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## Global Forum on Competition

### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from CUTS

-- Session III --

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## COMPETITION CONCERNS IN MARKETING AND DISTRIBUTION SEGMENTS OF THE INDIAN PHARMACEUTICAL INDUSTRY

-- CUTS --

1. A number of elements in the pharmaceutical industry and the overall healthcare sector have implications on the level of competition (and anticompetitive practices) in these markets, and the resulting impact on consumers. Some of the common consumer concerns like malpractices by doctors, behaviour of pharmacists and hospitals and of pharmaceutical firms proliferate when the providers get commercially motivated rather than looking at their role as custodians of public health in society. Issues of tied selling, exclusive supply and coercive distribution agreements etc. are considered as usual practice.

2. This paper examines some of these practices in the Indian pharmaceutical market – and explores if the competition law is adequate and the competition agency sufficiently empowered to curb such anticompetitive behaviour in this sector. One of the key constraints is the level of information asymmetry in the sector which leaves the consumers at the mercy of the healthcare provider.

### 1. Introduction

3. Competition is vital to the efficient functioning of markets in a market-led economy, both for the consumer and the producer. In the absence of competition, anticompetitive practices can stifle potential benefits of the market reforms process. Many developing countries have adopted national competition regimes over the last decade, but only a handful of them have developed a track-record of good competition enforcement. One of the reasons is that competition enforcement needs to be based on evidence, and generating such evidence in key sectors in developing (and least developed) countries is often a challenge.

4. In this paper, CUTS has attempted to present some of this evidence that it has collected over the last few years of its engagement in some of the segments of the Indian pharmaceutical industry. CUTS engagement in this sector, stems from its core business of protecting the interest of consumers. In India, consumers face a number of challenges in accessing good quality healthcare at affordable price. Some of these challenges originate from market imperfections and information asymmetry which are inherent to the Indian healthcare and specifically the pharmaceutical sector.

5. The Indian pharmaceutical industry is a complex market, with a large number of players associated with various components of this industry – from manufacturing to distribution. From an export-oriented perspective, the industry is highly regulated and one of the most evolved in terms of sophistication and application of science and technology. It is also one of the largest hubs of low-cost, generic medicine worldwide, and has evolved as the pharmacy for the developing world over time. Many developing countries also import a high volume of medicines from India.

6. Domestically, the nature of the pharmaceutical industry – where decision making is in the hands of doctors and pharmacists and not the consumer – leads to opportunistic behaviour by providers. Further, the regulatory framework is also fragmented and exacerbates negative outcomes in the market.

***As per the World Bank report (2012), India's 'out of pocket' expenses on healthcare is 86 percent which is among the highest in the world***

7. A large portion of the healthcare expenditure in India consists of 'out of pocket' spending by patients and their families. A substantial proportion of this (72 percent, as estimated in 2011) is accounted for by the cost of medicines.<sup>1</sup> Such expenses are directly responsible for households falling into poverty or having to sell assets or incur debts.<sup>2</sup> Availability and cost of drugs is, therefore, a key development challenge in India. It is essential to analyse if lack of competition (or anticompetitive conduct) in the pharma market can be directly attributed to the nature of the market and behaviour of actors – so that a solution (including using the Competition Act 2002, of India) can be explored.

8. A look at the Competition Act, 2002 shows that the legislation is adequately equipped to deal with some of these conducts in the pharmaceutical sector. The real hurdle, however, is generating the evidence for the competition agency to initiate any action. This paper presents some of the findings of CUTS that can be utilised by the competition enforcement agency to look more closely into this sector.<sup>3</sup> The evidence presented here has already been shared with the Competition Commission of India (through various means) – with the hope that the authority will take cognisance of facts and initiate some investigations soon.

