliates in the matter of grant of NOC attracts the provisions of Section 3(3) (b) read with Section 3(1) of the Act.

5.2 Issue of Product information Service (PIS):-

5.2.1 As per DG, the practice of obtaining PIS approval from the State Chemists and Druggists Association upon payment of the prescribed charges in the name of advertisement in the Associations' bulletin is also a *sine qua non* without which new products are not allowed to be launched or introduced in the distribution channels.

5.2.2 DG has mentioned that the payment of PIS charges by the pharma companies in the name of advertisement charge to the State Chemists & Druggists Associations at the time of the product launch or any change in product brand/dosage form/strength thereof in the respective PIS bulletins ensures not only deemed compliance of the law but also enables them to advertise and circulate product information to all the retailers at a very nominal cost. The logistical problems connected with circulating the price lists to every retailer of the country who sell their product may work out to be enormous apart from being very expensive. Thus, the DG was of the view that the system of PIS *ipso facto* does not appear to be intended to cause restraint of trade or being injurious to consumer interests.

5.2.3 However, DG has opined that the launch of product in market being made contingent on PIS approval by the concerned association of Chemists & Druggists can result in restraint of trade and lead to denial of market access/controlling of supply/market for any product of a company which can also deprive consumers of the benefits of such drugs. DG has noted many instances where the association of Chemists & Druggists refuse to grant PIS approval on a variety of factors, including asking for charges in excess of the prescribed charges in the MOU. The Secretary General of IDMA had also testified to this effect.

5.2.4 DG has also mentioned that as and when the different AIOCD affiliates ask for exorbitant charges which are not in line with the MOU and the AIOCD is unable to ensure adherence of its members to the terms of the MOU, due to a variety of reasons, the new product launches get delayed and cause hindrance to freedom of trade of the manufacturers and deprive the consumers of the products in question. As per DG, any attempt on part of the members of AIOCD and / or its affiliates to delay or withhold any PIS approval on any ground, which limits or controls supply or market thereof, had to be treated as a kind of boycott attracting the provisions of Section 3(3)(b), read with Section 3(1) of the Act.

5.3 Issue of Fixed Trade Margins:-

5.3.1 DG has stated that the practice of having fixed trade Margin is also an industry practice and forms a part of the MOUs between AIOCD, OPPI & IDMA. At para 14.0 of the DG report, DG has discussed the issue of fixed trade margins in detail and mentioned that it is the industry practice to grant trade margins to the wholesalers and retailers, for the scheduled drugs and the non scheduled drugs as under:

	Scheduled drugs / Imported drugs	Non- Scheduled drugs
Wholesalers	8%	10%
Retailers	10%	16%

5.3.2 DG has mentioned that for the scheduled (controlled) drugs, the margin is fixed at 16% for a retailer as per para 19 of the DPCO, 1995. The relevant provisions are as under:-

> "*19. Price of formulations sold to the dealer – (1) A manufacturer, distributor or wholesaler shall sell a formulation to a retailer unless otherwise permitted under the provisions of this order or any order made there under, at a price equal to the retail price, as specified by an order or notified by the government, (excluding excise duty, if any) minus sixteen percent thereof in the case of Scheduled drugs."*

5.3.3 Thus, while working out the price of scheduled drugs, the National Pharmaceutical Pricing Authority (NPPA) makes an allowance for 16% margin on price to retailer (as per DPCO, 1995) and 8% margin to wholesaler as per practice. However, DG also noted that for non-scheduled drugs (drugs not under price control), there is no statutory obligation to pay any specified margins to either the retailers or the wholesalers.

5.3.4 As per DG, the fact that trade margins have been decided for the wholesalers & retailers operating in the pharmaceutical market by way of an agreement between the trade & the industry means that the prices of drugs are directly or indirectly getting fixed and are not being determined by the independent market forces. It implies that the manufacturer while deciding the MRP of the

drugs cannot fix the prices without providing for the agreed minimum trade margins for the wholesalers & the retailers of the entire industry. Thus, as per DG, it is apparent that the MoU between the AIOCD, OPPI & IDMA have directly or indirectly led to the determination of the purchase or sale prices of drugs in the market and therefore the said conduct is in violation of Section 3(3) (a) of the Act.

5.4 Issue of Boycotts:

As per DG, the AKCDA & such other affiliates of AIOCD indulge in practices of boycott of pharma companies on various issues contained in the MOUs. DG has mentioned that in case of internal disagreements/factionalism within the association, different groups try to enforce their decisions on the pharma companies in the matter of appointment of stockist being made contingent on NOC from a particular faction, payment of PIS charges to a particular group etc. They also prevail upon the pharma companies to stop supplies to those stockist and retailers who are allegedly engaged in anti-associational activities. Such a concerted action had the effect of limiting or controlling supplies/distribution/availability etc. of drugs which causes appreciable adverse effect on competition and results in denial of market access for the pharma companies and non-availability of drugs to the consumers. Accordingly, DG has concluded that the practice of boycott falls within the mischief of Section 3(3) (b) read with Section 3(1) of the Act.

5.5 Gist of conclusions in the DG Report

5.5.1 DG has concluded that the act and conduct of AIOCD and AKCDA amounts to horizontal agreement amongst their members which is anti-competitive in nature. The practices carried on by their members on the issue of grant of NOC for

appointment of stockists, fixation of trade margins and collection of PIS charges and / or boycott of products of pharmaceutical companies had the effect of limiting and controlling the supply of drugs, directly or indirectly determining the sale / purchase price of medicines which are in contravention of the provisions of Section 3(3) (a) and 3(3) (b) read with Section 3 (1) of the Act.

5.5.2 As the conduct of AIOCD and AKCDA, as its affiliate, is predicated on the various MOUs signed between the AIOCD-OPPI-IDMA, DG has concluded that the decision amongst the members of OPPI & IDMA to enter into tripartite agreements between the AIOCD, OPPI & IDMA and to execute the decisions contained in the MOUs pertaining to NOC/LOC, PIS, Fixed trade margin also amounts to an anti-competitive agreement within the meaning of Section (3)(a) and 3(3)(b) read with Section 3(1) of the Act.

6. The Commission considered the investigation report of the DG dated 29.12.2011 along with the entire material placed for consideration in its meeting held on 10.01.2012 and after examining the same, the Commission decided to send a copy of the DG report to the Informant , All India Organization of Chemists & Druggists (AIOCD); All Kerala Chemists & Druggists Association (AKCDA); All Kerala Chemists & Druggists Association (not affiliated to AIOCD); Indian Drugs Manufacturers Association (IDMA) and Organization of Pharmaceuticals Producers of India (OPPI) to invite their comments/objections, if any, to the DG report. The Commission also directed all the parties to appear for oral hearing, if they so desire, either personally or through their authorized representatives. The Opposite Parties were also directed to file their financial statements for the last three years and to provide the names and addresses of the office bearers of their respective associations.

7. The matter was further considered by the Commission in its meeting held on 09.02.2012. Shri Amit Gupta, Advocate along with associates appeared on behalf of the informant. The Commission also considered the letters dated 8.2.2012 and 24.1.2012 received on behalf of AIOCD and OPPI requesting for adjournment by 8 and 4 weeks respectively. It was noted by the Commission that there has been no response from AKCDA, AKCDA (affiliated to AIOCDA) and IDMA. Considering the request of the parties for adjournment, the Commission decided to allow further time of 4 weeks to file replies to the DG report. The Commission also decided to send a copy of DG report to M/s Janseen Cilag Pharmaceuticals to invite its comments/objections.

8. Thereafter, the matter was considered by the Commission in its meeting held on 15.03.2012 in which Shri Amit Gupta, Advocate on behalf of the informant, Shri Samir Gandhi, Advocate for OPPI and Shri Aditya Narain, Advocate for M/s Janseen Cilag Pharmaceuticals appeared. The written submission dated 28.02.2012 filed by IDMA, written submissions dated 09.03.2012 and 12.3.2012 filed on behalf of the OPPI and the written submission dated 13.3.2012 filed on behalf of M/s Janseen Cilag Pharmaceuticals were taken on record.

9. Shri Yusuf Iqbal Yusuf, Advocate and Shri Ahmed Chunawala from AIOCD appeared before the Commission on 08.05.2012 and made oral submissions. The matter was again considered by the Commission in its meeting held on 24.05.2012 and 14.06.2012.. It was noted that AKCDA (affiliated to AIOCD) has not filed the financial statements for the last three years along with the names and addresses of their office bearers in spite of directions given by the Commission vide letters dated 18.01.2012 and 10.02.2012. The Commission also took note of the fact that the DG report sent to AKCDA vide letter dated 18.01.2012 and another letter dated 10.02.2012 sent to it have been received back undelivered with remarks "Unclaimed". In view of the above, the Commission decided to issue notices to AIOCD and AKCDA (affiliated to AIOCD) under Section 43 of the

Act. It was also directed that a copy of the DG report and other communication to AKCDA be sent on its alternate address.

10. The Commission in its meeting held on 26.07.2012 noted that AKCDA (affiliated to AIOCD) had not submitted any reply in response to the notice dated 21.06.2012 under Section 43 of the Act and therefore considered its conduct of not filing financial statements for the last three years and also names and addresses of office bearers of the association as non-compliance of the directions of the Commission. In view of non-compliance of directions, the Commission decided to impose penalty of Rs. 25,000/- per day on AKCDA (affiliated to AIOCD) with effect from 26.07.2012 for a period of 30 days. It was decided that in case the information is not furnished within 30 days, the penalty shall be Rs. 50,000/- per day for next 30 days and Rs. 1,00,000 per day thereafter till penalty amount culminates to Rs. 1 crore.

11. The Commission in its meeting held on 21.02.2013 observed that IDMA, OPPI and Janssen Cilag had filed their financial statements for last 3 years whereas the AICOD had filed the financial statements for last 3 years in case no. *20/2011*. The Commission decided to take the same into account in this case also. The Commission further observed that since DG did not find any violation of the Act against AKCDA (not affiliated to AIOCD), its financial statements are not required to be filed. The Commission being of the view that AKCDA (affiliated to AIOCD) deliberately did not comply with the orders nor had paid penalty imposed upon it for non-compliance of the order dated 10.01.2012 decided to proceed against it under Section 42(3) of the Act.

