



COMPETITION COMMISSION OF INDIA

Case No. 41 of 2011

In Re:

M/s Sandhya Drug Agency

Informant

And

Assam Drug Dealers Association
Barpeta Drugs Dealers Association
All India Organisation of Chemists & Druggists
Indian Drug Manufacturers Association
Organisation of Pharmaceutical Producers of India
Alkem Laboratories Limited, Mumbai

Opposite Parties

CORAM

Mr. Ashok Chawla Chairperson

Dr. Geeta Gouri Member

Mr. Anurag Goel Member

Mr. M. L. Tayal Member

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

Mr. S. L. Bunker Member

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Appearances

- 1. Shri Hrishikesh Baruah, Advocate for the Informant
- 2. Shri Arvind Kr. Sharma, Advocate for Assam Drugs Dealers Association &
- 3. Shri Arvind Kr. Sharma, Advocate for Barpeta Drug Dealers Association
- 4. Shri Yusuf Iqbal Yusuf, Advocate for All India Organisation of Chemists & Druggists
- 5. Shri D. B. Patil, Secretary General & Shri S. K. Arya, Jt. Director for Indian Drug Manufacturers Association
- 6. Shri Ravisekhar Nair, Advocate for Organisation of Pharmaceutical Producers of India

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 on 02.08.2011 by M/s Sandhya Drug Agency, Barpeta, Assam through its partner Shri Joysankar Saha (the Informant) against Assam Drug Dealers Association (ADDA), Barpeta Drug Dealers Association, (BDDA), All India Organization of Chemist and Druggists (AIOCD) and Alkem Laboratories Ltd. (Alkem) alleging abuse of dominant position by the aforesaid parties. The Informant is a wholesaler and supplier of various pharmaceuticals companies including Alkem in Barpeta district of Assam.
- 1.2 According to the information, ADDA is the Association of drug distributors, sellers and stockist in the state of Assam and is affiliated with AIOCD, the all India association of chemists and druggists. BDDA is the District Association of drug dealers in the district of

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Barpeta, State of Assam. As per the information, the aforesaid three associations are registered under the Societies Registration Act, 1860, whereas Alkem is a registered company engaged in manufacture, supply and sale of medicine and lifesaving drugs in India and abroad.

- 1.3 It has been alleged by the Informant that due to some political differences between the partner of the Informant firm and BDDA, ADDA in collusion with BDDA vide its letter dated 26.05.2011 directed Alkem to stop the supply of its products to the Informant. The Informant has also alleged that the stoppage of the supplies of products of Alkem was done by ADDA and BDDA in collusion with AIOCD.
- 1.4 As per the Informant, BDDA is a trade body which manages the distribution and supply of drugs in district Barpeta, Assam and enjoys a dominant position in the distribution and supply of drugs in the aforesaid district. Further, BDDA is affiliated to ADDA which in turn is affiliated to AIOCD, thus, AIOCD enjoys a dominant position in the distribution and supply of drugs in India. The Informant has also alleged that ADDA is a trade body which manages the distribution and supply of drugs in the state of Assam and enjoys a dominant position in the distribution and supply of drugs in the state of Assam. The Informant has further alleged that Alkem is acting in terms of the directions passed by AIOCD, ADDA and BDDA and has violated the provisions of Section 4 of the Competition Act, 2002 (the Act).
- 1.5 The Informant has also alleged that BDDA, ADDA, AIOCD and Alkem in collusion with each other have abused their dominant position. The Informant has further stated that while AIOCD and ADDA abused their dominant position in the state of Assam, BDDA has done so in the district Barpeta.
- 1.6 The Informant has sought the following reliefs in the matter:

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- (a) To direct Director General (DG) to institute an enquiry into the violation of Section 4 of the Act by the Opposite Parties;
- (b) To direct the Opposite Parties to refrain from taking any action, direct or indirect, to prevent any Pharmaceutical Manufacturing Company from supplying its manufactured goods to the Informant;
- (c) To direct the Opposite Parties to refrain from indulging in similar abusive conduct in the future;
- (d) To impose such penalty / cost on the Opposite Parties as may be deemed fit by the Commission;
- (e) To pass such other or further orders as may be deemed fit and expedient in the interest of justice.
- 2. The Commission considered the matter in its meeting held on 10.08.2011 and after giving thoughtful consideration to the allegations in the information held that there exists a *prima facie* case to direct the DG to cause an investigation into the matter. Accordingly, the DG was directed under Section 26(1) of the Act to conduct an investigation into the matter.
- 3. In pursuance of the direction of the Commission an investigation was done by the DG into the matter and the investigation report dated 27.12.2011 of DG was submitted to the Commission.

Findings of DG Report:

4. The DG has submitted that the trade associations, such as AIOCD, ADDA and BDDA are associations of persons who join together to form a common platform in furtherance of their common interests or commercial / business goals. The AIOCD is registered under the West

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Bengal Societies Registration Act, 1961 and ADDA and the BDDA are societies registered under the provisions of the Societies Act. The trade associations also function as association of associations (the so called second degree associations). The AIOCD is an association of state associations such as the ADDA, and the state associations like ADDA are the associations formed by the District Associations such as BDDA. The BDDA is a primary association of the chemists and druggists, i.e. the retailers and wholesalers in the district of Barpeta. Notwithstanding their status, if the activities of the trade Associations, in furtherance of the commercial / business interests of their members, are relatable to & impinge on production, storage, supply, distribution etc., then such conduct of trade associations would attract the provisions of section 3 of the Act. Since the trade associations are not merely an association of persons or enterprises but also have a separate legal existence, the trade associations are severally & collectively liable for breach, if any, of the Act.

5. <u>Issue of NOC</u>

- 5.1 On the basis of the evidence collected during the course of the investigation, the DG has observed that 'No Objection Certificate' (NOC) or 'Letter of Consent / Cooperation' (LOC) from the ADDA and BDDA are required to be furnished to the pharma companies by the prospective stockists.
- 5.2 The DG has stated that the pharma companies seldom appoint stockists who do not obtain NOC / LOC from the concerned association and that the requirement of NOC / LOC is a *sine qua non* for being appointed as stockist / wholesaler / distributor of pharmaceutical companies.
- 5.3 As per the DG, whatever may be the genesis and rationale for NOC in the Memorandum of Understanding (MOU) entered into between the AIOCD, IDMA and OPPI, the manufacturers face genuine problems in appointing stockists due to a very strict collective regimen enforced by the AIOCD and its state and district affiliates.

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Accordingly, the DG observed that the conduct of the AIOCD and 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.

6. PIS approval:

- 6.1 On the issue of Product Information Service (PIS), the DG has stated that ADDA grants PIS approval in the name of product advertisement service. 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 which is 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. The charges payable are on State wise basis except in Maharashtra where the district wise payment system is in vogue.
- 6.2 DG collected evidence during the course of investigation regarding the practice of PIS such as letters of ADDA and statements of various pharmaceutical companies and on the basis of the same has stated that the requirement of PIS approval is also a *sine qua non* for introduction of new products in the market by the pharmaceutical companies.
- 6.3 As per the DG report 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. Thus, DG has concluded that any attempt on the part of the members of the AIOCD and /or its affiliates to delay or withhold any PIS approval, on any ground, which limits or controls supply or

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market thereof has to be treated as violation of the provisions of section 3(3)(b), read with section 3(1) of the Act.