9. This paper starts with a brief introduction about the profile of the Indian pharmaceutical industry. It goes on to explain the prevailing regulatory framework in this sector – and highlights the fact that on certain grounds there seem to be challenges in the structure and the enforcement of these regulations. Further, there is lack of coordination between cogent regulatory areas/authorities – that seem to create opportunistic behaviour in the pharma industry. Certain illustrations of such behaviour is presented in next sections of this paper – it includes a brief account of practices both in the marketing and distribution segments of the pharmaceutical sectors in India, compiled from CUTS' own experience and other documented sources. It concludes with a section that provides some recommendations on how competition issues in this sector should be dealt with – going forward.

## **2. Industry Profile and Recent Trend**

***Indian pharmaceutical industry is ranked 3rd in volume and 14th in value terms global***

10. Until 1970, the Indian pharmaceutical market was dependent on imports and dominated by multinational corporations (MNCs). Drug prices were amongst the highest in the world. The scenario changed dramatically after the Patents Act of 1970 allowed process but not product patents for pharmaceuticals, enabling Indian firms to imitate foreign drugs by making minor modifications to the manufacturing process. In the same year, a new and far more extensive Drug Prices Control Order was promulgated, bringing a swathe of medicines under

stringent price controls. However, all these policies seem to have been put into reverse gear from the late 1980s. In particular, imports and foreign investment which had been kept at bay were now permitted to increase their penetration into the domestic market, and product patents were reintroduced in 2005 as part of India's obligations under the WTO (Trade Related Aspects of Intellectual Property Rights or TRIPs Agreement). These government actions totally changed the nature of the Pharmaceutical industry in India.

<sup>1</sup> Shiva Kumar, A. K. et al. 'India: Towards Universal Health Coverage', LANCET Journal, January 2011. ([www.thelancet.com](http://www.thelancet.com))

<sup>2</sup> Over the process of implementing its 'Support for India' Health Sector programme, the World Bank estimated that in 2004, 63 million individuals (nearly 12 million families) fell into poverty in India due to healthcare expenditure.

<sup>3</sup> This study does not with Mergers and Acquisitions (M&A) in this sector (though, there has been a flurry of mega M&As in the Indian pharma sector) or into the realm of Intellectual Property Rights (IPRs).

11. The Indian pharmaceutical sector today is one of the leading sectors in terms of its contribution to the country's gross domestic product (GDP). It has grown significantly in past five years and is expected to continue its double digit growth. Indian pharmaceutical industry ranks very high in the world, in terms of technology, quality and range of medicines manufactured. It is the third largest in terms of volume and fourteenth in terms of value.