12. Replies/objections of the Parties to the DG report:-

12.1 **Replies/objections of the Janssen Cilag Pharmaceuticals:-** The replies / objections of the Janssen Cilag Pharmaceuticals (Opposite Party No. 2) dated 13.03.2012 can be summarised as under:

12.1.1 It submitted that there is no allegation of contravention of the provisions of the Act against it and consequently it's name ought to be deleted from the array of opposite parties.

12.1.2 AS per it, it is an important feature of the pharmaceutical trade that majority of the stockists and the retailers are well organized and have a parent body known as the All India Organizations of Chemists and Druggists (AIOCD), being an All India body, which has affiliates in the different States and Districts. The AIOCD operates through state associations which in turn have district associations as their members and offer membership to individual stockists.

12.1.3 It submitted that the pharmaceutical companies are required to take into account the dictates of the AICOD, which had tremendous clout amongst the stockists and the retailers and can cripple the chain of distribution. It has contended that pharmaceutical companies are constrained to accommodate the demands of the AICOD, otherwise, they have to face the threat of boycott by AIOCD.

12.1.4 As per Opposite Party No. 2, under the Drugs Price and Control Order, 1995 ("DPCO") every pharmaceutical producer is not only mandated to issue a price list to its dealers but a list of certain information pertaining to the

products including its composition etc. in order to make the quality of the product known to the consumers. Since stockists form the intermediary between the producers and the retailers, the pharmaceutical companies are heavily dependent on their stockists for the dissemination of such information and distribution of their products. IT submits that the nature of the industry is such that product differentiation is being increasingly employed by pharmaceutical producers to compete with each other. New dosage forms, fixed drug combinations and new indications are the most usual product differentiation strategies. Therefore, the manufacturers who produce generic drugs compete mainly on factors (including but not limited to) such as price, brand image, service and efficiency

12.1.5 It submitted that it had appointed the Informant as its distributor, particularly in the District Palakkad, Kerala for a period of three years as per the terms and conditions of the Distributors Agreement dated 14.03.2011. The Opposite Party No. 2 had commenced supply of medicines of the Informant from 17.03.2011. However, it received letter dated 20.04.2011 from AKCDA intimating that the Informant is not a members of the Organization affiliated to AIOCD and the documents submitted by the Informant are not authentic and are rejected by AIOCD and it was requested that no further supply be made to the Informant. During the said period, there was also non-cooperation by distributors in Kerala with regard to placing of orders for their products. Accordingly, the Opposite Party No. 2 by email dated 26.04.2011 had intimated the Informant that documents submitted for its appointment are not authentic as per AICOD and accordingly, supplies shall be held back.

12.1.6 The Opposite Party No. 2 submitted that the Commission by Order dated 23.08.2011 had restrained it from giving effect to its email dated 26.04.2011

regarding termination of distributorship of the Informant and further restrained Opposite Party No. 1 from issuing any direction or threats to it to terminate the distributorship of the Informant. Accordingly, it had never terminated the Distributorship, but was constrained to suspend the supplies, temporarily and the same had resumed supplies of the products to the Informant.

12.1.7 The Opposite Party No. 2 has mentioned that before launching a new product, it obtains PIS approval from the concerned State Chemists & Druggists Association, affiliated to AIOCD as new products are not allowed to be launched or introduced in the distribution channels without such approval on payment of charges.

12.1.8 The Opposite Party No. 2 mentioned that it had fixed trade margin of 10% for distributors and 20% for retailers for all locally manufactured and traded non-scheduled formulations and 8% for distributors and 16% for retailers for all imported formulations. The above margins have been conventionally existing and followed.

12.2 Janssen (the Opposite Party No. 2) has filed another reply dated 21.03.2012. In this reply Janssen once again emphasized that since the Commission vide its Order dated 23.08.2011 had restrained it from giving effect to its e-mail dated 26.04.2011 regarding termination of distributorship of the Informant and had further restrained Opposite Party No. 1 from issuing any direction to it to terminate the distributorship of the Informant, it had never terminated the distributorship, but was constrained to suspend the supplies, temporarily and resumed supplies of the products to the Informant as per invoice dated 23.08.2011.It has further submitted that it follows its own policies in the matter of appointment of stockists and does not consult AIOCD or insist on NOC, even though members of State Associations affiliated to AIOCD obtain NOC on their

own account as a matter of trade and industry practice. In light of the above submissions, Opposite Party No. 2 has requested that the DG's report be disregarded as regards it as it had been wrongly impleaded as a respondent in the investigation.

12.3 **Reply/objections of the Indian Drugs Manufacturers Association (IDMA) dated 28.02.2012:-**

IDMA submitted its reply / comments to the DG report on 28.02.2012 in which it submitted as under:

12.3.1 IDMA replied that it does not agree with the conclusions drawn in the DG Report relating to the role of IDMA vis-a-vis the enquiry being conducted against the AIOCD leading to the said Report. It has also been submitted that IDMA is not in the business of manufacturing and marketing of drugs and pharmaceuticals and that it is formed to serve the mutual interest of its members.

12.3.2 IDMA contended that it does not practice anti-competitive activities. It further contended that one cannot conjecture that despite IDMA terminating the MOUs, it would not continue to desist the anticompetitive practice in future. As per IDMA, this allegation casts an aspersion on the reputation enjoyed for 50 years of existence by them.

12.3.3 It has submitted that for good measure it had issued a circular dated 1st February 2012 to all their members informing them of the termination of the MOUs with the AIOCD, so that they are warned that no such understanding now exists with the AIOCD and members were also advised that any action between each individual members and the AIOCD or any of its affiliates i.e. the state

organizations of Chemists and Druggists which violate the provisions of the Competition Act would be illegal and may lead to consequences as provided under the said Act.

12.3.4 IDMA filed one more reply vide letter dated 01.10.2012 in which it mostly reiterated the contents of reply dated 18.01.2012. IDMA emphasized that its dealing in the past as an association was with the AIOCD alone and not directly with the State Associations as the MOUs were signed with the AIOCD and not with any State Association. IDMA submitted that the dealings with the aggrieved parties in the cases before the Commission are principally with the State Associations and the AIOCD is added as a party in the capacity of parent organisation of the State Associations. It has further stated that it has no longer any relationship with parent organization and never had any dealing with the State Associations.

12.4 Reply/objections of the Organization of Pharmaceutical Producers of India (OPPI)

OPPI filed its reply vide letter dated 09.03.2012. The main points of the reply included the following:

12.4.1 OPPI submitted that it has been erroneously implicated as a respondent in the investigation by the DG. OPPI argued that it is irrational for an association of multinational pharmaceutical producers such as OPPI to limit the supply of its own products as it would be against its own business interest. OPPI submitted that it itself is the biggest victim of the practices adopted by AIOCD.

12.4.2 It was submitted by OPPI that while the OPPI had entered into MOUs with AIOCD between 1982 and 2003 to allow for the smoother functioning of the pharmaceutical industry, these MOUs were terminated when the Competition Act was enforced in 2009, based on the well-documented and recorded legal advice of the legal committee of the OPPI. OPPI did not renew these MOUs because of the advice of the legal committee despite receiving ultimatums from the AIOCD to do so by the 11th September 2009, failing which the AIOCD threatened to enter into individual MOUs with pharmaceutical companies. Despite such threats, the OPPI did not renew the said MOUs with AIOCD within or after the limit of 11.9.2009 and instead raised its concerns to the AIOCD through email dated 25.08.2010 on the possible implications of signing such MOUs under the Act. In this email, the Director General of OPPI had clearly pointed out that given the change in the legal environment it would not be appropriate for AIOCD to continue to require companies to make requests for seeking permission to introduce new drugs into the market. Therefore, OPPI was not party to any MOUs or agreements with AIOCD after the Act was enforced and hence, there is no basis for investigation under the Act.

12.4.3 OPPI submitted that it had introduced the PIS system in the expired MOUs as an entirely legitimate system which allowed companies to pay a nominal fee while launching a new product in the market, in return for which the respective local association affiliated to the AIOCD, would publish information and circulate it amongst all the dealers. This was an easy and efficient manner to comply with the requirements of the Drugs and Price Control Order (1995) ('DPCO'). However, this legitimate mechanism was grossly misused by the AIOCD which caused delays in introducing the new drugs due to various reasons including non-payment of exorbitant PIS fees,

which ultimately limited supply in the market for pharmaceutical drugs. The only reason why pharmaceutical companies are compelled till date to avail of the PIS approval mechanism, in spite of the expiry of the MOUs, while launching products in the market is because they face the risk of boycotts and delays if they do not get the approval from AIOCD. Therefore, it is submitted by OPPI that it is AIOCD which has acted in contravention of Section 3(3)(b) of the Act by misusing the PIS mechanism, and OPPI has always been a victim of such exploitative tactics of the AIOCD.

12.4.4 As per OPPI, it entered into a number of MOUs with AIOCD between 1982 and 2003 with the sole objective of helping its members to smoothly conduct their business in a very competitive market. OPPI is an association of research-based international and large pharmaceutical companies in India and also a scientific and professional body, which has the primary objective of creating and sustaining an environment conducive for innovation and growth and simultaneously, facilitating industry and stakeholder partnership through various advisory and consultative processes to achieve the healthcare objectives of the nation. A number of pharmaceutical companies, including those who are members of OPPI, were reported to have had their businesses seriously hampered due to the disorder created by AIOCD which reportedly included the boycott of drugs of OPPI members. It is submitted by OPPI that from time to time, the pharmaceutical companies have been a victim of AIOCD's conduct and severe disruptions have been caused to their trade by the actions of AIOCD.

12.4.5 OPPI further submitted that at no stage, did the Informant raise any allegations regarding the conduct of the OPPI. Even the order passed by the CCI under Section 26(1) of the Act did not find any cause of action against

OPPI. Therefore, it has submitted that the OPPI was neither the named nor intended respondent in this case and has, if anything all along, been a victim of AIOCD and its affiliate associations' exploitative conduct and there was no basis for the DG to implead OPPI as a respondent in this investigation.