7. Fixing of Trade Margins

- 7.1 The DG has noted from the replies of the various pharmaceutical companies that they pay trade margins to the wholesalers and retailers in terms of the MOUs between AIOCD, OPPI and IDMA. On the basis of the attestation on record of Alkem, USV Ltd, Novartis, Glaxo SmithKline, Comed Chemicals Ltd., Janssen division of Johnson & Johnson Ltd., German Remedies Division of Cadila Healthcare Ltd., Alembic Pharmaceuticals Ltd, Torrent Pharmaceuticals Ltd., Ranbaxy Laboratories Ltd., IDMA, OPPI and other parties, DG has observed that it is abundantly clear that it has become industry practice to grant fixed trade margins to the wholesalers and retailers.
- 7.2 The DG has observed that regardless of the rationale behind it, it is a fact that the trade margins have been decided for the wholesalers and retailers operating in the pharmaceutical market by way of an agreement between the trade associations and the pharmaceuticals industry. Therefore, the prices of drugs are directly or indirectly getting fixed and are not getting determined by the independent market forces. The DG has, thus, concluded that the MOUs between AIOCD, OPPI and IDMA have directly or indirectly led to the determination of the purchase or sale prices of drugs in the market which falls within the mischief contained Section in 3 (3)(a) of the Act.

8. Issue of Boycott

8.1 As per the DG, the ADDA itself furnished copies of several letters wherein the General Secretary of the Association had issued call of organizational movement / stoppage of purchase and sale of drugs of several companies on various dates to its members. The

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DG has mentioned in his report the instances of call of boycott 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
- 8.2 As per the DG, the call for organizational movements against the pharma companies have been issued by ADDA on various grounds *viz*, violation of MOUs between AIOCD-IDMA-OPPI by the pharma companies, non-payment of PIS charges etc,. ADDA had also kept the Joint Secretary, North East Zone, AIOCD informed regarding its call for boycott by enclosing a copy of such letters.
- 8.3 Similarly, the DG observed that ADDA has also furnished copies of several letters issued to pharma companies (including Alkem Laboratories Ltd.) directing them to stop supply / cancel appointment of stockists who are non members of their Association or who have

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indulged in anti associational activities. Several pharmaceutical companies and manufacturers' associations have also stated before the DG that their products have been boycotted by the AIOCD and its affiliated State / District Chemists and Druggists Associations.

- 8.4 On the basis of the above, the DG has observed that the AIOCD and / or its affiliated State / District Associations do boycott and / or issue threats of boycott on various issues to coerce the pharmaceutical companies to agree to their demands largely emanating from the MOUs signed between the AIOCD, OPPI and IDMA.
- 8.5 Thus, the DG concluded that the act of boycott, either to enforce the covenants of the MOUs / business guidelines and rules framed by ADDA and similar bodies or on account of internal dissentions, cannot be deemed to be pro-competitive in any manner. As per the DG, such a concerted action has the effect of limiting or controlling supplies / distribution /availability etc of drugs which causes appreciable adverse effect on competition (AAEC) and results in denial of market access for the pharma companies and non availability of drugs to the consumers. Accordingly, the DG was of the view that the practice of boycott falls within the mischief of Section (3)(3)(b) read with Section 3(1) of the Act.

9. Gist of conclusions drawn in DG report

On the basis of the analysis carried out, the DG has concluded as under:

(a) The act and conduct of ADDA and BDDA amount 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 including the second stockist, fixation of trade margins and collection of PIS charges and / or boycott of products of pharmaceutical companies has the effect of directly or

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indirectly determining the price of drugs and limiting and controlling the supply of drugs in contravention of the provisions of Section 3(3)(a) and 3(3)(b) read with Section 3(1) of the Act.

- (b) The business guidelines and rules framed by ADDA vide Resolution No. 07 dated 17.05.2009, which is based on the MOUs signed between AIOCD, OPPI and IDMA, amount to an anti competitive agreement in terms of Section 3(3)(b) read with Section 3(1) of the Act.
- (c) The activities / conduct of ADDA and BDDA are in concert with the policy of AIOCD on the issue of NOC / PIS charges and approval / trade margins etc. It has also been found that at times call for boycott is issued by ADDA on receipt of directions from AIOCD. As such, ADDA and BDDA act in concert with the AIOCD in contravention of Section 3(3)(a) and 3(3)(b) read with Section 3(1) of the Act.
- (d) As the conduct of ADDA and BDDA, an affiliate of AIOCD, are predicated on the various MOUs signed between the AIOCD, OPPI and IDMA, the decisions of OPPI and IDMA to enter into tripartite agreements with the AIOCD and to implement the decisions contained in the MOUs pertaining to NOC/ LOC, PIS, fixed trade margins also amount to an anti-competitive agreement within the meaning of section 3(3)(a) and 3(3)(b) read with section 3(1) of the Act.
- 10. After examining the entire material, the Commission decided that a copy of the DG report be sent to the Informant, ADDA, BDDA, AIOCD, IDMA and OPPI to invite their comments / objections. The parties were also directed to appear for oral hearing, if they so desire. They were also directed to file their financial statements for the last three years and also to provide the names and addresses of the office bearers of their respective associations. During the course of inquiry the Commission also directed that copy of DG report be sent to the office bearers of all the opposite parties with a direction to file their reply / objections alongwith the last three years' profit & loss account / balance sheet /turnover of the enterprise to which they represent.

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- 11. The matter was again considered by the Commission in its meeting held on 09.02.2012 in which Shri Nishant Das, counsel for the Informant, Shri Manish Goswami and Associates on behalf of ADDA and BDDA appeared before the Commission. During the course of personal hearing, the counsel of ADDA and BDDA submitted certified copy of the order dated 31.1.2012 of the Hon'ble High Court of Gauhati. As per the said order, ADDA and BDDA had filed petition before the Hon'ble High Court and the matter was listed for motion hearing on 13.2.2012 and till then the proceedings pending before the Commission had to remain suspended. In view of the same, the Commission decided to consider the case after 13.2.2012 upon receipt of communication from Hon'ble High Court of Gauhati.
- 12. The Commission in its meeting held on 06.09.2012 noted that the stay order granted in the matter had been vacated by the Hon'ble High Court of Gauhati vide order dated 06.08.2012. The Hon'ble High Court, while disposing of the writ petition, referring to the decision of the Hon'ble Supreme Court as rendered in *Competition Commission of India Vs Steel Authority of India Ltd & Anr*, has discarded the contention of the petitioners that before issuance of the notice under section 26 of the Act, the adverse parties are to be afforded with opportunity to be heard. In view of the same, the Commission decided to ask ADDA, BDDA and AIOCD for their comments / objections to the DG report and also to file their financial statements / balance sheet / turnover for the last three years. The aforesaid opposite parties were also directed to provide the names and addresses of their office bearers.
- 13. In response to the notice of the Commission AIOCD, BDDA, IDMA and OPPI filed their objections to the DG report and also argued their cases before the Commission. The Informant and BDDA did not file any reply although oral arguments were made by the counsel of BDDA Shri Arvind Kumar Sharma and on behalf of the Informant Shri Hrishikesh Baruah appeared before the Commission.
- 14. Despite being given sufficient opportunity as the BDDA did not file financial details in compliance of the direction of the Commission, the Commission decided to proceed against BDDA under Section 42 of the Act.

