CUTS Memorandum to Competition Commission of India on Anticompetitive Practices in Healthcare and Pharmaceutical Sector in India

July 12, 2012

1. **Healthcare** and **Pharmaceutical** are two sectors providing considerable 'social services and public goods' for the society. These are one of the few sectors with a significant 'public interest' element and having high impact on consumer wellbeing. However, both sectors are characterised by multiple imperfections which often lead to proliferation of market malpractices at various levels resulting in poor market outcomes. Strict enforcement of competition law is all the more necessary, given the high private participation in these sectors which is likely to remain high to meet the ever burgeoning demand of the increasing populace. The two sectors are interlinked and cannot be looked in isolation. Their interface also offers many avenues for in depth enquiry. The Competition Commission of India (CCI), although in a fledging state now, has a mammoth task ahead and is expected to establish a vibrant competition regime.

2. Health sector comprising of hospitals and allied services such as healthcare providers, medical education, equipment, diagnostics and pathological laboratories and even complex market like medical insurance. The distinct nature of health sector arises because of the asymmetries of information in this sector. Usually, it is the doctors and pharmacists who are the final decision makers and not the consumer as the latter lacks medical knowledge. On the other hand, pharmaceutical sector comprising of bulk and formulation drugs (includes branded and generic) manufactured by indigenous and foreign firms and its supply chain that involves stockiest, distributor, medical representative, doctors, chemist and finally the consumer.

3. There are a number of issues in these sectors that may curb competition. Anticompetitive practices, especially horizontal and vertical collusion in the supply chain, practices on the part of doctors, hospitals, and pharmaceutical firms which can take the form of tied selling, exclusive supply and distribution agreements, market allocation and even cartelisation can often be to the detriment of consumers. Such misconducts in healthcare are abetted by a weak regulatory environment coupled with structural factors.

4. The informational asymmetry in the healthcare sector makes it difficult to identify whether the practice is anticompetitive or not. However, a closer look at the Competition Act, 2002 shows that several practices in fact attract the provisions of the competition law. However, the hurdle is in identifying these at the micro level.

5. ***Some of the common competition concerns in these sectors include***:

- *Market failure due to information asymmetry*
- *International cartels such as vitamin cartels*
- *Collusions - vertical and horizontal collusion is common across players in the medical supply chain*
- *Abuse of dominance (IPR related) - The ownership of an IPR grants the company exclusive rights to produce and sell their drugs in the market for a limited period of time. Alas, often pharma companies engage in price gouging.*
- *Mergers and Acquisitions and FDI – the recent controversy over M&As and FDI in pharma where MNC acquisition would threaten the availability of affordable generic medicines. CCI has perhaps been given the responsibility of regulating Pharma FDI M&As*
- *Absence of an adequate regulatory framework for maintaining quality and standards of service provided*
- *Entry barriers and rent seeking in the medical education sector*
- *Issues in medical insurance sector – lack of regulation or control over providers' behaviour*

6. To tackle the above mentioned practices, the Competition Act, 2002 typically focuses on four enforcement mechanisms, including advocacy:

a) Anticompetitive Agreements (Section 3)
b) Abuse of Dominance (Section 4)
c) Combination Regulation (Sections 5 & 6)
d) Competition Advocacy (Section 49)

Anticompetitive Agreement: The specific anticompetitive practices of the pharmaceutical and health delivery system covered under Section 3 of the Act are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance. The prohibition of cartel agreements (price fixing, output restricting, market sharing or bid rigging) between enterprises or persons is also included under this section.

Abuse of Dominance: Abuse of dominance may arise in the pharmaceutical industry in the case of abuse of monopoly status granted by patents, which violates Section 4. Thus, in case pharmaceutical companies engage in overpricing patented products or are unreasonable with respect to licencing terms etc. then the competition law may be resorted to for remedies.