12.4.6 OPPI has also submitted that it had only received a notice to depose before the DG for case no. 20/2011 which it had duly complied with. But, its deposition in case no. 20/2011 has been used against it in the DG's report in two other matters including the present one. OPPI in this regard contended that using OPPI's evidence in other investigations without any prior notice or consent is in contravention principle of natural justice as well as of established principle of law that evidence taken in one case cannot be used against the accused in another case *(Peddi Venkatapathi v. State, 1956 Cri L J 478; Induslnd Media and Communications Ltd. v. Polycable and others, decided on 28.05.2010; Doat Ali alias Sheik Deoat Ali Sarkar and Ors. V. King-Emperor, AIR 1928 Cal 230)*.

12.4.7 OPPI has concluded that based on legal advice and an in-depth understanding of competition law requirements, it had introduced a comprehensive competition compliance policy listing out the "Do's and Don'ts" among all its employees, executives and members of the OPPI once the Competition Act came into force. This compliance policy sets out guidelines on the participation in trade associations as well as practices of trade associations which may be prohibited under the Act. OPPI regards competition compliance matters as an important part of its code of business, its set of integrity value, and its reputation.

12.4.8 OPPI contended that the DG cannot rely on purely circumstantial speculation to establish the existence of an agreement for the purpose of the Act. The DG has failed to discharge his burden to establish the existence of an agreement through direct and concrete evidence. In the absence of such conclusive proof, the DG has assumed that the MOUs entered into by OPPI with AIOCD between 1982 and 2003 constitute an agreement. Also, the DG completely disregards the minutes of the meetings of the OPPI held on 16.04.2010 recommending the termination of the MOUs with the AIOCD along with the correspondence between the two parties. Instead, the DG assumed that such MOUs cannot be said to have been terminated due to absence of a 'public declaration' of the termination.

12.4.9 OPPI further submitted that there is no agreement or decision or practice that exists between OPPI and its members that can be construed as an 'anti-competitive agreement' under Section 3(3) of the Act and the DG has not found any evidence to suggest this.

12.4.10 It is submitted by OPPI that the DG has comprehensively failed to show that there is an agreement to limit supply or fix prices amongst pharmaceutical producers acting through OPPI. While the margins for the wholesalers and retailers of scheduled drugs are determined by the DPCO, pharmaceutical producers were free to offer any rate of trade margin for distribution of non-scheduled drugs. OPPI had incorporated the practice of fixed margins for non-scheduled drugs in its MOUs in order to allow for a reasonable trade of margin for non-scheduled drugs, which was unregulated, unlike scheduled drugs.

12.4.11 OPPI further contended that the practice of offering a fixed trade margin emanates not because of any agreement among pharmaceutical producers or any mandate of the OPPI. On the contrary, it is the AIOCD which compels pharmaceutical producers to maintain trade margins at the fixed level for distribution of all types of products for all distributors.

12.4.12 OPPI submitted that pharmaceutical producers are under tremendous pressure to maintain minimum trade margins of 10% to wholesalers and 20% to retailers. It is true that prior to 2003, OPPI had entered into MOUs with AIOCD to offer fixed margins for non-scheduled drugs to address frequent disruptions in the distribution chain created by the stockists. However, after the termination of these MOUs, stockists have compelled pharmaceutical producers to maintain uniform trade margins in the market.

12.4.13 OPPI submitted that to its best knowledge and information, its member companies do not follow the practice of appointing stockists who have obtained a NOC from AIOCD either at the behest of OPPI or because of any mutual consensus among themselves. OPPI do not have any role in requiring such NOCs from its members.

12.4.14 Therefore, it is submitted by OPPI that it is not in violation of Section 3(3) read with Section 3(1) of the Act as it does not limit or restrict supply or the market through any agreements with AIOCD to enforce boycotts against pharmaceutical companies.

12.5 **Reply of AIOCD**

AIOCD filed its response to the DG report vide e-mail which was considered by the Commission in its meeting held on 08.05.2012. The gist of reply is as under:

12.5.1 AIOCD has submitted that the DG had failed to carry out any economic analysis in respect of the relevant market or any anti-competitive agreement in the report. It has further submitted that there is no evidence in the DG report showing the existence of any agreement between the members of the AIOCD to show the violation of Section 3 (3) of the Act.

12.5.2 AIOCD has submitted that it is an association of chemists & druggists and is covered under the definition of "enterprise" under Section 2(h) of the Act only by virtue of the service of introducing the new products launched by the drug manufacturing companies through its bulletins and charging the PIS for the said service. As per the AIOCD, the relevant product market, therefore, to be related to this "service" rendered by it and it can certainly not be the "market for pharmaceuticals in the Union of India" or that of "drugs sold by the stockists and retailers to the consumers", as determined by the DG. AIOCD has accordingly submitted that in the absence of an appropriate market definition the conclusion of violation of Section 3(3) (a) and Section 3(3) (b) drawn by the DG in the report cannot sustain in the eyes of law.

12.5.3 As per AIOCD, the DG had failed to collect any material evidence in support of his conclusion, except the statement of Informant which too is full of leading questions and suggestive answers without having been cross-examined by AIOCD and therefore are inadmissible in evidence.

12.5.4 AIOCD has submitted that the DG had shown utmost disregard to the established legal principles of examination of witnesses on oath in exercise of his power under Section 41(2) of the Act and therefore the documentary evidences attached with the report are not admissible in evidence.

12.5.5 As per AIOCD, the DG had based his conclusion entirely on the basis of the allegations made by the Informant without any corroborative independent evidence and thus contended that the allegations made by interested witnesses cannot be relied upon. AIOCD had alleged that the investigation had been conducted in a most casual manner sitting in New Delhi without any efforts to collect onsite evidence by discreet inspection to verify the veracity of the allegations made in the complaint.

12.5.6 AIOCD has submitted that NPPA regulates the fixation and revision of prices of bulk drugs and formulations and also monitors the prices of both controlled and decontrolled drugs in the country through the provisions of the DPCO. As per AIOCD, till date no complaint has been made before the NPPA for any violation of the DPCO.

12.5.7 AIOCD has submitted that the practice of NOC was evolved on the recommendation of the Mashelkar Committee appointed by the Union Health Ministry of the Government of India which had recommended that the Chemist and Pharmacists through their association should act as "watch dog" to prevent entry of spurious/ doubtful quality drugs purchased from unauthorized sources and had specifically reiterated that AIOCD should play an active role to educate their members and to cooperate with regulatory authorities to eliminate sale of spurious and sub standard drug by their members.

12.5.8 As per AIOCD, the MoU signed between AIOCD, IDMA and OPPI was in the above context and based on the recommendations of the Mashelkar Committee whereby the trade of sale of pharmaceutical products through chemists was organized in accordance with the DPCO and the practice of obtaining NOC from the state level associations of Chemists and Druggists was evolved to curb the proliferation of large number of stockists and wholesalers at the cost of the smaller retailers and the DG in his report had completely overlooked the growth of competition in the pharmacy trade and had thus failed to recognize the efforts made by AIOCD in organizing a balanced relationship between the large pharmaceutical companies and the small retailers.

12.5.9 As per AIOCD, the DG has also failed to examine any pharmaceutical company to verify the allegations made by the Informant regarding the alleged role of AIOCD in restricting the entry of new stockists/wholesalers etc.

12.5.10 Based on the above, AIOCD requested the Commission to reject the findings of the DG.

12.5.11 AIOCD has also submitted a letter dated 22.11.2012. With respect to the direction to furnish Profit and Loss A/c & Balance Sheet for the last three years for the enterprise of current office bearers, it submitted that all its office bearers are holding Honorary Posts and have no personal interest or profit of any nature whatsoever in the activities of the association. Furthermore, the office bearers of AIOCD are elected representatives for a fixed tenure of time and are answerable to the General Body of AIOCD from time to time. Moreover, the office bearers of AIOCD function under the directions and policies framed by the Central Body of AIOCD. AIOCD is a collection of State level Associations and as such the office bearers are mere representative of the State bodies at the National

level. As per AIOCD, the office bearers of AIOCD are so heavily involved in the activities and the management of AIOCD that they do not conduct any personal business of their own even though they may be sleeping / dormant partners or owners in the business which is being run by other persons on their behalf. Furthermore, AIOCD is a distinct and separate juristic body and cannot compel its office bearers to furnish the details in proceedings against it when such office bearers are personally not a party to the said proceedings and have not been served with any notice or demand in this respect.

12.5.12 AIOCD, in its response, has stated the similar situation arise in respect of the Karnataka Chemists and Druggists Association which resulted in filing of Writ Petition No. 2882/2012 before the Hon'ble High Court of Karnataka in which Hon'ble High Court had stayed the proceedings before the Commission.

12.5.13 Lastly, AIOCD requested the Commission to take on record the names and addresses of the office bearers, however, it requested to dispense with the condition for furnishing the Profit & Loss Account / Balance Sheet for the last three years in respect of the enterprise of the office bearers of AIOCD with a further request to not to penalize AIOCD for any lapse on this issue.

13. Decision of the Commission

On careful examination of the information, DG report, the submissions of various parties and other materials available on record, the Commission observes that the following issues arise for determination in the present matter:-

Issue No. 1:- Whether the actions and practices of AIOCD and its affiliated state association of Kerala, i.e. AKCDA on the issue of grant of NOC for appointment of

stockists, fixation of trade margins and collection of PIS charges and / or boycott of products of pharmaceutical companies are in violation of Section 3 of the Act?

Issue No. 2:- Whether OPPI and IDMA are also liable for violation of Section 3(3) of the Act alongwith AIOCD as the practices pertaining to NOC/ LOC, PIS, Fixed trade margin etc. followed by their members are arising out of the various agreements between AIOCD, OPPI and IDMA?

Issue No. 3 Whether the members / office bearers of the Executive Committees of AIOCD, AKCDA, OPPI and IDMA are also liable for violation of Section 3 of the Act?