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15. Reply from Indian Drug Manufacturing Association (IDMA):

IDMA submitted its reply / comments to the DG report on 18.01.2012 in which it submitted as under:

- 16.1 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.
- 16.2 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.
- 16.3 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.
- 16.4 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

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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.

16. Reply from OPPI:

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

- 16.1 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.
- 16.2 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

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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.

- 16.3 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.
- 16.4 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

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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.

- 16.5 OPPI contented that it has wrongly been included as a respondent by the DG in the investigation. As per OPPI, the information filed by the Informant related to the conduct of ADDA, BDDA and AIOCD only. These three organisations were accused of limiting and restricting supply of pharmaceutical drugs in India in collusion with a pharmaceutical company Alkem. However, the DG in his wisdom has also included OPPI as a respondent to in investigation and in doing so has completely misunderstood the role of OPPI in the pharmaceutical industry and implicated OPPI and its members for being a party to the cartel with AIOCD and its affiliate State and District Associations, the ADDA and BDDA whereas, in fact OPPI itself was a victim of the market distortions.
- 16.6 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. Instead, both, the information as well as the CCI's order only observed that it was the conduct of ADDA and BDDA that *prima facie* appeared to be limiting and controlling supply of drugs in the market. 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.
- 16.7 OPPI further submitted that the information filed by the Informant has been against ADDA, BDDA, AIOCD and Alkem a pharmaceutical company which is not a member of OPPI. The very basis for the DG's investigation is the anti-competitive nature of the expired MOUs, but since Alkem itself is not a member of the OPPI, any disruption in supplies to the Informant could not have been the consequence of the

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MOUs. Therefore, there was no basis, whatsoever, for the DG to implead OPPI in its investigation.

- 16.8 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 of 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; IndusInd 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).*
- 16.9 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.
- 16.10 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

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such MOUs cannot be said to have been terminated due to absence of a 'public declaration' of the termination.

- 16.11 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.
- 16.12 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.
- 16.13 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.
- 16.14 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.

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- 16.15 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.
- 16.16 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.

17. Reply from ADDA

ADDA in its reply dated 22.11.2011 has submitted as under:

- 17.1 ADDA has submitted that the entire crux of the controversy revolves around a purchase order dated 06-06-2011 which was placed by the informant on Alkem and which had been allegedly refused to be supplied by them on instigation of the ADDA. On the basis of the Annexure A-1 appended with the reply, ADDA submitted that supplies of medicines had never been stopped by the Alkem at any point of time and the bill for the order placed on 06.06.2011 was prepared on 30.06.2011 as is the prevailing practice in the entire pharmaceutical industry wherein bills are invariably prepared at the end of every month irrespective of the fact that the order for such invoice might have been placed at the beginning of the month. As per ADDA, an absolutely crucial and indispensable fact which goes to the root of the controversy is that the informant has never divulged in the entire application any information as to the period during which the supply of stock had been stopped.
- 17.2 As per ADDA, the Informant has approached the Commission with unclean hands and has deliberately mislead the Commission into believing that he had actually incurred some losses owing to the non supply of drugs and other essential medicines, whereas,

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the fact of the matter along with documentary evidence clearly demonstrate that supplies had never been stopped to the Informant.

- 17.3 ADDA, thus, contended that the entire genesis of the case as well as the consequential contemplation of initiation of investigation by the Commission, being based on a false and frivolous information supplied by the Informant, the all action contemplated in furtherance of the same has no legal legs to stand upon and the same is without due sanctity of law.
- ADDA has alleged that the Informant is guilty of willfully making false statements on oath before the Commission and thus is guilty of perjury. ADDA submitted that the Hon'ble Apex Court has repeatedly emphasized that anyone who indulge in immoral acts like perjury, prevarication and motivated falsehoods have to be appropriately dealt with, without which it would not be possible for any court to administer justice in the true sense and to the satisfaction of those who approach it in the hope that truth would ultimately prevail. In view of the same ADDA prayed that the Commission should draw up appropriate proceedings against the Informant and punish him accordingly. It further prayed that gauging by the extent of misrepresentation and distortion of facts and figures resorted to by the Informant, the Commission should drop / stay further proceedings in the investigation contemplated, if any already initiated against ADDA.
- 17.5 ADDA filed another response dated 22.10.2012 to the DG report. The gist of the same is as under:
 - 17.5.1 The ADDA contended that the entire basis of the information filed by the informant essentially revolves around two facets i.e. firstly being the stoppage of supply of drugs and medicines to the informant and the consequential loss of business which has been quantified to the tune of 1.25 crores. ADDA in this regard submitted that it had received a complaint from some members of BDDA against one of its member alleging that he is involved in anti-associational activities. Hence, the ADDA sought inquiry report from BDDA.

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The BDDA after holding inquiry into the matter submitted that the complaint received by ADDA was false and had been instigated by the informant. Other complaints were also received by BDDA from its members highlighting various anti-organizational activities perused by the informant. The ADDA on the basis of the conduct of the informant issued a letter dated 26.05.2011 to Alkem to stop the supplies to the informant. However, notwithstanding the letter dated 26.05.2011, Alkem never stopped the supply of drugs to the informant at any point of time and in fact the letter was never acted upon. ADDA thus alleged that it was deliberately suppressed by the informant that regular trade continued and is still continuing between informant and Alkem. Thus, as per ADDA the complaint filed by the informant is mischievous and motivated by extraneous considerations.

- 17.5.2 ADDA submitted that it is clear from the DG report that BDDA informed the DG that it had conducted a detailed inquiry in respect of the complaint lodged by some persons against one of the members of ADDA. The inquiry revealed that the wrong doing was the handy work of the Informant who went door to door and forcibly collected the signatures of the members of the association on plain paper. It is also revealed in the reply submitted by BDDA that it had received several representations from its constituent members highlighting various anti- organizational activities of the informant with requests for necessary disciplinary action against the informant and accordingly the BDDA requested its parent body i.e. ADDA to take necessary action against the informant for indulging in anti-associational activities.
- 17.5.3 ADDA also submitted that Alkem has also submitted that the allegation of non supply of drugs by it to the informant in pursuance of letter dated 26.05.2011 of ADDA is false in material particulars and the supply to the informant was continued till the date of filing of the information. It was also submitted that the informant had willfully suppressed the various invoices received from it in

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respect of supplies of medicines made from 26.05.2011 to 01.08.2011. ADDA also stated that Alkem had submitted that during the period 31.05.2011 to 30.06.2011 supplies could not be made to the informant on account of overdue outstanding against the company. The supplies were started on 30.06.2011 to the informant since the company paid some of the outstanding dues and promised to pay the remaining amount immediately upon delivery of goods. Therefore, in view of the replies of the BDDA and Alkem, ADDA contended that the allegations made in the information are false and mischievous as the supplies to the Informant were never stopped by Alkem on the letter issued by ADDA but the supplies were stopped on account of non-payment of outstanding dues.

