

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE****Excessive Pricing in Pharmaceutical Markets - Note by India****28 November 2018**

This document reproduces a written contribution from India submitted for Item 9 of the 130th OECD Competition Committee meeting on 27-28 November 2018.

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Introduction

1. Excessive pricing is arguably the most contentious subjects in the realm of competition regulation. Though primary motivation of competition policy is to prevent excessive prices, it is rarely seen as an independent issue in itself.¹ Being a resultant effect of some structural irregularities of the market, excessive pricing is rather seen as a self-correcting malady if such structural irregularities are cured. Besides practical challenges in applying various tests proposed in the economic literature for assessing unfairness of prices, the choice of efficient remedies has also invited protracted debate among regulators, practitioners and academia.

2. Based on the questions specified in the OECD letter dated 18th July, 2018, this contribution is divided into 3 parts. Part I deals with the statutory provisions and treatment of excessive pricing cases under the Indian competition law. Part II elucidates the pharmaceutical regulation (especially the price regulation) and cases received by the Commission in the pharmaceutical sector. Part III highlights the Indian competition enforcement experience against excessive pricing in pharmaceuticals.

1. Excessive Pricing under the Indian Competition Law

3. The Indian Competition Act, 2002 (the “Act”) covers both exploitative as well as exclusionary abuses. The new Act conforms closely to the principles of modern antitrust economics and as such does not target size or dominance of a firm as contrast to the erstwhile Monopolies and Restrictive Trade Practices Act, 1969. The emphasis is on conduct rather than the size of the firm. Section 4 of the Act prohibits abuse of dominant position by an enterprise or group, as defined in the Act. This may occur if such firm/group uses practices that have the effect of restricting the degree of competition which it faces, or unjustifiable exploitation of its market position.

4. The prohibitions, including both ‘exclusionary’ and ‘exploitative’ practices, are set out in Section 4(2) of the Act. Imposition of unfair price has been explicitly stated as an abusive act under Section 4(2) (a) (ii) which reads as follows:

“There shall be an abuse of dominant position, if an enterprise or a group “directly or indirectly imposes unfair or discriminatory price in purchase or sale (including predatory price) of goods or services”.

5. Evidently, a dominant firm, under the Act, abuses such dominance if it charges ‘unfair prices’ to its customers, which may include both unfairly high (excessive price) and unfairly low (predatory price) price. Thus, excessive price forms a subset of ‘unfair price’ in the Indian context.² Though ‘unfair price’ has not been specifically defined in the Act, the Commission has laid down guiding principles through cases where such issue was

¹ OECD Policy Roundtables, Excessive Prices, India (2011).

² *Id.*

under consideration. The case of *HT Media Super Cassettes*³ was an important judgement in this respect. Though the Commission did not find contravention on account of excessive pricing, it enunciated some important principles *vide* that judgement. Noting that ‘*determining whether a price is excessive is an uncertain and difficult task*’, the Commission held that *in the absence of the cost data it will be difficult, neigh impossible, to term the price charged by the opposite party at 661 INR per needle hour as unfair being excessive solely on the basis that it is higher than the price charged by the competitors of the opposite party.*

6. Any infringement of the provisions of Section 4, including that of the imposition of unfair price, pre-requires establishment of dominance of an undertaking in the relevant market. Dominance, as per the Act, refers to a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to – (i) operate independently of competitive forces prevailing in the relevant market; or (ii) affect its competitors or consumers or the relevant market in its favour. Section 19(4) of the Act stipulates that the Competition Commission of India (CCI or Commission) while inquiring whether an enterprise enjoys a dominant position or not should consider all or any of the following factors, namely:

- (a) Market share of the enterprise;
- (b) Size and resources of the enterprise;
- (c) Size and importance of the competitors;
- (d) Economic power of the enterprise including commercial advantages over competitors;
- (e) Vertical integration of the enterprises or sale or service network of such enterprises;
- (f) Dependence of consumers on the enterprise;
- (g) Monopoly or dominant position whether acquired as a result of any statute or by virtue of being a Government company or a public sectoral undertaking or otherwise;
- (h) Entry barriers including barriers such as regulatory barriers, financial risk, high
- (i) countervailing buying power; capital cost of entry, marketing entry barriers, technical entry barriers, economies of scale, high cost of substitutable goods or service for consumers;
- (j) Market structure and size of market;
- (k) Social obligations and social costs;
- (l) relative advantage, by way of the contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an appreciable adverse effect on competition;
- (m) Any other factor which the Commission may consider relevant for the inquiry.

7. It is only upon establishment of the dominance of the firm that the alleged abusive conduct is assessed. The underlying principle of the Act is not to control prices or profits

³ *In re M/s HT Media Limited & M/s Super Cassettes Industries Limited*, Case No. 40/2011, available at https://www.cci.gov.in/sites/default/files/C-2011-40_0.pdf

but to strive to preserve competitive conditions which would allow market forces to self-correct even if there is any irregularity.

1.1. Cases on Excessive Pricing

8. The Commission has considered some/few cases pertaining to allegations of excessive pricing, however, no case precedent has been laid down so far dealing exclusively with excessive pricing. While dealing with all such cases, the Commission has adopted a rather cautious approach, realising that intervening with the pricing policies of enterprises may end up seizing their incentives to invest.