Determination of Issues

14. <u>Issues No. 1</u>

14.1 The DG has observed that the act and conduct of AIOCD and AKCDA amounts to horizontal agreement amongst their members which are anti competitive in nature. The practices carried on by their members on the issue of grant of NOC for appointment of stockists, fixation of trade margins and collection of PIS charges and / or boycott of products of pharmaceutical companies, as per DG, has the effect of limiting and controlling the supply of drugs and directly or indirectly is determining the sale / purchase price of medicines which is in contravention of the provisions of section 3(3)(a) and 3(3)(b) read with section 3(1) of the Act. Therefore, It is necessary that the relevant sub-section (3) of section 3 of the Act may be looked into which reads as under :

> "*Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice*

carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which –

(a) directly or indirectly determines purchase or sale prices;

(b) limits or controls production, supply, markets, technical development investment or provision of services;

(c) ……..

(d) ……..

shall be presumed to have an appreciable adverse effect on competition.

14.2 For the purpose of appreciation of applicability of relevant provisions relating to anti-competitive agreements, it is useful to consider the various elements of section 3 of the Act in detail. Section 3(1) of the Act prohibits and section 3(2) makes void all agreements by association of enterprises or persons in respect of production, supply, distribution, storage, acquisition or control of goods or provisions of services which cause or likely to cause appreciable adverse effect on completion within India. Therefore, if the any agreement restricts or is likely to restrict the competition then it will fall foul of section 3 of the Act.

14.3 Further, section 3(3) of the Act applies not only to a agreement entered into between enterprises or associations of enterprises or persons or association of persons or between any person and enterprises but also with equal force to the *practice carried on or decision taken by any association of* enterprises *or association of persons* including cartels, engaged in identical or similar trade of goods and provision of services which has the purpose of directly or

indirectly fixing prices, limiting output or sales for sharing markets or customers. Once existence of prohibited agreement, practice or decision enumerated under section 3(3) is established there is no further need to show an effect on competition because then a rebuttable presumption is raised that such conduct has an appreciable adverse effect of competition and is therefore anti-competitive. In such a situation burden of proof shifts on the opposite parties to show that impugned conduct does not cause appreciable adverse effect on competition.

14.4 The next question is that whether the AIOCD (which comprises of the State Chemists & Druggists Associations) and AKCDA (which comprises of District associations of Kerala) is covered under the category of entities enumerated in section 3(3) of the Act.

14.5 In this respect the definition of 'enterprise' as provided in section 2(h) assumes significance and which runs as follows:-

> *"enterprise" means a person or a department of the Government, who or which is, or has been, engaged in any activity relating to the production, storage, supply, distribution, acquisition or control of articles or goods, or the provision of services of any kind ..... but does not include any activity of the Government relatable to the sovereign functions of the Government including all activities carried on by the departments of the Central Government dealing with atomic energy, currency, defense and space.*

14.6 It is noted by the Commission that AIOCD is a national level registered association of chemists and druggists, active since 1975. Its website mentions that at every district level, there are associations which are in turn affiliated to the State Associations and all these States and Union Territories Associations are affiliated to AIOCD. On its website, it also mentions that it has over 7.5 lakh members from retail chemists and pharmaceutical distributors / stockists. As per the information available on its website, AIOCD transact almost 95% of the overall pharmaceutical business in India which is currently growing @ 12 to13% basis yearly.

14.7 Likewise, as mentioned on its website AKCDA established in 1971 for the exclusive protection of the chemists fraternity is a trade organisation for 8000 pharmaceutical traders of Kerala. Having its head office at Ernakulum it has its own registered office in every revenue districts of Kerala.

14.8 In view of the above, it is clear that all the States and Union Territories Associations are affiliated to AIOCD and all the District level Associations are affiliated to the respective States and Union Territories Associations and accordingly AIOCD claims to have over 7.5 lacs members from retail chemists and pharmaceutical distributors / stockists. In view of the said position, it can be inferred that members/ constituents of AIOCD and AKCDA (though indirectly) are stockists and retailers of pharmaceutical companies who are engaged in the supply of pharma products to the consumers. Therefore, such members/constituents fall within the definition of 'enterprise' provided in the Act. Further, Section 3(3) of the Act not only covers agreements entered into between enterprises or associations of enterprises but also the practice carried on or decision taken by any association of enterprises engaged in identical or similar trade of goods or provision of services. Thus

all actions and practices of AIOCD and AKCDA, including entering into various MOU's with OPPI and IDMA by AIOCD, regarding issues such as NOC, fixation of trade margins and imposing PIS charges and conducting boycotts would fall squarely as 'practice carried on' or 'decision taken by' an 'association of enterprises' under Section 3(3) of the Act.

14.9 The Commission, therefore, holds that AIOCD and AKCDA, being associations of its constituent enterprises, are taking decisions relating to distribution and supply of pharma products on behalf of the members, who are engaged in similar or identical trade of goods; the practices carried on, or decisions taken by AIOCD/AKCDA as an association of enterprises are covered within the scope of section 3(3).

14.10 It is noted by the Commission that the investigation by DG has found the acts and conduct on part of AIOCD, AKCDA, OPPI and IDMA as anti-competitive. Therefore, it is necessary to examine such infringements by them as found substantiated by the DG, in order to arrive at a conclusion. Here, the conduct of only AIOCD and AKCDA is being examined and the conduct of OPPI and IDMA shall be examined while determining subsequent issues.

Issue of NOC:

14.11 The DG, on the basis of the replies / practices of the parties on record, had concluded that 'No Objection Certificate' (NOC) or 'Letter of Consent / Cooperation' (LOC) from the respective District / State Chemists and Druggists Associations affiliated to the AIOCD are furnished to the pharma companies by the prospective stockists and it is seldom the case that the pharma companies appoint stockists without meeting the requirement of NOC / LOC.

14.11.1 The DG had collected the following evidences during the course of investigation regarding the practice of NOC / LOC are as under:

(a) The AIOCD vide its reply dated 07.11.2011 has furnished a copy of its letter dated 01.11.2010 issued to all Sales-Marketing / Distribution- Logistics / Supply Chain Heads of Pharma Companies requesting them not to appoint any new stockists in the State of Kerala and Orissa (Utkal) without consulting AIOCD, Dadar- Mumbai Office. (Page No 81 of Vol II of the DG report marked as Annexure-I). The AIOCD had also furnished copy of its letter dated 10.12.2010 addressed to all office bearers and presidents / secretaries and executive committee members of AIOCD circulating guidelines on LOC for district and state associations.

(b) The President of AKCDA, Shri A N Mohan, in his statements recorded before DG office on 14.11.2011 and 22.11.2011, has furnished the following documents pertaining to NOC before the DG:

(i) A copy of the application for grant of NOC/LOC dated 11.12.2008 of Glowderma Lab Pvt. Ltd., addressed to the State Secretary, AKCDA. **(**Page No 341 of Vol II of the DG report and marked as Annexure-II).

(ii) A copy of the clearance certificate dated 12.03.2011 issued by the Kannur District unit of AKCDA, to the Central Pharmacy, Kannur, for being appointed as the ninth stockist of M/s Sun Pharmaceuticals Ltd.

(iii) A copy of letter dated 15.03.2011 issued by the Kannur District unit of AKCDA, to M/s Adithya Medisales Ltd. pertaining to grant of NOC to various parties for being appointing them stockist of M/s Sun Pharmaceuticals Ltd.

(iv) Letter of Mankind Pharma Limited dated 28.08.2008 requiring Charleson Enterprises Thrissur to obtain necessary clearance like NOC for being appointed as replacement for Poonam Medicals.

(v) Another letter of Mankind Pharma Limited dated 30.01.2010 addressed to Poonam Medicals asking it to fulfil the conditions specified therein in order to get supplies of drugs from it.

(vi) Letter dated 27.04.2009 written by Mr Anthony Tharian, General Secretary of AKCDA (Affiliated to AIOCD) to E-Merck. Asking it to rectify the steps taken by it to appoint a stockist, in view of the circular issued by J S Shinde, President, AIOCD.

(c) Moreover, SRM Associates, vide its reply dated 22.10.2011 has furnished the following documents to the DG:

(i) A copy of the NOC dated 13.05.2008 issued by the AKCDA to it for its appointment as stockist of Franco Indian Pharma Ltd.

(ii) A copy each of the letters issued to it by the pharma companies such as Win-Medicare Pvt Ltd. dated 12.08.2008, Ranbaxy Laboratories Ltd. dated 09.05.2009 and 09.06.2009, Dr. Reddy's Laboratories Ltd. dated 07.07.2010, Harbindus dated 27.10.2009 and Labinduss Limited dated 27.10.2009 asking it to obtain NOC/LOC for being appointed as stockist of the said companies.

(iii) Letter dated 27.04.2009 of AKCDA (affiliated to AIOCD) addressed to the Sales Manager, E-Merck wherein it refers to the circular given by Mr J S Shinde regarding the appointment of new stockists in Kerala and has requested the company to abide by the direction given by AIOCD in the matter of appointment of a stockist by them at Patthanamitta district.

(d) Further, Sree Padman Pharma & Company vide its reply dated 20.10.2011 has furnished to the DG copies of letters of various pharma companies requiring it to obtain NOC for being appointed as stockist. It had also furnished copies of clearance Certificates/NOC issued to it by the AKCDA which are listed below:

(i) Letters of pharma companies viz. M / S Aventis Pharma, letter dated 17.12.2003, M /S Ajanta Pharma Limited, letter dated 22.04.2002, Uni Orange Life Care Pvt. Ltd., letter dated 15.04.2005, Eris Life Sciences Pvt. Ltd., letter dated 18.10.2007, Mankind Pharma Pvt. Ltd., letter dated 19.04.2005, Torrent Pharmaceuticals Ltd., letter dated 08.10.2005, Flamingo Pharmaceuticals Ltd., letter dated 30.10.2007and Aristo Pharmaceuticals Ltd., letter dated 20.06.2005requiring it to obtain NOC/LOC.