17.5.4 ADDA submitted that the trade associations such as AIOCD, ADDA and BDDA are associations of persons who join together to form a common platform in furtherance of their common interest of commercial/ business goals. The large parts of activities of trade associations are protected as an expression of fundamental right of individuals. ADDA is affiliated to the AIOCD and AIOCD issues circulars and guidelines at frequent intervals to the affiliated associations like the ADDA for implementation, in principle, of all the clauses accepted vide different MOU's. The Memorandum of Association of the ADDA lays down the objects of the Association. The basic object of the ADDA is to develop and maintain friendly relations amongst its members and all other persons engaged in the trade and to fight for the legitimate demands and protect from injustice and deprivation from various corners; to promote and protect the trade; to collect and circulate statistics and information relating to the trade; to establish just and equitable principles in the trade to communicate or cooperate with Central -State Governments and other bodies for protection and improvement of the trade, industry and the persons engaged therein, etc. On the basis of these contentions ADDA has sought to emphasize that without the guiding principles of the AIOCD, ADDA and BDDA, the

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trade among the various manufacturers, wholesalers and retailers of drugs would not be smooth and peaceful.

On various issues discussed in the DG report, ADDA has submitted as under:

17.6 Grant of NOC for appointment of new stockists

- 17.6.1 On the issue of NOC, ADDA has submitted that the guidelines contained in the resolution of the ADDA are intended to bring about discipline and fair practices among members which are expected to increase the profitability and ensure proper distribution of medicines. It has further submitted that the business guidelines and rules framed by the ADDA are fully in consonance with the MOUs signed between AIOCD, OPPI and IDMA. All the members of the State- District Association of Assam practice the norms as spelt out in the guidelines. The adherence to the guidelines is ensured by ADDA by initiating discipline and advising the pharma companies.
- 17.6.2 ADDA has further submitted that MOU signed between AIOCD, OPPI and IDMA was signed as a guidance document to their members and to ensure uniformity and to bring about harmony and to make sure that medicines are available in the market at all times to service the demands of doctors, hospitals and patients. It contended that there are almost 6 lac retailers and thousands of stockist. Therefore, uniformity is required, otherwise the situation would become very chaotic with every stockist or retailer following different norms. It further contended that the MOU disallows big players to undercut and stifle competition.
- 17.6.3 ADDA has also submitted that most of the pharmaceutical companies who have filed their replies before the DG have submitted that issuance of NOC is good for the trade.

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- 17.6.4 ADDA has submitted that it is not mandatory for the companies to obtain NOC issued for appointment of stockists. Most of the pharmaceutical companies appoint stockists only on merit based on various parameters like financial / infrastructural capabilities etc. as decided by the pharmaceutical companies. It has stated that in fact, there are pharmaceutical companies namely Torrent Pharmaceutical Limited and Cadila Health Care Limited who have appointed stockists without NOC. It has also submitted that Ranbaxy has more than 3 stockists in the district, Dabur has more than 6-7 stockists in the district, Alkem has more than 4-5 stockists in some of the districts and Sun Pharma has more than 5-6 stockists in the district as per market demand.
- 17.6.5 ADDA contends that the requirement of NOC may in some ways restrict the right to freedom of trade and such conduct while creating barriers to new entrants in the market may foreclose competition by hindering entry into the market which can harm the consumers. However, the fact remains that the requirement of NOC is necessary as manufacturer and trade need each other and one without the other cannot remain in business. For the sake of mutual harmony and for creating a smooth business relationship, understanding between the trade and manufacturer / marketers of drugs and medicines is essential.
- 17.6.6 ADDA on the issue of NOC, finally submitted that the DG has held in his report that the issuance of NOC is violative of Section 3 (3) (b) read with Section 3 (1) of the Act and contends that it was not in its knowledge that the said practice being followed by them amounted to violation of the provisions of the Act. ADDA, on the other hand, was of bonafide belief that the said practice would facilitate smoother functioning of the business between the members and would ensure uniformity and make sure that medicines are available in the market at all times to service the demands of doctors, hospitals

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and patients. The system of issuing LOC satisfies the associations that there is a necessity of appointing a new stockist and that the company is not appointing additional stockist to dump stocks which may be expired in due course due to no sale. ADDA, thus, submitted that if Commission comes to a conclusion that the system of issuance of NOC for appointment of additional stockist is anti- competitive and against the provisions of the Act, it undertakes to immediately stop such trade activity even though it is not mandatory for the companies to have NOC for appointment of additional stockist.

17.7 PIS Approval

- 17.7.1 On the issue of PIS, ADDA submitted that the system of PIS is an efficient system for information dissemination which is being made available at a nominal cost charged by the associations. The negligible cost is immaterial to the eventual cost and price of the product, and the efficiencies of the information are clearly more than proportionate to the restrictions it imposes. In fact, internationally there is a move for greater information through PIS and strengthening the existing regulatory system specially for enabling more detailed universal classification of the drugs and chemicals between branded generic and generic and also strengthening the public information system where simple drugs are known to the consumers.
- 17.7.2 ADDA has further submitted that the business guidelines and rules framed by it are fully in consonance with the MOUs signed between the AIOCD, OPPI and IDMA. The guidelines and rules have been framed and are substantially the same as contained in the MOUs signed between AIOCD, OPPI and IDMA. As such, the guiding principles of AIOCD get enforced at the state level through the respective guidelines framed by the State Association such as the business guidelines framed by ADDA dated 17.05.09 It has submitted

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that the business guidelines and rules framed by ADDA vide resolution No. 07 dated 17.05.09 have been framed to maintain harmony between the trade and the members of the association to make available essential medicines in the market.

17.8 Fixing Trade Margins and Boycott

- 17.8.1 With regard to the issue of fixed trade margin, ADDA has submitted that National Pharmaceutical Pricing Authority itself makes an allowance for 16% margin on the price to retailer and 8% margin to wholesaler. It contends that in case the margins are not fixed but are decided by the market forces, then a scenario might emerge where the stockist may form a cartel and manipulate the pricing of the products. As per ADDA, uniformity of margins leads to safe trade practices and would not lead to a situation where the public would get the drugs at prices varying from place to place and shop to shop.
- 17.8.2 ADDA, therefore, submitted that the price of the drug (scheduled and non scheduled) is fixed by Government Authorities under DPCO 1995 and the trade margin is fixed by the government authorities and forms a part of the MOU between AIOCD, OPPI and IDMA and ADDA has no say in the matter of fixation of trade margins.
- 17.8.3 ADDA finally submitted that for the last two years it has not indulged in the practice of boycott and does not intend to resort to the said practice in future also.

17.9 **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:

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- 17.9.1 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.
- 17.9.2 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.
- 17.9.3 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.
- 17.9.4 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.
- 17.9.5 As per AIOCD, the DG had based his conclusion entirely on the basis of the allegations made by the Informant without any corroborative independent

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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.

