

ANNEXURE I

Report on

NATIONAL WORKSHOP ON OPTIONS FOR USING COMPETITION LAW/POLICY TOOLS IN DEALING WITH ANTI-COMPETITIVE PRACTICES IN PHARMACEUTICALS AND THE HEALTH DELIVERY SYSTEM

8 September, 2006, New Delhi

BACKGROUND

CUTS CCIER conducted a study entitled “*Options for Using Competition Law/Policy Tools in Dealing with Anti-competitive Practices in Pharmaceuticals and the Health Delivery System*”. The World Health Organisation (WHO) and the Ministry of Health and Family Welfare, Government of India, supported the project.

The overall objective of this project was to identify competition concerns in the pharmaceutical sector and health delivery system; examine the scope of competition policy and law in dealing with such concerns; and suggest an implementation strategy to enhance access to medicines and enhance the efficiency of health delivery systems.

The purpose of this workshop was to share the findings of this study with various stakeholders consisting of consumer organisations, health and competition experts, academia, consumer and other NGO activists and representatives of business associations and seek and incorporate their comments and observations on the report.

The workshop was divided into three sessions. Nitya Nanda, the Principal Investigator of the study from CUTS made a presentation on the study in the first session. This was followed by a panel discussion between experts from the Voluntary Health Association of India (VHAI), Indian Drugs Manufacturers Association (IDMA) and Competition Commission of India (CCI). In the third session, the participants raised their concerns on the issue.

DETAILS OF THE PROCEEDING

Welcome Note

Ujjwal Kumar (UK), National Consultant from the Ministry of Health and Family Welfare welcomed the participants on behalf of the Ministry and the WHO, India, and enlightened them about their work. A World Trade Organisation (WTO) cell has been set up in the Ministry of Health and the said project was implemented under its mandate. The main aim of the workshop was to discuss the outcome of the study, which has been commissioned by the Ministry to CUTS. Idea of this study was conceived under a new sub-programme area of WHO on Trade & Health which among other things endeavours to document the impact of globalisation on public health and public health policy and also to enhance coherence between trade policy and health policy. While flagging the studies commissioned and workshop organised for this purpose, UK briefly outlined on:

- Impact of Trade Related Intellectual Property Rights (TRIPS) on pharmaceutical prices in India carried out by the National Institute for

Pharmaceutical Education and Research, Chandigarh, institution under Ministry of Chemicals & Petro-Chemicals

- Implication of the WTO agreement on Sanitary and Phyto-sanitary Standards (SPS) & Technical Barriers to Trade (TBT) on access to health, carried out by Rajiv Gandhi Foundation
- Impact of offshoring of clinical trials in India carried out by National Law School, Bangalore
- Impact of mailbox patent application on access to health, just commissioned to Centre for Technology & Development, New Delhi

Access to health care is very high on the government's Agenda and this study is an attempt to know as to how competition law and policy can be used to enhance access to health.

With the advent of privatisation since 1991, more and more reliance is being put on private sector for meeting public health needs. Anti-competitive practices in the market place will surely pose hurdle in meeting such needs. Therefore, understanding the competition dynamics of pharmaceutical sector and health delivery system is *sine-qua-nun* for taking any law policy measure to rectify any adverse situation. In the post-TRIPS and post-Product Patent era, the common logic is, we will slowly move towards more monopolistic market situation in the pharmaceutical sector. The current spurt of mergers and acquisitions will further aggravate the situation.

In India, where the consumer meets around 80 percent of health expenses, allowing an unregulated profit motive monopoly could be detrimental to an access to health. The government and respective regulators will have to keep a close eye on the competition situation and proactively take necessary action where any abuse is apparent. In this regard, expectations from the upcoming competition regime under the new competition act, which has been devised to suit the changed economy architect of India, are high.

The present study is a first of its kind in India that has seen the access to health issue from the competition policy perspective. The study has, apart from secondary literature, also used primary data through survey in four metros and Ahmedabad and has taken opinions from stakeholders like doctors, hospitals, pharmaceuticals companies, chemists, and consumer organisations. UK congratulated CUTS and reinforced that this is not the end. The recommendations made in the study are to be implemented for desired results. For this, there is a need to debate and further streamline the recommendations and come out with an action plan.

Outlining the sessions of the programme, UK preceded further, requesting Nitya Nanda, the Principal Investigator, to share the findings of the study with the participants.

Pradeep S Mehta, Secretary General, CUTS, took this opportunity to introduce Mr. P Venkatash, Director, Ministry of Consumer Affairs, himself a participant – to the other participants.

