



सत्यमेव जयते



COMPETITION LAW AND PHARMACEUTICAL SECTOR

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Views presented are strictly personal. Usual disclaimer applies.



Key Features of Indian Pharma. Sector

- Regulations governing the sector are designed to
 - ✓ Promote research and innovation
 - ✓ Ensure safety of drugs
 - ✓ Control public and private expenditure
- One of the largest and most advanced pharmaceutical industries among the developing countries
- Characterised by information asymmetry and supplier induced demand where by consumption decisions are taken by the prescribing physician and not directly by the consumers of the pharmaceutical products.



Drug Price Regulation



- Price regulated by Government *vide* Drug Price Control Orders (DPCOs)
- Price of drugs covered in the National List of Essential Medicines (NLEM) are regulated.
- List of essential medicines is not static but is dynamic due to many reasons such as changing disease burden.
- National Pharmaceutical Pricing Authority (NPPA) is responsible for fixation and revision of prices of scheduled drug
- In a departure from earlier practise of regulating prices of bulk drugs i.e. active pharmaceutical ingredient, DPCO 2013 regulates the price of the only drug formulation.



Drug Price Regulation



- Market-based pricing has been adopted keeping in mind that (i) essential medicines have to be made accessible at affordable prices; and (ii) at the same time supporting the growth of the pharmaceutical industry.
- Price caps are determined based on simple average of prices of all brands having market share of more than 1%.
- Annual price increase limited to changes in wholesale price index.
- Price of non-scheduled medicines are also monitored by NPPA and a maximum increase allowed for such medicines is 10%.



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Unfair practices in pharmaceutical sector

CCI has dealt with few cases involving anti-competitive practices of the trade associations in the pharmaceutical sector in the form of vertical restraints.

Some of the conducts analysed are:

- Non-appointment of a stockist or a wholesaler from amongst the non-members of the respective trade association;
- Requirement of a No Objection Certificate (NOC) from the association for appointment of stockist or wholesaler. These NOCs pertained to the following:
 - Associations formulated guidelines for its members to obtain permission/NOC before which they could become a stockist of a particular company;
 - Associations forced the stockists not to sell the products of a pharmaceutical company unless NOC was obtained by them from the existing stockists of that pharmaceutical company operating in that area.



Unfair practices in pharmaceutical sector



- Associations fixed trade margins below which the stockists were not allowed to sell;
- The distributors/ retailers were not allowed to give discounts to customers;
- Compulsory approval from association for introduction of drugs in the market- Product Information Service (PIS); and
- Requirement for routing bids for supply of drugs to the government and the hospitals through authorized stockist only

Above terms and conditions were found to restrict the ability of enterprises to supply and sell drugs in the market and thus were anti-competitive in nature. Fines were imposed and cease & desist orders passed.



Unfair practices in pharmaceutical sector



- Recently, CCI has initiated an investigation into Swiss pharmaceutical company Roche for unfair business practices.
- Roche has been found, *prima facie*, of misusing its dominant status to obstruct the entry of biosimilars of its famous breast cancer medicine *i.e.* Trastuzumab.
- It has been alleged that Roche attempted to foreclose the market for its competitors by indulging in vexatious litigation, influencing the regulatory authorities, making misrepresentations to tender authorities, disparaging the reputation of biosimilars, *etc.*
- However, CCI is yet to arrive at any conclusion in this case.



Thanks

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