- 17.9.6 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.
- 17.9.7 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.
- 17.9.8 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

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balanced relationship between the large pharmaceutical companies and the small retailers.

- 17.9.9 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.
- 17.9.10 Based on the above, AIOCD requested the Commission to reject the findings of the DG.
- 17.9.11 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.

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- 17.9.12 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.
- 17.9.13 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.

Decision of the Commission

18. On the careful examination of the information, DG report, submission 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 Assam, i.e. ADDA and District Association of Barpeta i.e. BDDA 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

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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, ADDA, BDDA, OPPI and IDMA are also liable for violation of Section 3 of the Act?

Determination of the Issues

19. <u>Issue No.1</u>

19.1 The Commission notes that DG in his report has concluded that the act and conduct of ADDA and BDDA are in concert with the policy and decisions of AIOCD and amounted 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 including the second stockist, fixation of trade margins and collection of PIS charges and / or boycott of products of pharmaceutical companies have been held by DG to have the effect of limiting and controlling the supply of drugs in contravention of the provisions of section 3(3) 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. The section 3(3) reads as under:

"Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any persons 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-

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- (a) directly or indirectly determines purchase or sale prices;
- (b) limits or controls production, supply, markets, technical development investment or provision of services;

(0)		
(c)	 	

(1)			
<i>(d)</i>	 	 	

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

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

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- 19.4 In the backdrop of the legal provisions as discussed above, it needs to be examined whether the AIOCD which comprises of the State Chemists & Druggists Associations and ADDA which comprises of District Associations like BDDA as well as BDDA which comprises of retailers and wholesalers in the district of Barpeta are covered under the category of entities enumerated in section 3(3) of the Act.
- 19.5 In this respect the definition of 'enterprise' as provided in section 2(h) assumes significance 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.

- 19.6 The Commission notes that AIOCD is a national level registered association of chemists and druggists. Its website shows 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 is also mentioned that it has over 7.5 lakh members from retail chemists and pharmaceutical distributors / stockists. Going by its own claim on its website, AIOCD transact almost 95% of the overall pharmaceutical business in India which is currently growing @ 12 to13% basis yearly.
- 19.7 Likewise, as submitted by ADDA in its reply dated 22.10.2012 ADDA and BDDA are associations of persons who join together to form a common platform in furtherance of their common interest of commercial / business goals. The basic

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object of these associations is stated to be the development and maintenance of friendly relations amongst its members and all other persons engaged in the trade to promote and protect the trade.

- 19.8 In view of the foregoing, there is no dispute to the fact 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 ADDA (indirectly) and that of BDDA (directly) 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, ADDA and BDDA including entering into various MOUs 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.
- 19.9 The Commission, therefore, holds that AIOCD, ADDA and BDDA, 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/ADDA/BDDA as an association of enterprises are covered within the scope of section 3(3) of the Act.

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19.10 It is noted by the Commission that the investigation by DG has found the acts and conduct on part of AIOCD, ADDA, BDDA, 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, ADDA and BDDA is being examined and the conduct of OPPI and IDMA shall be examined while determining subsequent issues.

Issue of NOC

- 19.11 The DG, on the basis of the replies / practices of the parties on record has observed that 'No Objection Certificate' (NOC) or 'Letter of Consent / Cooperation' (LOC) from the ADDA and BDDA are furnished to the pharma companies by the prospective stockists. As per DG, while the same may or may not be a requirement of the individual pharmaceutical companies as far as appointment of prospective stockists are concerned, it is seldom the case that the pharma companies appoint stockists without meeting the requirement of NOC / LOC.
- 19.12 The DG has collected the following evidence during the course of investigation on the practice of NOC / LOC:
 - ADDA has furnished copies of various letters / LOCs issued by ADDA,
 BDDA and other District Associations for appointment of stockists.
 - b) ADDA has also furnished copies of various letters issued by it and by various District Associations to pharmaceutical companies directing to stop supplies / cancel appointment of stockists which have been appointed without NOC.
 - c) The BDDA has also furnished copies of various letters / LOCs issued by it for appointment of stockists, which have been made part of the DG report.
 - d) The various pharmaceutical companies and associations of manufacturers have also attested to the requirement of NOC / LOC before the DG-

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- Alkem, vide its reply dated 20.10.2011, has stated that it requires NOC / LOC from prospective distributor / wholesaler.
- ii. USV Ltd., vide response dated 28.06.2011, has stated that it follows industry practice and that NOCs are brought by the stockist and wholesalers being members of the local association.
- iii. Novartis India Ltd,(NIL) vide its letter dated 16.08.2011 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.
- iv. GlaxoSmithKline (GSK), vide its reply dated 17.08.2011, had informed that a letter of confirmation signed by the AIOCD is furnished to them by the stockists as part of appointment documentation.
- v. Comed Chemicals Ltd., vide its reply dated 24.08.2011, 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.
- vi. Janssen division of Johnson & Johnson Ltd, vide its reply dated 16.08.2011, 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.
- vii. German Remedies Division of Cadila Healthcare Ltd, vide its reply dated 23.08.2011, stated that it follows industry practice on the issue of NOC.
- viii. Alembic Pharmaceuticals Ltd, vide its reply dated 12.09.2011, had 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.
- ix. Torrent Pharmaceuticals Ltd., vide its reply dated 19.08.2011, stated that it requires prospective distributors to bring NOC from concerned State

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- 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.
- x. Ranbaxy Laboratories Ltd, vide its reply dated 29.08.2011, had stated that the interested parties do provide reference letters to emphasize their credibility, track record and merits of their applications.
- xi. The OPPI vide its reply dated 27.07.2011 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, 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.
- 19.13 On the basis of above, it is clear that the requirement of NOC / LOC is made a *sine* qua non for appointment of 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.
- 19.14 The Commission notes from the statement of Shri Aniruddha Rajurkar, Vice President, German Remedies, a division of Cadila Healthcare Ltd. appointment of

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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....."

19.15 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

19.16 The Commission notes that that in terms of the business guidelines and rules for retail Chemists and Stockiest/Wholesalers as made applicable by ADDA upon its constituent District Associations, the NOC/LOC for appointment of new stockiest is given by the District Association i.e. BDDA. Guideline 5 issued vide the Resolution No. 7 dated 17.05.2009 of the executive committee of ADDA prescribes that LOC is to be issued by the District Association under the signature of District General Secretary. The DG collected copies of various letters/LOC issued by BDDA are part of the DG report. It reaffirms the fact that the guidelines regarding NOC/LOC issued

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by the ADDA are being enforced by the BDDA. Therefore, it is amply clear that it is the BDDA which grants NOC/LOC for appointment of new stockiest.