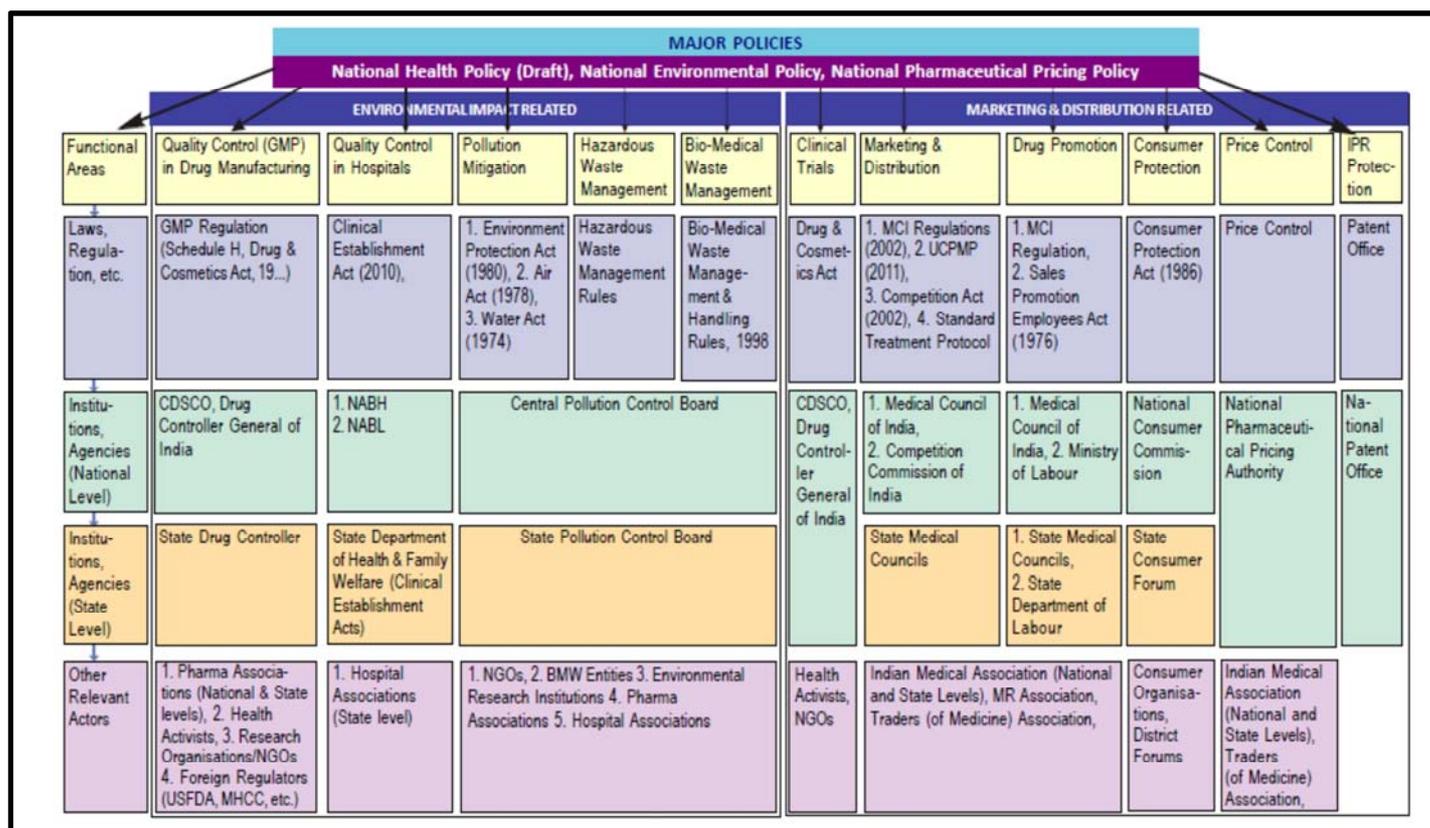
### **Key Feature of the Industry**

|                              |   |
|------------------------------|---|
| Supply                       | High for therapeutics segments, which is typical of a developing market   |
| Demand                       | Very high for certain therapeutic segment. Varies as life expectancy, literacy increases and with increase in life style diseases   |
| Barriers to entry            | Distribution network, patents, plant approval by regulatory authority, clinical trial, long approval period   |
| Bargaining power of customer | Low, as information asymmetries are high and consumption choice is not in the hand of consumers   |
| Competition                  | Though, the sector is highly fragmented with more than 20,000 firm, the top 300 companies control 70 percent of the market. It is to be noted that a number of anticompetitive practices pervade the pharmaceutical industry including collusion, cartelisation, abuse of dominance, etc. |

### **3. Regulatory Framework of the sector**

#### **3.1 Overall Regulatory Architecture – Allocation of Duties**

12. The figure below provides an idea about the regulations pertaining to various aspects of the pharmaceutical sector (and overall healthcare sector) in India – and its application at the different (administrative) levels. This figure provides a comprehensive idea of various aspects of the pharmaceutical industry that are covered by specific regulations, such as clinical trials, marketing and promotion of drugs, price control, consumer welfare, etc. Healthcare (under which pharmaceuticals are handled) is a subject that is handled at the state-level, as per the division of administrative duties in India. So, while the national government develops policies, it is the state that is entrusted with their enforcement. It is often the enforcement where problems exist.