(ii) Copies of NOC / clearance certificate / permission letters issued to it by the AKCDA to take up stockistship of various pharma companies had been placed at page Nos. 622, 631 to 634 and 636 to 640 of Vol III of the DG report and marked as Annexure-VII

(e) All the pharmaceutical companies and association of manufacturers on record have also attested to the requirement of NOC / LOC.

(i) GlaxoSmithKline (GSK), vide its reply dated 17.08.2011, has informed that a letter of confirmation signed by the AIOCD is furnished to them by the stockists as part of appointment documentation.

(ii) Comed Chemicals Ltd., vide its reply dated 24.08.2011, has stated that as and when it needs to have alternate / second C&A agent then the new

applicant has to obtain NOC from the respective State association and follow the norms as per the prevalent practice and guidelines of their associations and/ or as per the terms as enumerated in the understanding/ MOU between IDMA, AIOCD & OPPI.

(iii) Janssen division of Johnson & Johnson Ltd, vide its reply dated 16.08.2011, has stated that as a matter of trade and industry practices, the members of the State Chemists and Druggists Associations affiliated to AIOCD obtain NOC on their own account.

(iv) German **Remedies** Division of Cadila Healthcare Ltd, vide its reply dated 23.08.2011, has stated that it follows industry practice on the issue of NOC.

(v) Alkem Laboratories Ltd., vide its reply dated 20.10.2011, has stated that it requires NOC / LOC from prospective distributor / wholesaler.

(vi) Alembic Pharmaceuticals Ltd, vide its reply dated 12.09.2011, has stated that stockists and wholesalers, being members of local associations provide them a reference from the association and certification that they have complied with the requirements to conduct business.

(vii) Torrent Pharmaceuticals Ltd., vide its reply dated 19.08.2011, has stated that it requires prospective distributors to bring NOC from concerned State Chemists & Druggists Associations affiliated to AIOCD for their appointment. It has however, also submitted vide its response dated 24.11.11 that it has appointed around 111 stockists during the period 2008 to 2011 in the states of Andhra Pradesh, Gujarat, Tamil Nadu and Uttar Pradesh without obtaining NOC from the Association based on the

declaration/ verbal confirmation from the stockists that there is no requirement of any NOC / clearance from the Association for the same.

(viii) Ranbaxy Laboratories Ltd, vide its reply dated 29.08.2011, has stated that the interested parties do provide reference letters to emphasize their credibility, track record and merits of their applications.

(ix) Novartis India Ltd,(NIL)vide its letter dated 16.08.2011 has stated that it believes that AIOCD requires its members to obtain No Objection Certificate from AIOCD or its affiliated State / District Associations before being appointed as a stockists by pharmaceutical companies.

(x) USV Ltd., vide response dated 02.08.2011, has stated that it follows industry practice and that NOCs are brought by the stockist and wholesalers being members of the local association.

(xi) The OPPI vide its reply dated 27.07.2011 has furnished copies of its MOUs signed with AIOCD between1982 to 2003, in which the requirement of NOC has been clearly stated. It has further submitted vide its reply dated 07.11.2011 that in view of the trade experience and to avoid trade related disruptions and surprises, OPPI member companies may at times be constrained to approach AIOCD/ its affiliated bodies in such matter.

(xii) The IDMA, vide its reply dated 11.7.2011 & 03.08.2011, has also submitted copy of the Memorandum of Understanding between IDMA-OPPI and AIOCD dated 12.09.2003 where from it is seen that the trade bodies have agreed to the manner of appointment of stockists.

14.12 From the examination of the above, it is clear that the requirement of NOC / LOC from AIOCD (through respective State and District Associations) is there for being appointed as stockist / wholesaler / distributor of pharmaceutical companies. This is also strengthened from the fact that during the course of investigation by DG, most of the pharmaceutical companies has stated that in the matter of appointment of stockist, they are guided by the MOU's between AIOCD, OPPI and IDMA.

14.13 The Commission notes from the statement of Shri Aniruddha Rajurkar, Vice President, German Remedies, a division of Cadila Healthcare Ltd. appointment of stockist without seeking NOC from the concerned association is an exception. The relevant excerpts of the statement of Shri Rajurkar are reproduced hereunder:

> *"……. As a matter of fact the appointment of stockists without NOC is an exception rather than the general practice and the company has been able to appoint them since they met our criteria of appointment……"*

14.14 The Commission also notes from the reply dated 27.07.2011 of OPPI that the members of OPPI are constrained to approach AIOCD or its affiliate state / district associations for appointment of stockists. The relevant excerpt from the reply of OPPI is reproduced hereunder :

> *"In our considered view it is not necessary for any pharmaceutical company to consult with the AIOCD or its affiliated state / district associations for the appointment of stockists ....' '……. However, in view of the trade experience and to avoid trade related disruptions and surprises, OPPI member companies may at times be constrained to approach*

AIOCD or its affiliated state / district associations in such matter .....

14.15 The Commission in this regard has considered the submission of AIOCD that the practice of NOC has evolved to prevent entry of spurious/doubtful quality drugs purchased from unauthorized. However, the fact that the effect of the practice of NOC which results into problems to the consumers and limits or controls the supply in the market outweighs the submission of AIOCD in this regard. Thus, the Commission holds that the conduct of AIOCD and its State affiliate i.e. AKCDA in the matter of grant of NOC attracts the provisions of Section 3(3)(b) read with Section 3(1) of the Act.

Issue of PIS :

14.16 As per DG, the practice of obtaining PIS (Product Information Service) approval by the Pharma companies from the respective State Chemists and Druggists Associations affiliated to the AIOCD is followed, almost in every case and enforced far more strictly than the NOC. The Pharma companies have to obtain PIS approval from the respective State Chemists and Druggists Associations affiliated to the AIOCD before they can introduce new products in the market. PIS approval entails payment of prescribed charged for the purpose of publication of the product information in the PIS bulletin, published State wise. The PIS bulletin is generally a part of the magazine published at periodic intervals by the respective State Chemists and Druggists Associations affiliated to the AIOCD.

14.12.1 The evidences collected during the course of investigation regarding the practice of PIS are as under:

a) The AIOCD vide its reply dated 07.11.2011 has furnished the following documents:

(i) A copy of the letter dated 01.11.2010 issued by it to all Sales-Marketing / Distribution- Logistics / Supply Chain Heads of pharma companies requesting them to send their contribution towards PIS for the State of Kerala and Orissa (Utkal), to AIOCD, Dadar-Mumbai office till further instructions from AIOCD Mumbai office.

(ii) Letter dated 12.10.2009 issued by it to all Marketing Heads / Distribution Heads of Pharma companies directing them to forward all New Product Launch Advertisement for the State of Karnataka only to Karnataka Chemists and Druggists Association affiliated to AIOCD.

(b) A copy of the receipt dated 27.08.2011 of a sum of Rupees 10,000/- issued by the AKCDA (Affiliated to AIOCD) to Alchem International Limited towards advertisement charges.

(c) The Informant vide communication dated 18.08.2011 has furnished the following evidences relating to payment of PIS charges by Dyota Numandis Pharma Pvt. Ltd. to the various State/District Chemists and Druggists Associations:

(i) Receipt No. 1581 dated 26.09.2003 issued by the Federation of Gujarat State Chemists and Druggists Association for Rs. 4000/ towards advertisement charges from Dyota Numandis Pharma Pvt. Ltd.

(ii) Receipt Nos.10764 dated 27.03.2006 and 10810 and 08.04.2006, respectively, issued by Utkal Chemists and Druggists Association, each for Rs. 5000/ from Dyota Numandis Pharma Pvt. Ltd towards PIS.

(iii) Receipt dated 17.02.2005 issued by Nagpur Dist. Chemists and Druggists Association for Rs. 2000/ towards advertisement from Dyota Numandis Pharma Pvt. Ltd.

(iv) Receipt dated 16.06.2006 issued by the Sikkim Chemists Association for Rs. 3500/ towards advertisement charges from Dyota Numandis Pharma Pvt. Ltd.

(v) Receipt dated 17.09.2004 issued by the Dist. Gwalior Chemists Association for Rs. 10000/ towards printing and circulation charges from Dyota Numandis Pharma Pvt. Ltd.

(vi) Receipt No. 8715 dated 13.05.2006 issued by the Pradesh Chemist Patrika (official organ of the Rajasthan Chemist Association) for Rs. 20000/ towards circulation charges from Dyota Numandis Pharma Pvt. Ltd.

(vii) Receipt Nos.10637 dated 03.06.2006 issued by Utkal Chemists and Druggists Association, for Rs. 30,000/ from Dyota Numandis Pharma Pvt. Ltd towards PIS.

(d) Receipt dated 20.08.2008 for Rs.2000/ issued by the AKCDA towards advertisement charges on launching a new product "LIPOPHAGE", to Franco Indian Pharmaceuticals Pvt. Ltd.

(e) Geo Paul & Company, vide its reply dated 26.11.2011 has stated that due to insistence for NOCs from the State Association, it has not been appointed as stockists for new Pharma companies, because of absence of NOC from the State Association affiliated to AIOCD and since the manufacturers follow the dictates of AKCDA/AIOCD and do not appoint stockists without NOC from AKCDA/AIOCD.

(f) GlaxoSmithKline has informed that PIS is in the form of advertisement through a publication of AIOCD for creating awareness amongst the trade of new product launches and that it is guided by the same.

(g) Comed Chemicals Ltd. has submitted that whenever new products are introduced or any change in packing, formulation or pricing is done then the company pays for the PIS to the concerned Chemists and Druggist Association for advertisement**.**

(h) Janssen division of Johnson & Johnson Ltd, the O.P.No.2 has stated that before launching a new product the company obtains Product Information System approval by paying charges for advertisement as new products are not allowed to be launched or introduced in the distribution channels without such approvals. It has submitted that Biopatch of Janssen was not allowed to be launched in the state of Gujarat on account of the same.

(i) German Remedies Division of Cadila Healthcare Ltd has stated on the issue of PIS approval that it follows the prevalent industry and market practice.

(j) Alkem Laboratories Ltd. has also stated that it requires PIS approval and pays charges for the same in terms of MOU dated 12th Sep 2003.