- 19.17 The Commission notes that the ADDA has itself admitted the requirement of NOC may in some ways restrict the right to freedom of trade and such conduct while creating barriers to new entrants in the market may foreclose competition by hindering entry into the market which can harm to the consumers. However, it has sought to justify the requirement of NOC by stating that it is necessary for creating smooth business relationship and harmony.
- 19.18 The Commission further notes that ADDA has submitted that it was not in its knowledge that the said practice being followed by them amounted to violation of the provisions of the Act, on the other hand, it was under bonafide belief that the said practice would facilitate smoother functioning of the business between the members and would ensure uniformity and make sure that medicines are available in the market at all times to service the demands of doctors, hospitals and patients.
- 19.19 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 sources as well as submission of the ADDA that it is necessary for creating smooth business relationship and harmony. 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 and ADDA in this regard. Thus, the Commission agrees with the conclusion of DG that the conduct of AIOCD and its affiliates i.e. ADDA and BDDA in the matter of grant of NOC attracts the provisions of Section 3(3)(b) read with Section 3(1) of the Act.

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Issue of PIS:

- 19.20 On the issue of PIS, DG has observed that ADDA grants PIS approval in the name of Product Advertisement service. 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. The charges payable are on State wise basis except in Maharashtra where the district wise system is prevalent. The product information covers the information as per Form V of the Drug Price Control Order (DPCO). The PIS charges are payable per entry in the PIS bulletin and entry means product brand / dosage form / strength. As per DG report, for payment of PIS charges the different States / Union Territories have been categorized into two categories, 'A' States & 'B' States wherein the respective PIS charges are Rs. 2000/- and Rs. 500/- per entry. The SSI units are eligible for 50% concessional PIS charges.
- 19.21 The DG had collected following evidence during the course of investigation regarding the practice of PIS:
 - (a) ADDA had furnished a copy of its letter dated 16.09.2010 issued to all its office bearers, all district president / secretaries enclosing list of companies which have paid PIS charges with the aim to identify the names of companies which have not paid PIS charges and / or their products for which PIS charges have not been paid. Copy of the letter was placed at page Nos. 202-207 of Volume II of the DG report which had been marked as Annexure-I therein. Similarly ADDA had also furnished a copy of its letter dated 04.01.2011 to Kokrajhar District Association requesting to take necessary measures to yield PIS charges from companies which have not paid PIS.

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- (b) The ADDA had also furnished copies of several letters issued to various Pharmaceutical companies directing them to pay PIS Charges (Product Advertisement Charges) @ Rs. 2000/- per product as per norms of All India Trade-Industry agreement.
- (c) The pharmaceutical companies and manufacturers' associations on record have also stated before the DG that payment of PIS charges are mandatory for introducing new drugs in the market. The DG had mentioned the statements / replies of the following companies in his report:
- (d) Alkem vide its reply dated 20.10.2011, had stated that it seeks PIS approval (or consent in any other form), on launch of a new product in a territory and pay charges in terms of MOU dated 12.09.2003 (between AIOCD-OPPI-IDMA).
- (e) The USV Ltd. had 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 had also stated that such approvals are obtained from concerned State/District Associations of Chemist & Druggists affiliated to AIOCD.
- (f) Novartis had 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 had 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.
- (g) GlaxoSmithKline had 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.

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- (h) Comed Chemicals Ltd. had 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.
- (i) Janssen division of Johnson & Johnson Ltd had stated that before launching a new product the company obtains PIS approval by paying charges for advertisement as new products are not allowed to be launched or introduced in the distribution channels without such approvals.
- (j) German Remedies Division of Cadila Healthcare Ltd had stated that it follows the prevalent industry and market practice on the issue of PIS.
- (k) Alembic Pharmaceuticals Ltd. had stated that on the issue of PIS, it follows the industry practice, which varies in different States.
- (l) Torrent Pharmaceuticals Ltd had submitted that it seeks PIS approval from concerned State/District Associations affiliated to AIOCD.
- (m)Ranbaxy Laboratories Ltd did not furnish a direct response to the query and had 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) The OPPI had furnished copies of all the eight MOUs signed with AIOCD between1982 to 2003 wherein the issue of PIS had been mentioned. It had, 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.

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- (o) IDMA had also furnished copy of the Memorandum of Understanding between IDMA-OPPI and AIOCD dated 12.09.2003 and had also submitted relevant extracts of the same pertaining to PIS. It had further stated that its member companies obtain PIS approval in terms of the aforesaid MOU.
- 19.22 From the assessment of evidences as provided by DG, the Commission observes that like the practice of NOC the requirement of PIS approval from the State Association on payment of prescribed charges in the name of advertisement in the bulletin is also a *sine qua non* for introduction of new products in the market by the pharmaceutical companies. In absence of this approval, no new products are allowed to be introduced in distribution channel.
- 19.23 The rationale for making payment of the prescribed charges for PIS approval has been given by Shri Anirudha Rajurkar, Vice-President, German Remedies (at page no. 64 of DG report) in which he explains that the PIS approval helps to circulate and inform to large number of retailer regarding price and availability of new products
- 19.24 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.
- 19.25 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

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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.

- 19.26 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.
- 19.27 On the issue of PIS, ADDA submitted that the system of PIS is an efficient system for information dissemination which is being made available at a nominal cost charged by the associations. The negligible cost is immaterial to the eventual cost and price of the product, and the efficiencies of the information are clearly more than proportionate to the restrictions it imposes.
- 19.28 ADDA has further submitted that the business guidelines and rules framed by it are fully in consonance with the MOUs signed between the AIOCD, OPPI and IDMA. As such, the guiding principles of AIOCD get enforced at the State level through the respective guidelines frame by the State Association such as the business guidelines frame by ADDA dated 17.05.09 It has submitted that the business guidelines and rules framed by ADDA vide resolution No. 07 dated 17.05.09 have been framed to

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maintain harmony between the trade and the members of the association to make available essential medicines in the market.

- 19.29 In this regard, as also held in MRTP case no. C-127/2009/DGIR(4/28) in the matter of Varca Druggist & Chemist & Ors. and Chemist & Druggist Association of Goa, and also 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 scheme and provisions of the Act as for finding contravention under Section 3, the delineation of relevant market is not required. The justifications forwarded by ADDA in this regard are also not tenable.
- 19.30 In view of the preceding discussion and assessment of evidence forwarded by DG, the Commission holds that the actions of AIOCD and its affiliate State Association ADDA, requiring mandatory PIS approval for launch of any new drug which consequently results into delay in reaching the drugs to the consumers and also delaying or withholding of PIS approval on any ground, is in violation of the provisions of Section 3 (3) (b) read with Section 3(1) of the Act.

<u>Issue of Fixed Trade Margin</u>

- 19.31 DG, on the basis of the replies of the various pharmaceutical companies, has observed that the pharmaceutical companies pay trade margins to the members of the wholesalers and retailers in terms of the MOUs between AIOCD, OPPI and IDMA.
- 19.32 The DG had stated replies of following pharmaceutical companies in this regard:
- (a) Alkem Laboratories Ltd had stated that as regards the trade margins, it follows MOU dated 12th September, 2003 entered between IDMA, OPPI and AIOCD. The official of the company had also stated that trade margins are 10% to the stockists and 20%

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to the retailers for non schedule drugs (page Nos. 436 & 465 of Volume III of the DG report which had been marked as Annexure-IV therein).