(Source: Rethinking Business Responsibility in India, CUTS 2013)

### 3.2 Regulations Equipped to Handle Malpractices related to M&D

13. The mechanisms to regulate the pharmaceutical and healthcare provider market are quite blurry, although there are several key institutions that, taken together, could play a valuable role. They include the Medical Council of India (MCI); the Departments of Health in individual states; Department of Pharmaceuticals through industry wide codes; associations of qualified practitioners (such as the Indian Medical Association); Competition Commission of India and a judicial system that allows consumers to approach a consumer court to seek justice for medical negligence.

14. From analysis undertaken by CUTS<sup>4</sup> it is evident that there is lack of coordination in the implementation of these regulations between the national level and the state levels. The varying degree of effectiveness of state level regulators (function of human and financial capacity of a particular state) leads to differential outcomes in addressing market practices across different states. Further, CUTS research has also revealed the lack of synergies between different regulations/regulatory agencies dealing with the same issue.

15. Such a fragmented nature of regulations and problems in their implementation seem to act as a trigger for opportunistic behaviour by market-players in this sector (in fact in the entire healthcare sector). In the next section, some illustrations of such behaviour have been presented to substantiate the above position.

<sup>4</sup> Batham, Vikash, Rijit Sengupta and Vasanthi Srinivasan (2013), "Rethinking Business Responsibility in India pp 124"

#### 4. Anticompetitive concerns in the Pharmaceutical sector

16. Consumers trust doctors to act in their best interests. However, most consumers are largely unaware of the influence of the pharmaceutical industry's marketing practices on the healthcare professionals they rely on. The impact of drug marketing on availability, price and quality of drugs at the consumers end are well recognised by industry insiders. A survey conducted by PriceWaterhouseCoopers showed 94 percent of industry stakeholders said that pharmaceutical companies spent too much money on advertising.<sup>5</sup> Unethical marketing and trade practice by pharma companies in India is often considered as a 'usual practice'. The problem is compounded due to absence of proper regulatory and government actions.

##### Box 1. Documented Collusion between Doctors and Pharmaceutical Firms

- Piramal Healthcare in Mumbai took some 200 diabetologists in late January 2010 and then a batch of oncologists in mid-March to Turkey. Some of these travellers were investigated by MCI
- Dr. Reddy's Lab in Hyderabad paid for about 200 doctors to visit Hyderabad in January 2010
- Navi Mumbai-based Wanbury dispatched some 100 doctors to Dubai in mid-February 2010 and put them up at the luxurious Dhow Palace Hotel. Cox and Kings handled the package tour at a cost of about Rs.40,000 (US\$660) per person
- Johnson & Johnson generously sponsored some 300 kidney specialists (along with spouses) to attend a 3-hour "scientific conference" in Singapore with stay extended by another 3 days
- LG Pharma paid for some 200 nephrologists to visit Turkey for holiday
- \*Ranbaxy sponsored the visit of some 400 prescribers to Bangkok

*Source: Monthly Index of Medical Speciality (MIMS), New Delhi, April 2010*

17. Anticompetitive conduct in the pharmaceuticals sector in India can range from cartelisation to vertical arrangements among service producers in the supply chain. Although there has been no systematically documented and compiled evidence of such activities in India, information garnered from various sources point towards this tendency. Some facts and figures (pertaining specifically to the pharmaceutical sector, and more broadly to public healthcare in India) extracted from various source by CUTS are presented below:

#### 5. Practices related to Marketing and Promotion of Drugs

18. The relationship between the pharma industry and medical professionals has been in debate in India for several years now. Pharma companies have been influencing doctors so that they prescribe their medicines. While the doctor should ideally be prescribing the cheapest and the most readily available drugs – a practice that would ensure that consumers derive maximum possible benefits from competition among pharmaceutical firms – in reality, firms often try to capture the market through inappropriate market practices involving collusion with doctors. This, in turn, implies that consumers are often denied value for money spent on both the services of physicians as well as medicines.