Combination Regulation: Sections 5 & 6 of the Competition Act provides for merger review beyond a certain threshold level which would be defined as the turnover of the group to which the enterprise would belong after the completion of the acquisition or merger. This has become crucial especially after the introduction of product patent regime in India. A special carve out for pharma mergers under the threshold needs to be designed and implemented

Competition Advocacy

S.No	Issues	CUTS Opinion
1.	**Addressing Information Asymmetry**	• Competition depends on smooth and free flow of information. One of the major factors causing distortions in the pharmaceutical markets is with regard to information asymmetry among consumers. While there is range of choice open to consumers, the exercise of choice is determined by several factors but the critical factor is on the availability of information. • It is necessary to strengthen the public information system where simple drugs are known to consumers.
2.	**Curbing Anticompetitive Agreements and Collusive Practices in the Market**	• Generating awareness among consumers about different types of anticompetitive agreements and collusive practices prevalent among manufacturers, retailers and health-care providers. • Enhanced role of the CCI under Section 3 of the Act to curb anticompetitive agreements. • Strict Penal provisions under the Medical Council of India Act and the Regulations on malpractices of healthcare providers. • Need for cooperation between CCI and Sectoral Regulatory Agency. Coordination of National Pharmaceutical Pricing Authority (NPPA) and CCI in monitoring price controls is essential.
3.	**Strengthening the Compulsory Licencing System**	• There has been only a single compulsory licence which was granted in India, and that too, very recently to

		Hyderabad based firm Natco to manufacture the generic version of Bayers cancer drug Nexavar. The results were immediate as the price of the one month dose of Natco drug is around 8,000 compared to 2,54,000 to Bayers patented drug. Flexibilities under Trade Related Aspects of Intellectual Property rights (TRIPS) allow for issue of compulsory licences. Department of Industrial Policy and Promotion (DIPP) and patent offices must be advised for creating an effective and deterrent compulsory licencing mechanism to make drugs accessible under the essential facilities doctrine.
4.	**Vigilance in M&A takeovers of Pharmaceutical Companies**	• As recommended in the High Level Committee report for tighter rules for mergers and takeovers in the pharmaceutical sector by the CCI. This is a great step. This calls for greater role of CCI and NPPA in dealing with anticompetitive outcomes of mergers and closely monitoring the rise in prices (if needed) as a result of such a merger.
5.	**Advocacy for speedy adoption of Clinical Establishment & Registration Act, 2010**	• The state government should be persuaded to adopt the Clinical Establishment and Registration Act, which would bring some uniformity in the healthcare delivery by making the registration of all clinical establishments mandatory and prescribing enhanced penalty for defaulters.
6.	**Statutory status for Uniform Code for Pharmaceutical Marketing Practices (UCPMP)**	• The draft code is voluntary in nature. This should be made statutory as it lays down strict guidelines on the most common and well-known areas of violation, such as exaggerated claims, audio visual promotions, activities of medical representatives, providing of samples, gifts, hospitality and sponsorships by pharma companies.
7.	**Transferring Department of Pharmaceutical to Ministry of Health**	• It was even recommended in the Planning Commission's high level expert group led by Dr Srinath Reddy. The report said that public interest would be served best by transferring the Department of Pharmaceuticals to

		the Health Ministry. • This recommendation should not be ignored as it is only appropriate that pharmaceuticals should be placed directly under the Ministry which is responsible for ensuring quality, safety and efficacy of drugs and is accountable for unhindered availability of all essential drugs in the public healthcare system
8.	**Breaking Entry Barriers in Medical Education Sector**	• The newly established board of Medical Council of India (MCI) to amend the Establishment of Medical College Regulations, 1999 so that it provides a eligibility criteria allowing entities other than universities and trusts, such as private hospitals to enter into medical education, and also facilitate establishment of new medical colleges by making qualifying criteria quality-centred rather than quantity-centred.
9.	**Adoption of Standard Treatment Guidelines across States for Public and Private Establishments**	• The Government of India may like to adopt the Standard Treatment Guidelines, prepared by the WHO India Office in collaboration with Ministry of Health.
10.	**Adoption of Centralised Drug Procurement Model in States**	• All state governments to adopt Tamil Nadu and Rajasthan type model for the procurement of drugs and health products for public health system.