(k) Alembic Pharmaceuticals Ltd. has stated that on the issue of PIS, it follows the industry practice, which varies in different States.

(l) Torrent Pharmaceuticals Ltd has submitted that it seeks PIS approval from concerned State/District Associations affiliated to AIOCD.

(m) Ranbaxy Laboratories Ltd has not furnished a direct response to the query and has stated that the information on new product launches are published in newsletters/mailers and such decisions are taken by the company on various factors including the trade custom of the pharmaceutical sector.

(n) Novartis has stated that it seeks PIS approval from AIOCD or its affiliated State Associations and that without such approvals new products are not allowed to be launched or introduced in the distribution channels. The company has also stated that obtaining a PIS on the payment of a fee is a mandatory requirement under the Drugs (Price Control) Order, 1995 (DPCO) as intimated to them by AIOCD.

(o) The USV Ltd. has submitted that it follows industry practice of Product Information Services (PIS) approval (or consent in any other form) which varies from state to state. It has also stated that such approvals are obtained from concerned State/District Associations of Chemist & Druggists affiliated to AIOCD.

(p) The OPPI has furnished copies of all the eight MOUs signed with AIOCD between1982 to 2003 wherein the issue of PIS has been mentioned. It has, however, stated that its members companies may be compelled by AIOCD/ its affiliated bodies to seek PIS approval and without such process the new products are not allowed to be launched or introduced in the distribution channels.

(q) IDMA has also furnished copy of the Memorandum of Understanding between IDMA-OPPI and AIOCD dated 12.09.2003 and has also submitted

relevant extracts of the same pertaining to PIS. It has further stated that its member companies obtain PIS approval in terms of the aforesaid MOU.

14.12.2 After examining the evidence given by the DG, the Commission observes that the practice of PIS approval from the State Chemists and Druggists Association on payment of the prescribed charges in the name of advertisement in the Association Bulletin is something in absence of which new products cannot be introduced in the distribution channel.

14.12.3 One of the justification for making payment of the prescribed charges for PIS approval is explained to be that it helps to circulate and inform large number of retailers regarding price availability of new products in absence of which the pharmaceutical companies may have to bear huge time, money and resources to provide the same information regarding the product and pricing to the retailers. The statement of Shri Aniruddha Rajurkar, Vice President, German Remedies, a division of Cadila Healthcare Ltd. before the DG given at page no. 74 of the DG report in this regard may be noted.

14.12.4 The DG, in this regard, has observed that the payment of PIS charges by the pharma companies in the name of advertisement charges to the State Chemists & Druggists Associations at the time of the product launch or any change in product brand / dosage form / strength thereof in the respective PIS bulletin ensures not only deemed compliance of the law but also enables it to advertise and circulate product information to all the retailers at a very nominal cost. However, the launch of product in the market being made contingent on PIS approval by the concerned association of Chemists & Druggists sometimes results in restraint of trade and leads to denial of market access / controlling of

supply / market for any product of a company which can also deprive consumers of the benefits of such drugs.

14.12.5 The DG has mentioned that there are many instances where the association of Chemists & Druggists refuses to grant PIS approval on a variety of factors, including asking for charges in excess of the prescribed charges in the MOU. The Secretary General of IDMA has also testified to this effect. As and when the different AIOCD affiliates ask for exorbitant charges, the new product launches get delayed and cause hindrance to freedom of trade of the manufacturers and deprive the consumers of the products. The DG, in view of the same, has concluded that any attempt on the part of the members of AIOCD and or its affiliates to delay or withhold any PIS approval on any ground which limits or controls supply or market thereof has to be treated as a kind of boycott, thus attracting the provisions of Section 3(3) (b), read with Section 3(1) of the Act.

14.12.6 AIOCD, in its reply to the DG report, has emphasized that the conclusion of DG is not based on any economic analysis and also that the relevant market has been determined by the DG incorrectly. As per AIOCD, the relevant product market with respect to AIOCD has to be related to the PIS service rendered by it and therefore has contended that in absence of an appropriate market definition, the conclusion of violation of Section 3(3) (a) and 3 (3) (b) drawn by the DG in his report is not sustainable in the eyes of law.

14.12.7 In this regard, as also held in MRTP *case no. C-127/2009/DGIR(4/28) in the matter of Varca Druggist & Chemist & Ors. Vs. Chemist & Druggist Association of Goa* and in *case no. 20/2011 in the matter of Santuka Associates and AIOCD & Ors* the Commission is of the view that the contention raised by AIOCD are flawed and contrary to the scheme and provisions of the Act, as for

finding contravention under Section 3, the delineation of relevant market is not required.

14.12.8 Further, the Commission is of the view that whereas the payment of PIS charges by the pharma companies as advertisement charges, at the time of the product launch or any change in product brand, dosage, form, strength etc. in the respective PIS bulletins may ensure certain compliances which also might enable advertisement and circulation of product information to all the retailers at a very nominal cost, nevertheless; the launch of product in the market made contingent upon PIS approval results in restraint of trade and leads to denial of market access . Moreover, any attempt on the part of the members of the AIOCD and or its affiliates to delay or withhold any PIS approval on whatever ground requires more serious consideration and cannot be justified. There can be no denying to the fact that it ultimately deprives the consumers of the benefits of such drugs.

14.12.9 In view of the preceding discussion and assessment of evidence forwarded by DG, the Commission holds that actions of AIOCD and its affiliate State Associations AKCDA requiring mandatory PIS approval for launch of any new drug which ultimately results into delay in reaching the drugs to the consumers and also delaying or withholding PIS approval in any ground, is in violation of the provisions of Section 3 (3) (b) read with Section 3(1) of the Act.

Issue of Fixed Trade Margin:

14.12.10 DG has observed that it is apparent that the MOUs between the AIOCD, OPPI & IDMA have directly or indirectly led to the determination of the purchase or sale

prices of drugs in the market and the said conduct therefore falls within the mischief contained in Section 3(3)(a) of the Act.

14.12.11 As per DG, whatever be the level of competition *inter se* amongst the stockists, the agreement to give fixed trade margins to the wholesalers & retailers while determining the MRP of a product has the effect of directly or indirectly determining the purchase or sale prices of drugs in the market and the said conduct of AIOCD, OPPI & IDMA causes injury to the consumers. It has the effect of causing harm to the consumers and determining the sale and purchase prices of drugs which is presumed to cause an appreciable adverse effect on competition within the meaning of Section 3(3) (a) & Section 3(1) of the Act.

14.12.12 In this regard, the DG had collected following evidence :

14.12.12.1 The replies of the various pharmaceutical companies on the issue of the trade margins to the retailers and wholesalers:

a) GlaxoSmithKline has informed that trade margins for scheduled drugs are guided by the DPCO. It has also stated that the non-scheduled drugs, excluding those determined by the Government under the DPCO, the trade margins are decided based on its internal costing and other parameters which includes the AIOCD-MOU.

b) Comed Chemicals Ltd has also stated that the trade margins for wholesalers and retailers are as per the norms / guidelines agreed by and between IDMA, AIOCD and OPPI. It has further stated that for scheduled drugs the margin for wholesaler is 8% and for retailers the margin is 16%; for non-scheduled products the margins for wholesalers is 10% and for retailers is 20%.

c) Janssen division of Johnson & Johnson Ltd has furnished the margin structure followed by the company, which is as under:

i. 10% for distributors and 20% for retailers for all locally manufactured and traded non scheduled formulations;
ii. 8% for distributors and 16% for retailers for all imported formulations.

d) It has further stated that none of its products are covered under the DPCO.

e) German Remedies Division of Cadila Healthcare Ltd has stated it follows the DPCO guidelines for scheduled formulations and industry practice / past practice of the company for non scheduled formulations. This means that for scheduled drugs the margin for wholesaler is 8% and for retailers the margin is 16%; for non-scheduled products the margins for wholesalers is 10% and for retailers is 20%.

f) Alembic Pharmaceuticals Ltd has stated that for scheduled formulations, the margin is fixed at 8% for wholesaler stockists and 16% for Retailers as per DPCO, 1995 and for non-scheduled formulations it is 10% for wholesaler stockists and 20% for retailers.

g) Alkem Laboratories Ltd has stated that as regards the trade margins, it follows MOU dated 12th September, 2003 entered between IDMA, OPPI and AIOCD.

h) Torrent Pharmaceuticals Ltd**.** has stated that it follows the DPCO norms for scheduled formulations and for non scheduled formulations it follows the prevailing industry practice.

i) Ranbaxy Laboratories Ltd has stated that the trade margins for DPCO products are as per the stipulations of the DPCO and for the non scheduled formulations, is generally around 10% of the margin for the stockists and 20% of the margin for the retailers.

j) Novartis has stated that the trade margins of non scheduled drugs are fixed on the basis of market considerations and do not exceed 10% for wholesalers and 20% for retailers and that the trade margins for scheduled drugs are fixed on the basis of the DPCO and is 8% for wholesalers and 16% for retailers.

k) USV Ltd**.** has submitted that it follows the industry practice, which is 16% for retailers and 8% for wholesalers for scheduled formulations as per para 19 of the DPCO 1995 and 20% for retailers and 10% for retailers for non-scheduled formulations.

l) IDMA, OPPI and all other parties**,** whose replies / statements are on record, have also attested to the above industry practice.

14.12.12.2 Therefore, considering the above position coming out of the evidence on record, it cannot be doubted that there is a practice of fixed trade margins to the retailers and wholesalers in the pharmaceutical markets with respect to non-scheduled drugs also.

14.12.12.3 From the examination of the evidence given by the DG, Commission observes that the practice of fixed trade margins results from the MOU's between AIOCD, OPPI and IDMA. The Commission also notes that as a result of the above said industry practice the trade margins are not being determined on a competitive basis nor are allowed to fall below the agreed percentages. The Commission, in this regard, further notes that while the margin of 16% for retailer is fixed for scheduled (controlled) drugs in terms of para 19 of the DPCO, for non-scheduled drugs there is no statutory obligations to pay any specified margins either to the retailers or to the wholesalers.