Session I – Presentation on Research Findings, Nitya Nanda

CUTS' Work on Competition Policy Issue

Nitya Nanda (NN) started with a brief introduction about CUTS' work on competition policy issues in the last several years, in India as well as other countries. CUTS has already worked on pharmaceutical sector (among other sectors) vis-à-vis competition policy under one of its' study viz. "Towards a Functional Competition Policy for India" i.e. *FunComp* and this study is an extension of that. Findings of the earlier studies have been largely incorporated in the present one.

Overview of the Indian Pharmaceutical Industry

Giving an overview of the pharmaceutical industry in India, NN explained that the pharmaceutical industry in India was almost non-existent before 1970. As on date, India is a prominent producer and is able to meet 95 percent of its requirements. Prices of drugs in India are much lower compared to other countries, the reason being an absence of a patent regime in India, so far. Globally, the Indian pharmaceutical industry garnered attention during the debate on TRIPS and public health. Indian companies are now producing drugs at one-tenth the price of other countries'. In spite of the presence of big multinationals, the market leaders are some of the Indian companies. Though there is a presence of large number of pharmaceutical industries, some drugs are dominated by a handful of companies.

Peculiarities in the Sector

Highlighting the fact that it is not consumers, but doctors and sometimes chemists who are the decision makers the pharmaceutical industry including the health delivery system, is most prone to anti-competitive practices. While, in developed countries like Japan, US, and EU, where the cost of medicines or treatment are borne either by the government or the insurance companies, in India, the cost is borne out of the consumer's pocket.

In such a scenario, companies are in a position to lure the doctors or the chemists to sell their brand in lieu of commission or higher margin, respectively. In this regard, mandatory generic prescription i.e. prescription by the common chemical name of the drug instead of the branded name, can be useful to check nexus between doctor and the pharmaceutical company. However, this may also lead to position of the consumers vulnerable in the hands of the pharmacists pushing for brands with higher margins. Further, tied selling also exists in cases of hospitals and diagnostic centres.

Most developed countries have adequate provisions to regulate the doctors, pharmacies and the industries to keep a check on the prices. Briefly touching upon the history of price control mechanisms adopted and subsequently revised in India, NN observed that while there are provisions to keep a check on the pharmaceutical industries, there is an inadequacy of provisions to regulate doctors and chemists.

Competition Concerns

Though there has been no evidence of cartelisation in the pharmaceutical industry, the chemists or pharmacists operate as an association or cartel under All India Organisation of Chemists and Druggists (AIOCD). AIOCD is known to launch boycotts against drug companies to grab higher profit margins.

A rising awareness as to Intellectual Property Rights (IPRs) in India has also raised competition concerns in the form of the patent holder exercising or imposing unjustifiable condition on the licence holder. In this context, it was suggested to bring IPR related abuses and the responsibility of granting compulsory licences under the Competition Commission of India (CCI). Mergers & Acquisitions (M&As) on the national and international arena, which lead to dominance of the market share by few, may also raise competition concerns.

Recommendation was made to standardise and accredit the diagnostic centres and hospitals to ensure quality output to the patients.

NN shared the survey results conducted on the doctors, pharmaceutical industry, consumer organisations, hospitals and the pharmacists with the participants bringing to the lights various facts at the ground level.

On the issue of data protection and data exclusivity, it was observed that granting a long period to data protection/exclusivity could be detrimental to consumer interests.

The study also called for proper and overall monitoring at the distribution level to check entry of spurious drugs in the market. An account of how anomalies exist in the pricing of the drugs was also made.

Session II - Panel Discussion

1. Gajanan Wakankar

With a brief note of thanks, Gajanan Wakankar (GW) appreciated the timeliness of the workshop when several things are happening with regard to pricing, date exclusivity and competition law of India. GW also complimented the work done in the form of exhaustive study under the project especially in the situation where different players with conflicting interests exist. Further, GM emphasised on the fact that he is representing indigenous pharmaceutical manufacturers only and not the multinationals.

He highlighted some observations from the study. Pointing to the recommendation made in the main report, while he agreed to most of them, there were reservations on a few.

Data Protection & Data Exclusivity

Multinational pharmaceutical manufacturers were able to introduce data protection and data exclusivity during the Uruguay round. Although, at present, the text available requires only the protection of data, it does not require data exclusivity. The current regulation in India satisfies the TRIPS agreement requirements i.e. protection of data from people for unfair commercial use.