- (b) USV Ltd. had 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 (page Nos. 526-528 of Volume III of the DG report which had been marked as Annexure-VI therein).
- (c) Novartis had 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 (page Nos. 529-535 of Volume III of the DG report which had been marked as Annexure-VII therein).
- (d) GlaxoSmithKline had informed that trade margins for scheduled drugs are guided by the DPCO. It had 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 (page Nos. 536-537 of Volume III of the DG report which had been marked as Annexure-VIII therein).
- (e) Comed Chemicals Ltd had 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 had 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%.(page Nos. 538-540 of Volume III of the DG report which had been marked as Annexure-IX therein).
- (f) Janssen division of Johnson & Johnson Ltd had furnished the margin structure followed by the company as follows: -10% for distributors and 20% for retailers for

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all locally manufactured and traded non scheduled formulations -8% for distributors and 16% for retailers for all imported formulations. It had further stated that none of its products are covered under the DPCO (page Nos. 541-549 of Volume III of the DG report which had been marked as Annexure-X therein).

- (g) German Remedies Division of Cadila Healthcare Ltd had stated that it follows the DPCO guidelines for scheduled formulations and industry practice / past practice of the company for non scheduled formulations which 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% (page Nos. 550-556 of Volume III of the DG report which had been marked as Annexure-XI therein).
- (h) Alembic Pharmaceuticals Ltd had 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 (page Nos. 557-558 of Volume III of the DG report which had been marked as Annexure-XII therein).
- (i) Torrent Pharmaceuticals Ltd. had stated that it follows the DPCO norms for scheduled formulations and for non scheduled formulations it follows the prevailing industry practice (page Nos. 559-561 of Volume III of the DG report which had been marked as Annexure-XIII therein).
- (j) Ranbaxy Laboratories Ltd had 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 (page Nos. 562-565 of the DG report which had been marked as Annexure-XIV therein).

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- (k) IDMA, OPPI and all other parties, whose replies / statements whose statements were recorded by the DG have also attested the industry practice regarding fixed trade margins.
- 19.33 In view of 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 market with respect to the non-scheduled drugs also.
- 19.34 From the examination of the evidence given by the DG, the Commission observes that the practice of fixing the 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.
- 19.35 The Commission has also noted from the DG report that the Director General of OPPI on the issue of trade margins have provided some justification/rationale for it. The relevant excerpts from his statement are reproduced hereunder:

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DPCO products, the non DPCO products (without price control) should merit slightly higher margin."

- 19.36 With regard to the issue of fixed trade margin, ADDA has submitted that National Pharmaceutical Pricing Authority itself makes an allowance for 16% margin on the price to retailer and 8% margin to wholesaler. It contends that in case the margins are not fixed but are decided by the market forces, then a scenario might emerge where the stockist may form a cartel and manipulate the pricing of the products. As per ADDA, uniformity of margins leads to safe trade practices and would not lead to a situation where the public would get the drugs at prices varying from place to place and shop to shop.
- 19.37 ADDA, therefore, submitted that the price of the drug (scheduled and non scheduled) is fixed by Government Authorities under DPCO 1995 and the Trade Margin is fixed by the government authorities and forms a part of the MOU between AIOCD, OPPI and IDMA and ADDA has no say in the matter of fixation of Trade Margins.
- 19.38 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.
- 19.39 The Commission further observes that the contention of ADDA and 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.

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19.40 On examination of the origin of the practice of fixed trade margin, justification forwarded by the parties and DG's observation in this regard, the Commission is of the view that there is no reason to disagree with the DG's observation 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 and 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

- 19.41 On the issue of Boycott, it is noted that ADDA itself has furnished copies of several letters to the DG wherein the General Secretary of the Association had 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. On the basis of the same, DG had observed that the call of boycott had been made against the following companies: Comed Chemicals Limited Piramal Health Care Limited Pharmed Limited Lupin Limited VHB Life Sciences Limited Sun Pharmaceuticals Ind Limited Alembic Limited Ranbaxy Laboratories Limited Unichem Laboratories Limited Morepen Laboratories Limited Alkem Laboratories Limited Cosmic Life Sciences Limited Dr. Morepen Limited Wockhardt Limited Ajanta Pharma Limited Abbot India Limited Khandelwal Laboratories Private Limited.
- 19.42 As per the DG report, the call for organizational movements against the pharma companies had been issued by ADDA on various grounds such as unfair practices including non-settlement of expiry / return claims of member firms, non settling of grievances of member firms, violation of MOUs between AIOCD, IDMA and OPPI

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by the pharma companies, nonpayment of PIS charges, on call / message given by AIOCD for boycott etc. It is also noted that whenever a call for boycott was issued, AIOCD also had been kept informed. DG had mentioned instance where ADDA had informed the Joint Secretary, North East Zone / AIOCD regarding its call for boycott by enclosing it a copy of such letters.

- 19.43 Similarly, ADDA had also furnished to the DG copies of several letters issued to Pharma companies (including Alkem) directing them to stop supply / cancel appointment of stockists who are non members of their association or who have indulged in anti associational activities.
- 19.44 Following Pharmaceutical companies and manufacturers' associations had also stated that their products have been boycotted by the AIOCD and its affiliated State / District Chemists & Druggists Associations:
 - (a) Glaxo Smithkline Ltd. in its reply had stated that 'In the past there have been instances where our products have been boycotted by the AIOCD or its affiliated State / District Associations'.
 - (b) Novartis India Ltd. had 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 this 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.
 - (c) Janssen had also replied that the products of its Consumer Products Division were boycotted in the year 2002 and they had moved the MRTP

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Commission in this regard. It had 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.

- (d) Comed Chemicals Ltd. had 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.
- (e) Alembic Pharmaceuticals Ltd, in response to the DG's query regarding instances of boycott faced by it had not denied the same but had not furnished specific details and has only stated that there are differences between them and the concerned Association which were mutually sorted out in due course.
- (f) Ranbaxy, USV, Alkem 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.
- 19.45 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.
- 19.46 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.

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- 19.47 Based on above the facts and evidence, it is clear that the AIOCD and / or its affiliated State / District Trade Associations do boycott and / or issue threats of boycott on various issues to coerce the pharmaceutical companies to agree to their demands.
- 19.48 From the examination of the evidence given by the DG, the Commission observes that the AIOCD and its affiliate State and District Associations, here ADDA and BDDA, indulge in practice of boycotting pharma companies on various issues contained in the MOUs. The DG, in this regard, had observed that the act of boycott, either to enforce covenants of the MOUs 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.
- 19.49 ADDA on the issue of boycott has submitted for the last two years it had not indulged in the practice of boycott and does not intend to resort to the said practice in future also.
- 19.50 On assessment of DG's observation and recognizing the fact that such boycott deny the market to the pharma companies when AIOCD and its affiliate State and District Associations i.e ADDA and BDDA, try to enforce their decision on the pharma companies on the appointment of stockist (issue of NOC), payment of PIS charges etc, the Commission holds that such boycott have the effect of limiting or controlling supplies/distribution/availability of drugs which causes AAEC as it results in denial to market access to the pharma companies and non-availability of drugs to the consumers.
- 19.51 The Commission, therefore, is of the considered view that the act of boycott by AIOCD, ADDA and BDDA is in contravention of the provisions of Section 3(3) (b) read with Section 3(1) of the Act. Thus, the Commission concludes that the conducts

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of AIOCD, ADDA and BDDA 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 i.e ADDA and BDDA 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 ADDA and BDDA are in violation of provisions of Section 3(3)(a) and 3(3)(b) of the Act respectively. However, it is clarified that regarding the practice of PIS, the District Associations have no role and the bulletin is published and the approval is granted by the State Federations / State Units of AIOCD (ADDA here), therefore the liability for this anti-competitive conduct can be fastened only on ADDA only.