14.12.12.4 The Commission has also noted from the DG report that the Director General of OPPI (at page 79 of the DG report) on the issue of trade margins have provided some justification/rationale for it. The relevant excerpts from his statement are reproduced hereunder:

> *"…… 10% and 20% trade discount were mutually agreed between the industry and the AIOCD before Competition Law came in place for the manufacturers to conduct their business in a predictable and smother way. The similar process was followed even in DPCO 1995 i.e. 8% for wholesalers and 16% for retailers for the products under price control. The trade demand were at that time when the government has specified 8% and 16% margin for DPCO products, the non DPCO products (without price control) should merit slightly higher margin."*

14.12.12.5 AIOCD on the issue of fixed trade margins has contended that NPPA regulates the fixation and revision of prices of bulk drugs and formulations and also monitors the prices of both controlled and decontrolled drugs in the country through the provisions of the DPCO. As per AIOCD, till date no complaint has been made before the NPPA for any violation of the DPCO.

14.12.12.6 The Commission in this regard observes that the contention of AIOCD that NPPA regulates the fixation and revision of prices of bulk drugs and formulations and also monitors the prices of both controlled and decontrolled drugs in the country through the provisions of the DPCO are not correct. In fact, while the margin for scheduled (controlled) drugs are fixed in terms of para 19 of the DPCO, for non-scheduled drugs there is no statutory obligations to pay any specified margins either to the retailers or to the wholesalers.

14.12.12.7 On examination of the origin of the practice of fixed trade margin, justification forwarded by the parties and DG's observation in this regard, as also held by the Commission in case no. *20/2011 (Santuka Associates Pvt. Ltd. Vs AIOCD & Ors.*), Commission observes that the agreement to give fixed trade margins to the wholesalers and the retailers has the effect of directly or indirectly determining the purchase or sale prices of the drugs in the market. The Commission, accordingly, holds that the said conduct of AIOCD, it constituents and affiliates fall within the mischief contained in Section 3(3) (a) of the Act. There could be no denying to the fact that had there been no fixed trade margins, competition amongst the retailers would have forced them to reduce their trade margins resulting into sale of drugs at prices even below the MRP.

Issue of Boycott:

14.12.12.8 As per DG, the AIOCD & its affiliated State / District Chemists & Druggists Associations also resort to the practice of boycott of pharmaceutical companies / their products to enforce the requirement of NOC, PIS approval & fixed Trade Margins. DG on the basis of the documents on record has observed that the Pharma companies often stop supplies to the stockists under the threat of boycott of sale / purchase of the products of the company by the AIOCD & its affiliated State / District Chemists & Druggists Associations.

14.12.12.9 The evidence collected in this regard by DG are as under:

(a) The President of AKCDA, Shri A N Mohan, in his statements recorded before DG on 14.11.2011 and 22.11.2011, has furnished the following documents:

(ii) A copy of letter dated 31.05.2011 issued by the Drugs Controller addressed to M/S J B Chemicals & Pharmaceuticals directing it to resume supplies to Lakshmi Agencies, Pathanamitha without further delay.

(iii) A copy of the petition dated 04.05.2011made before the District Collector, Thrissur by SRM Associates against the AKCDA, AIOCD, and others seeking inquiry to be made against the respondents for non supply of medicines to it by Medopharm.

(iv) Letter of Variety Medicals, dated 10.03.2011 complaining to the Assistant Drug Controller Thrissur regarding the activities of its business rivals to stop supplies of German Remedies to it.

(b) Letter dated 01.04.2011 addressed to the Drugs Controller by SRM Associates regarding refusal of sale of drugs by a super stockist of M/S Medopharm Laboratories, Chennai.

(c) A copy of the petition made by SRM Associates before the District Collector dated 04.05.2011seeking for an inquiry to be conducted and action be taken against the AKCDA for instructing Medopharm, a drug manufacturer to terminate its distributorship.

(d) Letter of the Drugs Controller dated 15.02.2010 addressed to the Managing Partner, Medi Drugs, CA of Unichem Labs requiring it to explain the refusal to sell drugs to SRM Associates.

(e) Letter of AKCDA dated 29.05.2006 addressed to all stockists of Alembic that as per the AIOCD, the non co operation movement with Alembic has been withdrawn and that all stockists should co operate with the said company as in the past.

(f) Several pharmaceutical companies and associations of manufacturers have also stated that products of pharma companies have been boycotted by the AIOCD and its affiliated State / District Chemists & Druggists Associations:

i. Glaxo Smithkline Ltd. in its reply to the DG office has stated that 'In the past there have been instances where our products have been boycotted by the AIOCD or its affiliated State / District Associations.

ii. Janssen (O.P.No.2) has also replied that the products of its Consumer Products Division were boycotted in the year 2002 and they had moved the MRTP Commission in this regard. It has further informed that Janssen was forced to withhold supplies to the Peeveear Medical Agencies, Kerala in view of the boycott on purchase of the Company's products with effect from 12.04.2011 to 26.04.2011. It has also submitted that its product Biopatch was not allowed to be launched in the State of Gujarat.

iii. Comed Chemicals Ltd. has also stated that it did have a problem in this regard towards the end of the 2009 and that the issue was resolved with the State Association upon intervention of AIOCD.

iv. Alembic Pharmaceuticals Ltd, in response to DG office query regarding instances of boycott faced by it has not denied the same but has not furnished specific details and has only stated that there are differences between them and the concerned Association which are mutually sorted out in due course.

v. Ranbaxy, Alkem and USV Ltd. have not furnished categorical reply regarding instances of boycott faced by them and have generally taken the plea that they are not aware of boycott of

their products by the AIOCD / its affiliated State / District Associations.

(g) Novartis India Ltd. has also stated that 'The Company has in the recent past i.e. over the last couple of years faced some instances of threats as well as a few instances of trade boycott in various parts of the country.' In this regard DG office has also collected copies of news items dated 11.04.2009 and 13.04.2009 which reveal that approximately 60 drugs and formulations of Novartis were boycotted for 2-3 days in Mumbai and Thane on the grounds of alleged 'unethical promotion' of 'Khatika Churna-Calcium Sandoz @ 250' and the pharma traders in Mumbai vowed to extend the boycott to other parts of the country.

(h) Copies of several letters issued by Assam Drugs Dealers Association, affiliated to AIOCD, wherein the General Secretary of the Association has issued call of organizational movement / stoppage of purchase and sale of drugs of several companies on various dates starting from 11.01.2010 till 19.09.2011 to all its members. The call of boycott has been made against the following companies:

i. Comed Chemicals Limited
ii. Piramal Health Care Limited
iii. Pharmed Limited
iv. Lupin Limited
v. VHB Life Sciences Limited
vi. Sun Pharmaceuticals Ind Limited
vii. Alembic Limited
viii. Ranbaxy Laboratories Limited
ix. Unichem Laboratories Limited

x. Morepen Laboratories Limited

xi. Alkem Laboratories Limited

xii. Cosmic Life Sciences Limited

xiii. Dr. Morepen Limited

xiv. Wockhardt Limited

xv. Ajanta Pharma Limited

xvi. Abbot India Limited

xvii. Khandelwal Laboratories Private Limited

Similarly, there are several letters issued to several Pharma companies directing them to call back the goods despatched to several stockists who are non members of their Association or who have indulged in anti Associational activities. All the above said documents have been collected by the DG in connection with Case No. *41 of 2011 (In the matter of Sandhya Drug Agencies versus Assam Drug Dealers Association and others*) and were collectively enclosed and marked as Annexure-XXII to the DG report.

(i) The OPPI in its reply dated 27.07.2011 has stated that since 2009 and even earlier, periodically, many OPPI members have complained about trade boycotts from AIOCD and its affiliated state chemist and druggist associations. It has also stated that the exact details of each such threat of boycott/boycott have not been documented by OPPI.

(j) IDMA in its reply dated 03.08.2011, has stated that to their knowledge, there has been no such activity of boycott between 2009 to date. It has also mentioned that in most cases companies do not send them complaints in writing due to the fact that companies do not want to antagonize the AIOCD.

14.12.12.8 The OPPI in its reply dated 27.07.2011 had stated that since 2009 and even earlier, periodically, many OPPI members have complained about trade boycotts from AIOCD and its affiliated state chemist and druggist associations. It has also stated that the exact details of each such threat of boycott/boycott have not been documented by OPPI.

14.12.12.9 IDMA in its reply dated 03.08.2011, had stated that to their knowledge, there has been no such activity of boycott between 2009 to date. It has also mentioned that in most cases companies do not send them complaints in writing due to the fact that companies do not want to antagonize the AIOCD.

14.12.12.10 Considering the above facts evidence, it cannot be disputed that the AIOCD and /or its affiliate State/District Trade Associations do boycott and/or issue threats of boycott on various issues to coerce the pharmaceutical companies to bow to their demands.

14.12.12.11 From the examination of the evidence forwarded by the DG, the Commission observes that AIOCD and its affiliates indulge in practice of boycotting pharma companies on various issues contained in the MOU's. The DG, in this regard, has observed that the act of boycott, either to enforce covenants of the MOU's or otherwise, has the effect of limiting or controlling the supplies, distributions, availability of drugs which causes AAEC for the pharma companies and non-availability to the consumers.

14.12.12.12 On assessment of DG's observation and recognizing the fact that such boycott deny the market to the pharma companies when AIOCD and its affiliates State Associations like AKCDA try to enforce their decision on the pharma companies on the appointment of stockist (issue of NOC),

mandatory payment of PIS charges etc, the Commission holds that such boycott have the effect of limiting or controlling supplies/distribution/availability of drugs which cause AAEC as it results in denial to market access to the pharma companies and non-availability of drugs to the consumers.

14.12.12.13 The Commission, thus, is of the considered view that the act of boycott by AIOCD & AKCDA is in contravention of the Section 3(3)(b) read with Section 3(1) of the Act. Thus, the Commission concludes that the conducts of AIOCD and AKCDA result into limiting supply of drugs and numbers of players in the market. It had been fully established by DG that no person can be appointed as wholesaler or stockist without NOC of the concerned association. Likewise, it is also a fact that without PIS approval no pharma products of the companies can be supplied in the market. The practice of fixed trade margins ultimately results into fixing the price of the pharmaceutical products. Moreover, the boycott by AIOCD and its affiliates like AKCDA has the effect of limiting or controlling the supply and market of the pharmaceutical products. The Commission holds that the said conduct of AIOCD and its affiliates namely AKCDA are in violation of provisions of Section 3(3)(a) and 3(3)(b) of the Act respectively.