The term 'Data Exclusivity' does not form any part in the TRIPS agreement. This was demanded by the US delegation during Uruguay round. It was discussed and rejected time and again in the ministerial conferences. Hence, there should not be any provision for data exclusivity in the country.

Pricing

GW presented a CII study reflecting that only 15 percent of total expenditure on health care is spent on medicines indicating that prices of medicines in our country are quite low. Most of the expenditure is incurred on hospitalisation, diagnostic centres, doctor's fees, etc.

Japan and India are the only two countries where multinational pharmaceutical corporations do not have control over the market. This has been achieved in India due to 1970 Patents Act, prior to which, multinational pharmaceutical corporations controlled nearly 80 percent market share of the Indian market. Now their market has come down to 15 percent only, the rest being controlled by the indigenous generic drug industry.

Indigenous drug manufacturers are providing the drugs at the lowest and economical prices, which form one of their ultimate goals. While pursuing the goal, there are many players in the field and the government and consumer organisations, hold different opinions, and therefore the procedure of pricing face lot of controversies.

The Drug Prices Control Order 1995 is the operating system at the moment, which regulates the pricing. It has a system of scheduled drugs, which covers up to 28-30 percent of the market with about 74 molecules and non-scheduled drugs covering the rest.

GW highlighted one of the tables prepared in the CUTS report, a comparative analysis of the prices of drugs before and after the decontrol of DPCO in 1995 and 1998, pointing to a steep increase in the prices after decontrol.

In response to the inference drawn, GW clarified that the drugs mentioned in the table are basically bulk drugs. In the present WTO regime, facilitating import and exports, prices of the bulk drugs are more or less at par with the international level. When the prices of the bulk drugs in the domestic market go up, more imports take place and vice versa. What has happened in 1995 and 1998 is no longer applicable now, as the mechanism of open export and import has changed the whole scenario. Further, rise in prices is more due to inflation at the compounded rate of four percent. Considering all this, prices have either not increased or if it has, not risen by more than five percent.

Another table indicating the prices of certain drugs as more in India than in Canada and the UK was also questioned. GW observed that the prices mentioned are the government procurement prices in UK and Canada and these prices are generally 50 percent of the actual retail prices.

Further, with the constant monitoring by the National Pharmaceutical Pricing Authority in India (NPPA) over prices, it is very unlikely that the companies raise the prices. Even if they do, they are mandated to lower the prices by NPPA. Prices of drugs in India are still the lowest.

Competition is the best way to bring prices down to a reasonable level. Rigid price control will drive out good medicines from the market. Also, it will adversely affect exports to the tune of 20,000 crore, mainly done by the indigenous industries.

Miscellaneous Issues

Generic Drugs Prescription: GW was doubtful if this would work in lieu of some practical difficulties faced in maintaining quality control over the non-branded drugs.

Declining Access to Health: Access to health according to GW has been improving as indicated by the factors such as increased life expectancy.

Collusive & Anti-competitive Practices: GW assured of co-operating with the government, opposing such practices.

Access to Health to BPL Population: GW assured co-operating with the government in providing access to health to the population below poverty line.

Role of the CCI: GW opined that the role of CCI as an impartial referee would be diluted if it were conferred with the power to grant compulsory licensing.

2. G R Bhatia

G R Bhatia (GRB), from the CCI emphasised on the necessity of creating awareness among the consumers and manufacturers regarding the usefulness and benefits of the Competition Law. The government has enacted the Competition Act in 2002, through which the CCI came into being. India is not new to the Competition law regime. The instrumentality of the new law makes it more efficient than the Monopolies & Restrictive Trade Practices (MRTP) Act. But, the CCI is yet to become fully functional and substantive provisions of the law are yet to be made operational, as now it is only permitted to undertake the competition advocacy.

The new competition law strikes a balance between the two stakeholders, of consumers and businessmen, as it protects the interests of the consumers as well as ensures freedom of trade to the market participants.

GRB stressed on the need to promote competition and competition law, because it makes possible the abundance of goods at an affordable price to the consumer. Further, anti-competitive practices like cartelisation and price-fixing not only affect the consumers, but also the business houses that are the consumers of inputs for producing their product.

With regard to anti competitive agreements in IPRs, GRB observed that IPRs do confer monopoly and there is a need to confer monopoly to provide incentive to the innovator of the formulation of medicine. He, however,

emphasised that the new law is an improved version of the MRTP Act. Under the MRTP Act, there was no specific provision to deal with the abuse of IPRs. Any IPR holder exercising unreasonable restrictions on the licence holder will be guilty of anti-competitive practice. It is left to the wisdom of CCI to decide as to what is unreasonable. This will take care of anti-competitive practices emanating from IPRs.