<sup>5</sup> PricewaterhouseCoopers.2007. Pharma 2020: *The Vision, Which Path will you take*. Accessed on 1 October 2007 at: <http://www.pwc.com/gx/eng/about/ind/pharma/pharma2020final.pdf>

### 5.1 Evidence from CUTS investigation

19. From the experience of working at the ground-level, CUTS has realised that one of the means for assessing malpractices in this sector (to cover both pharmaceuticals and healthcare providers) is by undertaking ‘prescription audit.’<sup>6</sup> Over the years – CUTS has developed its ability to manage such exercises undertaken by experienced medical professionals and analyse the data with the help of these professionals. In this section, some illustrations are provided from some of these exercises of CUTS.

20. In a pan-India survey carried out by Voluntary Consumer Action Network, in association with Consumer Unity & Trust Society (CUTS) in 1995, data of over 2000 prescriptions were collected by consumer groups across six states of Indian – West Bengal, Rajasthan, Gujarat, Maharashtra, Tamil Nadu and Andhra Pradesh. The survey revealed that there was a gross tendency to prescribe useless medicines, like tonics, restoratives, vitalisers and vitamin formulations (irrational prescription), when these were not necessary.

21. Another study by CUTS in 2010 in two states of India (Assam and Chhattisgarh), revealed that a mere 20 percent of the total consumers covered by the survey obtained medicines from the public hospitals they visited. Doctors in these hospitals were prescribing drugs of certain companies which were not available in the hospital (where such drugs, if available are provided free of cost). These drugs were, however, available with the private chemists shop just outside these public hospitals. Similarly, the tendency of poly-pharmacy (prescribing more than four drugs in a single prescription) was found in 57 percent prescriptions in Chhattisgarh and in 52 prescriptions in Assam respectively.<sup>7</sup>

22. Another critical dimension is that while it is illegal for doctors in India to accept gift in cash and in kind as per the Medical Council of India (MCI) Regulation 2002, this is a rampant practice, and enforcement of the law is rarely done.<sup>8</sup> While the MCI Regulation 2002 talks about penalising doctors if found guilty of accepting gifts, there is no mention of the fact that actions would also be taken against the gift-giver (i.e. the pharmaceutical company). This could have promoted deterrence.

23. In the same vein, there are practices where other actors in the healthcare supply chain are engaged in. These are also common, as CUTS research has shown at the micro-level:

- **Collusion between doctors and hospitals.** One of the indicators of the collusion between doctors and hospitals is the exponential increase in the number of *caesarean* deliveries in the last two decades. The average (biologically accepted) *caesarean* rate should not exceed 10-15 percent; but in certain urban hospitals it is as high as 80 percent.<sup>9</sup> This is profitable both for the doctors and the hospitals.
- **Collusion among doctors and diagnostic laboratories.** Diagnostic tests and investigation is yet another area where the interest of the patient is sacrificed to the commercial motives of the actors. The doctor gets a cut from each reference s/he makes to the diagnostic clinic. A physician referring his patients to a specialist for further treatment does so, on the basis of an arrangement in which part of the fees thus earned by the specialist goes to the physician.

<sup>6</sup> Conducting an audit of prescriptions written by doctors, when a patient visits the doctor at a government or a private healthcare facility

<sup>7</sup> These findings and more can be found in the CUTS publication, *Unholy Alliance in Healthcare* (2011), which can be downloaded from: [www.cuts-cier.org/COHED/pdf/Unholy\\_Alliances\\_in\\_Healthcare\\_Services-COHED.pdf](http://www.cuts-cier.org/COHED/pdf/Unholy_Alliances_in_Healthcare_Services-COHED.pdf)