20. Issue No 2:

- 20.1 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?
- 20.2 DG has concluded that as the conduct of AIOCD and its affiliates, i.e., ADDA and BDDA is emanating from the various MOUs signed between the AIOCD-OPPI-IDMA, the decision amongst the members of OPPI & IDMA to enter into tripartite agreements between the AIOCD, OPPI & IDMA and to execute the decision contained in the MOUs pertaining to NOC/ LOC, PIS, Fixed trade margin also

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amounts to an anti-competitive agreement within the meaning of section 3(3)(a) and 3(3)(b) read with section 3(1) of the Act.

- 20.3 In this regard, the Commission notes from the DG report that OPPI vide its letter dated 07.11.2011 submitted that its Executive Committee had not renewed the MOUs with the AIOCD despite the best efforts of AIOCD and, therefore, contended that all previous arrangements, including the MOUs between the two associations stand expired and have not been renewed. Similarly, IDMA vide its forwarding letter dated 20.12.2011 submitted a resolution dated 02.12.2011 adopted by its Executive Committee wherein it was resolved that all the MOUs entered between IDMA and AIOCD between the years 1982 to 2003 and deemed to be operative on the said date have been terminated. These resolutions were also received / noted and accepted by the President of AIOCD.
- 20.4 However, DG has concluded that the anti competitive practices of AIOCD, OPPI and IDMA are still in force since OPPI and IDMA have failed to show that they have issued any public statement or have even intimated their members to the effect that the MOUs between AIOCD, OPPI and IDMA have been terminated. As per DG, the submissions of OPPI and IDMA in this regard do not have any substance and are merely an attempt on their part to wriggle out of their culpability in terms of the provisions of the Competition Act 2002.
- 20.5 However, leaving apart the observation of DG on possibility of continuance of the anti-competitive 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 MOUs between them, can be the subject of examination under section 3(3) of the Act.
- 20.6 In this regard, the Commission notes 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.

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Similarly, IDMA, formed in 1961, as noted from its website, has about 750 wholly Indian large, medium and small companies and State Boards in Gujarat, Himachal Pradesh, Uttaranchal, Haryana, Tamil Nadu and West Bengal as its members.

- 20.7 Thus, it can be seen that OPPI and IDMA are 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 agreements amongst the entities engaged in identical or similar trade of goods or provision of services.
- 20.8 In the light of the facts and legal position detailed above, it is apparent that AIOCD, OPPI and IDMA cannot be said to be the entities engaged in identical or similar trades of goods or provision of services. Therefore, the MOUs between AIOCD, OPPI and IDMA cannot be examined for violation of Section 3(3) (a) and 3(3) (b) of the Act as has been done by DG.
- 20.9 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

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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.

20.10 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.

21. Issue No. 3

- 21.1 After having dealt with the first two issues the Commission proceeds to decide the issue no. 3 i.e. whether the members / office bearers of the Executive Committees of AIOCD, ADDA, BDDA, OPPI and IDMA are also liable for violation of Section 3 of the Act?
- 21.2 As held by the Commission in its order in MRTP case no. C-127/2009/DGIR (4/28) in the matter of Varca Druggist & Chemist and Ors. Vs. Chemists & Druggists Association, Goa, in case no. 20/2011 in the matter of Santuka Associates and AIOCD & Ors 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

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

- 21.3 In the present matter, the Commission in its meeting held on 10.01.2012 and 06.09.2012 had asked the ADDA, BDDA, AIOCD, IDMA and OPPI to furnish the names and addresses of its office bearers and annual turnover of the enterprises / firm, which they represent for the last three years. The Commission in this regard notes that the required details have not been received from all the parties so far. Therefore, the Commission decides to deal with the issues of passing orders under Section 27 of the Act against the individual members separately when the requisite information is submitted by them to the Commission. Further, in view of the findings given on Issue no.2 the Commission holds that the office bearers of OPPI and IDMA cannot be held liable for contravention of provisions of section 3 of the Act.
- 21.4 With regard to the conduct of Alkem, Commission notes that DG has not found any violation by it. The Commission also is of the view that the grievance of the Informant mainly arises out of the practices of AIOCD, ADDA and BDDA for which they have been held liable. Under the circumstances, there seems no need to pass any specific order against Alkem in the matter.

Order

22. As the Commission has found AIOCD, ADDA and BDDA 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. The Commission notes that the financial statements of only AIOCD and ADDA are available, as BDDA has not filed its financial statements yet. 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

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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 alongwith 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. BDDA has not filed its financial statements yet, therefore a decision on the quantum of penalty upon BDDA will be taken on the receipt of its financial statements. As per the financial statements submitted by ADDA it had the following turnovers / receipts during the preceding three years i.e. 2008-09, 2009-10 & 2010-11:

Name	Turnover / Receipts for Financial Years (In Rupees)							
	2008-09	2009-10	2010-11					
ADDA	37,04,957.37	52,61,850.85	78,66,119.85					

23. The Commission after considering the facts and circumstances of the present case is of the opinion that it is appropriate to impose penalty @ 10% of the average of the receipts for financial years 2008-09, 2009-10 & 2010-11 on ADDA. Therefore in exercise of powers under Section 27 (b) of the Act, the Commission imposes penalty on ADDA as under:

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Name	2008-09		2009-10		2010-11		
	Gross	10% of	Gross	10% of	Gross	10% of	Average
	receipt /	receipt /	receipt /	receipt /	receipt /	receipt /	of (A),
	turnover	turnover	turnover	turnover	turnover	turnover	(B) and
	(Rounded	(Rounded	(Rounded	(Rounded	(Rounded	(Rounded	(C) [(A)
	off) (In	off) (In	off) (In	off)(In	off) (In	off) (In	+(B)+(C)
	Rs.)	Rs.)	Rs.)	Rs.)	Rs.)	Rs.)	÷ 3 (In
		(A)		(B)		(C)	Rs.)
ADDA	37,04,957.37	3,70,496	52,61,850.85	5,26,185	78,66,119.85	7,86,612	5,61,097

- 24. Accordingly, the Commission passes the following orders under Section 27 of the Act against the aforesaid three contravening entities:
 - (i) AIOCD, ADDA, BDDA and their members are directed to cease and resist from indulging in and following the practices which have been found anti-competitive in violation of Section 3 of the Act in the preceding paras of this order.
 - (ii) The AIOCD, ADDA and BDDA 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 OPPI, IDMA and to Alkem 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.

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- (iv) The Penalty of Rs. 5,61,097 is also imposed ADDA. The penalty shall be paid by ADDA within 60 days from the date of receipt of copy of this order.
- 25. 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

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