He also pointed out categorically that the new competition law is not against healthy competition or dominance. But the new law is against the abuse of dominance. With regard to mergers and acquisitions, GRB agreed that mergers lessen competition, but as per the provisions of the new competition law, competition is no longer related to the number of players. In this context, he gave the examples of Pepsi and Coke. In this case, though the number of players is two, yet consumers are benefiting from the rivalry between the two. It is the responsibility of CCI to ensure that such rivalry exists.

He also dismissed the charge against the new competition law that it delays the process of a merger. CCI has been provided with 90 working days to raise objections, if any on the merger, after the voluntary notification has been served. If no objection is raised, the merger is deemed to be solemnised.

Citing the example of the HLL & TOMCO merger, as post-merger consequences, shareholders have benefited, as market value of shares have gone up and even the financial institutions have benefited due to the enhanced financial soundness of the company. But, the government has suffered as the tax liability of the merged entity has gone down. Further, the merger has not even benefited consumers by way of increased volume or better quality or decreased prices. Hence, mergers need to be regulated.

GRB agreed that the pharmacists and druggists have been a hindrance between the manufacturing sector and the ailing patients. This is due to the fact that the MRTP Act has been a reformatory law, while the new competition law is not only reformatory, but also will act as deterrent.

GRB also mentioned that CCI has an Expert Advisory Committee headed by Vijay Kelkar and eminent legal experts who will from time to time evaluate the new findings, as law is an ever-evolving thing. He also cautioned the audience that the CCI should not be confused with agencies like Securities and Exchange Board of India (SEBI) & Insurance Regulatory Development Authority (IRDA). This is because the former are market regulators who can issue licence, while the CCI is only the referee who decides how to play and not who will play.

3. Mira Shiva

Mira Shiva (MS) opined that though the CCI exists and even if there is a lot of hue and cry on the drug pricing issue, what is most unfortunate is that a vast number of people in India are without medicine. MS expressed her concern over affordability of prices of drugs falling outside the purview of essential drugs. Moreover, the production pattern of a pharmaceutical industry should

be structured to ensure sufficient production of price-controlled drugs. MS raised the question that as elementary drugs are not available to the people, the central concern should be as to how to handle this denial.

She recommended uniform pricing of drugs. Holding that she is not against profitability of the pharmacists and druggists and that they are free to maximise their profit she emphasised that such profits should come through economies of scale and not by malpractices.

In India, only 0.9 percent of the Gross Domestic Product (GDP) is put on health. 80 percent of the price for the medicine has to be paid out of the pockets of the consumers. Moreover, there is a 'Medical Mafia', which is controlling the medicine price in India, which literally implies 'pharmaceuticalisation' of medicine prices. So, if this price fixation is left to the market forces, then this will adversely affect the public health system in India. Hence there has to be a price control order in India. Competition alone is not the solution. Aggressive competition may lead to wiping out of certain healthy options.

MS emphasised that health education is must for the consumers in making right choices. This will help to prevent unethical behaviour and will promote a healthy consumption practice as well.

She also emphasised the need for medical, social, and prescription audits to check unscrupulous behaviour of doctors.

4. Anurag Bhargava

Virtually, every country in the world regulates drug prices. This mechanism is not unique to India. However, what is unique is the partial control, putting few drugs under price control. Only 13 percent of the drugs are under price control.

Though there are thousands of producers, for a particular disease, there are very few players. This creates oligopoly in the market, which renders consumers with little or no choice. In this highly privatised system, the government when it is not able to provide drugs, should, in all necessity, protect consumers from the distorted market.

Despite having an industry producing 40,000 crore worth of drugs in India, India is a country with the largest number of people who lack access to drugs, as per the WHO report, 2004. 649 million people in the country cannot access drugs for common ailments and others. . Considering this state of affairs, health care should form the top most priority among the policy makers, which unfortunately is not happening.

The drug policy in India is formulated by the Ministry of Chemicals and not by the Ministry of Health, which is again very peculiar. Policy is thus not guided by a health objective.

The consumer is paying many times more than he should pay. There have been many instances where same drug or formulation is sold at substantially different prices under different brands. The final price paid by the consumer has no relation to the cost of the manufacturer. Drug companies are allowing exorbitantly high trade margins upto 1000 percent, to the retailers, which do not happen in any other commodity.