<sup>8</sup> A rare case of enforcement here: [www.hindustantimes.com/india-news/jandk/j-amp-k-hc-restrains-docs-from-accepting-gifts-from-pharma-firms/article1-1165955.aspx](http://www.hindustantimes.com/india-news/jandk/j-amp-k-hc-restrains-docs-from-accepting-gifts-from-pharma-firms/article1-1165955.aspx)

<sup>9</sup> Times of India, November 12, 2011

## 6. Practices related to the Distribution of Drugs

24. This Indian pharmaceutical sector is one of the fastest growing industries, which has maintained its decent growth rate even in the face of the financial turmoil. However, the rapid growth has not led to considerable improvements in availability of medicines at the consumer end which emanates from a number of factors, including fragmented nature of the distribution network, limited advancement in regulatory reforms, and presence of strong lobbies of traders involved in supply of pharmaceutical products across the country.

25. The pharmacy owners in India are banded together to form a huge cartel in the guise of a trade association – All India Organisation of Chemists and Druggists (AIOCD). In the past, the AIOCD has been known to launch boycotts against drug companies to win higher profit margins. AIOCD has also forced some drug companies to sign "memorandums of understanding" in which they agree to increase profit margins to pharmacies.

26. Coercive practices in the distribution sector exist since a long time, as even the erstwhile MRTP Commission<sup>10</sup> intervened in a few cases involving the AIOCD. However, Monopolies and Restrictive Trade Practices Commission (MRTPC) was not effective, as the law was weak/limited. CCI has enough powers to tackle issues, given that the law provides for adequate powers. Thus, the recent action by CCI on penalising AIOCD is a move in the right direction.

### 6.1 Action initiated by CCI [Case concerning All India Organisation of Chemists and Druggists (AIOCD) and its State and District level Associates]

27. It all started when a clearing and forwarding agent of USV Limited (a healthcare company/drug manufacturer), from Cuttack named, M/s Santuka Associates Pvt. Ltd decided to take on AIOCD for limiting and restricting the supply of pharmaceutical drugs. There were other two similar cases handled by the CCI, *Varca Chemist and Druggist and others vs Chemists and Druggists Association, Goa and Vedant Bio Sciences vs Chemists & Druggists Association of Baroda*. However, the case of Santuka Associates is significant as it is directly against the national level association (AIOCD) whereas the other two were against their state level associates.

28. Santuka approached the Commission and filed the, alleging AIOCD of *following anticompetitive practices* in distribution of pharmaceutical products in India:

- **Requirement of No Objection Certificate (NOC).** Drug manufactures could not appoint any person/agency for distribution of its drugs in the distribution chain unless the said person has a NoC from state association.
- **Mandatory Advertisement on Launch of New Drugs.** The AIOCD ask mandatory payments from drug manufacturers for a service called the Product Information Service (PIS). Under the said service, AIOCD issued a PIS bulletin, which is a part of the magazine published by the respective state associations.
- **Playing with the Margins.** The trade margins for controlled drugs are regulated by the Central Government through Drug Price Control Order, 1995 (DPCO). However, the Trade Margins of uncontrolled drugs were fixed by AIOCD under a Memorandum

*AIOCD is a national level trade association of chemists and druggists, active since 1975, representing nearly 750,000 chemists all over India*

<sup>10</sup> The erstwhile competition enforcement agency of India – MRTPC

of Understanding that existed between AIOCD and associations of pharmaceutical manufacturers, such as Indian Drugs Manufacturers Association (IDMA) and Organisation of Pharmaceutical Producers of India (OPPI). MoU binds drug manufacturers to offer 10 percent margin to whole-sellers and 20 percent margin to retailers for sale of their drugs.

- **AIOCD's Way or Highway.** AIOCD & State Associations boycotted the drug manufacturers who did not adhere to the requirements stated above, namely the NoC, the PIS and the trade margins by issuing directions to players in the distribution chain. At various occasions, on directions issued by AIOCD, the drug manufacturers often stopped supplies to the stockists who disobeyed these directions.