15. Issue No. 2:

15.1 As the practices followed by the AICOD is predicated on the various agreements between AIOCD, OPPI and IDMA, next issue which requires determination is whether the practices pertaining to NOC / LOC, PIS, Fixed Trade Margin etc. followed by the members of OPPI and IDMA also amount to anti-competitive

agreements within the meaning of Section 3(3) (a) and 3(3) (b) read with Section 3(1) of the Act?

15.2 DG has come to conclusion that the decision amongst the members of OPPI and IDMA to enter into a tripartite agreements between AIOCD, OPPI and IDMA and to following the decision contained in the MOU's pertaining to NOC/LOC, PIS, fixed trade margins amounts to an anticompetitive agreement within the meaning of Section 3(3)(a) and 3(3)(b) read with Section 3(1) of the Act.

15.3 The relevant Section 3(3) of the Act has already been discussed in detail while determining the preceding issue. For the sake of brevity, the same is not being reproduced here.

15.4 The Commission has noted that OPPI vide its letter 07.11.2011 had submitted that its executive committee has not renewed the MOU's with AIOCD and had, thus, contended that the previous arrangements including the MOU's stands expired. It is also noted that IDMA vide its letter 20.12.2011 had also forwarded a resolution dated 02.12.2011 of its executive committee wherein it has been resolved that all the MOU's entered between IDMA and AIOCD between the years 1982 to 2003 have been terminated.

15.5 DG, not being satisfied with the justification offered by OPPI and IDMA in this regard, had observed that neither OPPI nor IDMA has intimated that they have issued any public statement or have even intimated there members that the MOU's between AIOCD, OPPI and IDMA had been terminated. The DG had also observed on the basis of replies of various pharmaceutical companies who are affiliated to OPPI that the agreement (understanding) of the parties, which was earlier documented by way of MOU's between AIOCD, OPPI and IDMA, is very much practiced by them. With regard to the resolution of IDMA, the DG has observed

that there is no evidence to suggest that its members do not practice the content of the MOU's any longer.

15.6 In view of the above, DG had observed that the stand of OPPI and IDMA that the various MOU's signed between AIOCD, OPPI and IDMA had been terminated or stood expired, does not have any substance and appeared to be an attempt on their part to wriggle out of their culpability in violation of the Act. The DG had, therefore, concluded that the anticompetitive practices of AIOCD, OPPI and IDMA are enforced not withstanding above said communications.

15.7 However, leaving apart the observation of DG on possibility of continuance of the practice by OPPI and IDMA, the basic issue arising for consideration of the Commission here is that whether the conduct of AIOCD, OPPI and IDMA, arising out of the various MOU's between them, can be the subject of examination under Section 3(3) of the Act.

15.8 In this regard, it has been noted by the Commission that OPPI, established in 1965, describes itself on its website as an association of research based international and large pharmaceutical companies in India and also as a scientific and professional body. IDMA, formed in 1961, as noted from its website, has about 750 wholly Indian large, medium and small pharmaceutical companies and State Boards in Gujarat, Himachal Pradesh, Uttaranchal, Haryana, Tamil Nadu and West Bengal as its members.

15.9 Thus it can be seen that OPPI and IDMA are the associations of manufacturers of pharmaceutical products whereas, on the other hand, AIOCD is the all India association of chemists & druggists. Further, Section 3 (3) of the Act captures

anti-competitive agreement amongst the entities engaged in identical or similar trade of goods or provision of services.

15.10 In view of the facts and legal position detailed above, it is apparent that AIOCD, OPPI and IDMA cannot be said to be the associations of enterprises who are engaged in identical or similar trades of goods or provision of services. Therefore, the MOU between AIOCD, OPPI and IDMA cannot be examined for violation of Section 3(3) as has been done by the DG.

15.11 Moreover, the fact which should also not be lost sight of is that the associations like IDMA and OPPI do not stand to gain by restricting / limiting the supply of products of their own members. Such limiting or restricting would obviously be against the very interest of the members of said associations. OPPI has submitted that it itself is the biggest victim of the practices adopted by AIOCD. OPPI had further submitted that the PIS system was grossly misused by AIOCD which ultimately limited supply in the market for pharmaceutical drugs. OPPI has emphasized that the only reason why pharmaceutical companies are compelled till date to avail of the PIS approval mechanism is that they face the risk of boycott and delays if they do not get the approval from AIOCD. Further, the Commission also notes that IDMA vide its resolution dated 02.12.2011 has resolved that all the MOUs entered between IDMA and AIOCD during the years 1982 to 2003 deemed to be operative on that date have been terminated and IDMA has informed its members the same through a separate circular dated 01.02.2012. Likewise, OPPI also submitted that all the MOUs with AIOCD were terminated when the Act was enforced in 2009, based on the well documented and recorded legal advice of its legal committee and the MOUs were not renewed despite receiving ultimatums from AIOCD.

15.12 In view of the above discussion the argument advanced by these associations that they are compelled to maintain fixed trade margins by AIOCD under the threat of boycott appears to have some force. The Commission in this regard is of the view that the OPPI, IDMA and its members appear to be victims of the exploitative tactics of AIOCD and their conduct of entering into MOU with AIOCD should not be treated at par with the conduct of the AIOCD. Therefore, IDMA and OPPI cannot be held liable for violation of the provisions of the Act.

16. Issue No. 3:

16.1 After having decided the first two issues, the Commission now proceeds to decide the third issue i.e. whether the members / office bearers of the Executive Committees of AIOCD and AKCDA are also liable for violation of Section 3 of the Act?

16.2 As held by the Commission in its orders in MRTP case no. *C-127/2009/DGIR (4/28)* in the matter of *Verca Druggist & Chemist and Ors. Vs. Chemists & Druggists Association, Goa* and in case no. *20/2011* in the matter of *Santuka Associates Pvt. Ltd. Vs . All India Organization of Chemists and Druggists & USV Ltd., Mumbai,* and other similar matters, in case of association of enterprises comprising of entities which themselves are enterprises, liability for anti-competitive conduct may arise two fold. While the association of enterprises may be liable for breach of section 3 of the Act embodied in a decision taken by the association, the constituent enterprises of association may also be held liable for contravention of section 3 of the Act arising from an agreement or concerted practice among them. Moreover, the anti-competitive decision or practice of the association can be attributed to the members who were responsible for running the

affairs of the association and actively participated in giving effect to the anti-competitive decision for practice of the association.

16.3 In the present matter, the Commission had asked the AIOCD and AKCDA (affiliated to AIOCD) to furnish the names and addresses of its office bearers, but the same had not been provided by them so far. Therefore, the Commission decides to deal with the issue of passing orders under Section 27 of the Act with respect to the office bearers of these associations separately, after the receipt of the requisite information in this regard.

17.1 With regard to the conduct of Janssen, Commission notes that the DG has not found any violation by it. The Commission is also of the view that the grievance of the Informant mainly arises out of the practices of AIOCD and AKCDA for which they have been held liable by the Commission. Under the circumstances, there seems no need to pass any specific order against Janssen in the matter.

Order under section 27 of the Act:-

17. As the Commission has found the AIOCD and AKCDA (affiliated to AIOCD) in violation of the provisions of Section 3(3) (a) and Section 3(3) (b) of the Act, the Commission now proceeds to pass suitable orders under Section 27 of the Act against the said entities, including penalty. In this regard, it is noteworthy that the Commission, in exercise of powers under Section 27 (b) of the Act, after considering the facts and circumstances in case no. *20/2011 (Santuka Association Pvt. Ltd. Vs. AIOCD and Ors.)*, besides passing the cease and desist orders, has imposed penalty @ 10% of the average of the receipts for financial years 2008-09, 2009-10 & 2010-11 on AIOCD amounting to Rs. Rs. 47,40,613/- . It is also noted that facts of this case are similar to that of the above referred Case No. 20/2011 and the Commission has found AIOCD guilty of same

violation in that case. It is further noted that AIOCD has deposited the penalty and has also filed undertaking of compliance along with affidavit of Shri Suresh Gupta, General Secretary, AIOCD. Therefore, considering these factors and the fact that violations in the present case are same as in Case No. 20/2011 and the instances of the violations are for the period much prior to the order of the Commission in the said case, the Commission does not consider it appropriate to impose any further monetary penalty upon AIOCD. The AKCDA, affiliated to AIOCD, has not submitted its financial statements and the Commission has initiated separate proceedings against it in this regard. Therefore, the matter of penalty against AKCDA will be considered separately at appropriate stage.

18. Accordingly, the Commission passes the following orders under Section 27 of the Act against AIOCD and AKCDA:

(i) AIOCD, AKCDA and its members are directed to cease and desist from indulging in and following the practices which have been found anti-competitive in violation of Section 3 of the Act.

(ii) AIOCD and AKCDA are further directed to file an undertaking that the practices carried on by their members on the issue of grant of NOC for appointment of stockists, 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 this order.

(iii) AIOCD shall issue a letter to the organization of pharmaceutical producers of India, IDMA and to Janssen that there was no requirement of obtaining an NOC for appointment of stockists and the pharmaceutical companies, stockists, wholesalers were at liberty to give discounts to the customers.

(iv) It shall also inform all Chemists & Druggists and all its members and associations by sending a circular / letter that they were free to give discounts to the customers.

(v) It shall also issue circular that PIS charges were not mandatory and PIS services could be availed by manufacturers / pharmaceuticals firms on voluntary basis.

19. Secretary is directed to send a copy of this order to the concerned parties for compliance immediately.

Sd/-
(Ashok Chawla)
Chairperson

Sd/-
(Anurag Goel)
Member

Sd/-
(M. L. Tayal)
Member

Sd/-
(S. L. Bunker)
Member

New Delhi

Date: 09.12.2013