Addressing the dichotomy existing between the terms essential and life saving, Anurag Bhargava (AB) recommended that there cannot be any difference between the two, as essential drug can be life saving and vice versa.

AB raised the issue of exorbitant amount spent by the drug companies to promote their products. According to an estimate, the top 50 companies in India have spent an amount to the tune of Rs 5840 crore on their drug promotion, which ultimately falls on consumers and this needs to be regulated.

Session III - Floor Discussions

One of the participants from the Consumer VOICE observed that while free competition in consumer products is desirable for consumer welfare, drugs cannot be left to unfettered market forces. Regulation is absolutely necessary to keep a check on spurious drugs.

Also recommended was the revelation of the first point price by the pharmaceutical companies for a consumer's understanding on both cost of production and the subsequent margins thereof.

G C Mathur from Binty urged to bring transparency in justifying the maximum retail price of a drug. Consumers should know the amount and rate of taxes they are paying to buy a medicine. It is evident in many cases that retailers are pocketing some four-six percent of drug price in the name of taxes.

One of the participants questioned the relevance of competition policy and law in a scenario where 80 percent of the population in rural and tribal areas are denied access to health. Family primary health centres in some areas do not even have basic sulphur drugs. Competition policy and law may help in reduction of retail prices of the drugs, but cannot ensure access of medicines to the poor and people in remote areas.

GM called for reconciling the differences existing on state tax, municipal tax and VAT between various states to bring in more transparency and uniformity of pricing of the drugs.

Tarun Das from *Institute of Integrated Learning in Management* insisted to include the subject of access to medical education and training in the report. Further, proper management of hospitals and health centres is also an important issue, which India lacks.

UK made a vote of thanks to the participants, requesting them to mention their concerns, which were not flagged during this workshop due to time constraint, via letters and emails.

ANNEXURE II

NATIONAL WORKSHOP ON

OPTIONS FOR USING COMPETITION LAW/POLICY TOOLS IN DEALING WITH ANTI-COMPETITIVE PRACTICES IN PHARMACEUTICALS AND THE HEALTH DELIVERY SYSTEM

8 September, 2006, New Delhi

PARTICIPANTS IN ATTENDANCE

1. P. N. Anand, DCM, New Delhi
2. Nupur Anchlia, CUTS Mumbai Resource Centre, Mumbai
3. H. K. Awasthi, Consumer VOICE, New Delhi
4. Anurag Bhargava, Jan Swasthya Sahayog, Bilaspur
5. G. R. Bhatia, Competition Commission of India, New Delhi
6. Aditya Bhattacharjea, Delhi School of Economics, New Delhi
7. Thaneshwar Bir, National Institute of Health & Family Welfare, New Delhi
8. Bhaswati Das, Council for Social Development, New Delhi
9. Tarun Das, Institute of Integrated Learning in Management, New Delhi
10. S. Deepa, British High Commission, New Delhi
11. Priyanka Dutta, CUTS Calcutta Resource Centre, Calcutta
12. Savita Hanspal, Consumer VOICE, New Delhi
13. Shobha Iyer, Citizen Consumer & Civic Action Group (CAG), Chennai
14. Smita John, CUTS International, Jaipur
15. Surendra U. Kanstiya, Surendra Kanstiya Associates, Mumbai
16. Ujjwal Kumar, Ministry of Health & Family Welfare (MoH&FW), New Delhi
17. Savita Madan, Chetna Consumer Club, New Delhi
18. G. C. Mathur, BINTY, New Delhi
19. R. Mehrotra, Ministry of Health & Family Welfare (MoH&FW), New Delhi
20. Pradeep S Mehta, CUTS International, Jaipur
21. Nitya Nanda, CUTS International, Jaipur
22. Sanghamitra Sahu, The Indian Council for Research on International Economic Relations (ICRIER), New Delhi
23. K. Satyamurty, Consumer Guidance Society, Ahmedabad
24. Mira Shiva, Voluntary Health Association of India, New Delhi
25. Paramjit Singh, Consumer VOICE, New Delhi
26. Siddharta Singh, ASSOCHAM, New Delhi
27. M. C. Verma, ITLI, New Delhi
28. Gautam Vohra, Development Research and Action Group (DRAG), New Delhi
29. P. Venkatesan, Department of Consumer Affairs, New Delhi
30. G. Wakankar, Indian Drug Manufacturers' Association (IDMA), New Delhi