29. The Commission in its investigation found AIOCD and its affiliates guilty of conducting above anticompetitive practices citing in its order that:

- Conduct of AIOCD and its affiliates in granting of NoC before the appointment of stockists/distributors leads to limiting the of supply of drugs in the market, in contravention of section 3(3)(b) of the Act.
- Requirement of advertisement for launching a product in the markets results in entry barrier and hence restrict supply of drugs in the market drugs in violation of Section 3(3)(b) of the Act.
- Fixing of trade margins for stockists/distributor amounts to fixing of prices violating section 3(3)(a) of the Act.
- Finally, on the issue of boycotting drug manufacturers, the Commission remarked that such illegal acts have a far-reaching effect on the distribution and availability of drugs, results in Appreciable Adverse Effect on Competition (AAEC). The consequence is not only denial to market access but also rampant non-availability of the drugs to the consumers.
- Penalty could have been stringent

*Alas, the fine based on association's turnover is grossly inadequate, and should have been levied on the members' turnover constituting the association*

30. In view of the above anticompetitive practices, the Commission imposed a maximum penalty of Rs 47.40 lakhs on AIOCD (10 percent of its turnover). Further, the Commission also directed AIOCD and its affiliates to cease and desist from such activities in future

31. The CCI imposed the maximum possible fine of 10 percent of the associations' turnover. But as this largely comprised their membership fees, it was negligible relative to their members' turnover from selling drug

## 7. Conclusion

32. The problem of unethical drug promotion can be countered to a great extent by preparation of treatment guidelines, conducting periodic prescription audits and consumer education. The government should frame comprehensive legislation to make all healthcare professionals accountable to the system and ensure that the drug companies comply with the national criteria for drug promotion as well as WHO Ethical Criteria for Medicinal Drug Promotion.

33. Pharmaceutical companies should realise that aggressive marketing of drugs promotes irrational use. Self-regulation plays a key role here. Recently, pharma giant GSK and Abbott declared that it will not be paying doctors to promote their drugs. This is a much appreciated initiative from leading players in the industry that has for long been accused of unethical sales and marketing practices by governments, regulators and even healthcare providers.

34. Department of Pharmaceutical, the concerned ministry for the pharma Industry in India should enforce a mandatory code for the companies to follow stringently. They should learn from the example of US Food and Drugs Administration (FDA) as how it has mandated strict regulations to curb unethical promotions. These include mandated disclosure by pharmaceutical companies of the expenditure incurred on drug promotion, ghost writing in promotion of pharma products to attract disqualification of the author and penalty on the company and vetting by FDA of drug related material in continuing medical education.

35. The recent order of CCI described above in the AIOCD case is bound to have some impact on the distribution of medicines in India as well as prices charged to consumers. A drug manufacturer may appoint any person or agency, and any number of persons and agencies, at any level in its distribution chain as it may deem fit without any fear of repercussions from the traders' body. It may also set up an exclusive distribution channel managed by itself for distribution and sale of its medicines. Further, drug manufacturers can launch and distribute their new products without publishing information of their products in PIS bulletins.

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

37. In case any drug manufacturer or concerned party is victim of any anticompetitive practice described above, it may notify the CCI who will take appropriate action as required

38. As consumers, we need to be more vigilant about the prevailing market practices and aware of such laws that protect them from being a victim of anticompetitive conduct. This is a sector that CUTS is committed to continue being closely engaged with in the future – and one of the ways forward is to work hand in hand with the pharmaceutical associations in the country going forward.

#### Suggested action points

- *Suo Moto* action by CCI on the basis of complaint from relevant sources
- Strict enforcement of MCI regulations to regulate healthcare providers
- Mandatory code of conduct for pharmaceutical marketing and promotional practices
- Periodic scrutiny of prescription patterns at both government and private healthcare facilities
- Formulations of standard treatment guidelines and awareness on rational use of drugs
- Prescriptions of generic drugs as far as possible

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