9. One of the cases (*namely*, the ‘*Auto Parts*’ Case⁴) where unfair pricing was under consideration, the order of the Commission highlights an interesting and extensive discussion on the challenges in the methodologies and potential remedies in such cases. In the *Auto parts* case, the Commission considered the cost-based test evolved by the ECJ in *United Brands* case and noted that there was a substantial price difference between rates at which spares are sourced by the automobile companies and the price at which they were sold to end consumers. The average markup varied from 100 per cent to 5000 per cent. The Commission further compared the profits these automobile companies were making from sale of automobiles as well as from spare parts business separately. The data revealed that the margin from spare parts business exceeded the margin from car business substantially. In fact several automobile companies were incurring overall losses from the sale of cars, however profits were being generated from sale of spares parts, possibly because of the fact that these automobile manufacturers were able to mark-up the price of spare parts without any competitive constraints in the after-market. The Commission took cognizance of the inherent objection by various commentators to price regulation but also clarified that some markets cannot self-correct, thus necessitating regulatory intervention. The relevant excerpt from the said order capturing the crux of Commission’s observations and findings on unfair pricing is reproduced below:

It is pertinent to note that several commentators have objected to price regulation from a policy perspective, arguing that in the absence of market failures, excessive prices motivate potential competitors to enter into the market and are therefore self-correcting. However, the Commission is of the opinion that in certain industry/sectors the prevalent excessive pricing practices may not be self-correcting, i.e., as in the present case, where the OEMs have insulated themselves from all possible competition in the aftermarket, (a) through their network of restrictive contracts and (b) pursuant to the fact that spare parts of various models of automobiles are not interchangeable with other brands, have ensured that they are the only source of supplying spare parts for its brand of automobiles in the aftermarkets, thereby significantly enhancing such enterprise’s degree of exploitative pricing. For example, as per the data tabularized in table 8 above, Fiat marks up the price of its top 50 spare parts (on the basis of consumption) from 19.93% - 4817.17%. Under the existing competitive structure of the Indian automobile aftermarket, Fiat will not be subjected to any competitive constraints either from the other OEMs (due to limited interchangeability between spare parts of various brands of automobiles) or from the independent repairers (due to denial of access to the aftermarket of spare parts and diagnostic tools) to self correct its

⁴ Case No. 03 of 2011, *Shamsher Kataria v. Honda Siel & Ors.*, Case No. 03 of 2011 decided on 25th August, 2014, available at https://www.cci.gov.in/sites/default/files/032011_0.pdf.

pricing abuses unless the structure of the market is modified to allow competition. Therefore, the Commission is of the opinion that the exploitative pricing conduct by each OEM (as evident from Table 8 above) is a manifestation of lack of competitive structure of the Indian automobile market. The Commission is therefore of the opinion, that structurally modifying the competitive nature of the Indian automobile market will itself induce market self-correcting features, by enhancing consumer-choice and access of independent repairers to effectively compete in the Indian aftermarket. Such remedies, in the opinion of the Commission shall have a rationalizing effect on prices of the products in the Indian automobile aftermarket.

10. Thus, the Commission realised that certain markets may not be capable of self-correcting, necessitating the prescription of remedies. In order to devise remedy to rectify unfair pricing, the Commission identified the structural issues in the auto spare parts' market. Instead of pronouncing any pricing remedies, the Commission directed the automobile companies to have an effective system to make the spare parts and diagnostic tools easily available through an efficient network. They were also directed to sell spare parts in the open market without any restriction, including on prices and to work towards standardization of an increasing number of spare parts in such a manner that they can be used across different brands, like tyres, batteries *etc.*, which would keep a check on their ability to charge abnormally high prices and also give more choice to consumers as well as repairers/service providers.

11. Another case where contravention of unfair pricing was established pertains to transportation sector. In *Shivam Enterprises vs Kiratpur Sahib Truck Operators Co-operative Transport Society Limited & Ors.*⁵, the Commission found that the Kiratpur Sahib Truck Operators, through their association, imposed unfair prices for transportation services in contravention of the provisions of Section 4(2)(a)(ii) of the Act.

12. In another case⁶ pertaining to agriculture sector, the Commission while ordering investigation *prima facie* held that *charging of trait value (fee) payable on the basis of MRP (maximum retail price) of the seed packet apparently has no economic justification in light of the fact that performance of the Bt cotton crop depends not only on the BT cotton technology but also on other factors like genetic composition, climatic conditions etc. and appears to be unfair.* The Commission is yet to finally adjudicate this case. Similarly, in another case which is under investigation, the Commission has ordered investigation against *Ericsson*⁷ for charging unfair, discriminatory and exorbitant royalties on its patented technology (Standard Essential Patents) compared to royalties charged by other patentees for patents similar or comparable to those held by it.

⁵ Case No. 43/2013, available at https://www.cci.gov.in/sites/default/files/432013_0.pdf.

⁶ *Department of Agriculture, Cooperation & Farmers Vs. M/s Mahyco Monsanto Biotech (India) Limited. & M/s Nuziveedu Seeds Limited (NSL) v. Mahyco Monsanto Biotech (India) Limited (MMBL) & ors*, Ref. Case No. 02/2015 and Case No. 107/2015, available at https://www.cci.gov.in/sites/default/files/Ref%2002-2015%20and%20107-2015%20-26%281%29%20order_10.02.2015.pdf.

⁷ Case Nos. 50 & 76/2013 and Case No. 04/2015 [*Micromax Informatics Limited & Ors. v. Telefonaktiebolaget LM Ericsson (Publ)*], available at https://www.cci.gov.in/sites/default/files/502013_0.pdf.

13. Besides this, the Commission had the occasion to deal with many other cases where excessive pricing was alleged but was not found to be established. Either the entity/firm was not found to be dominant⁸ (thus, not leading to any possible case of abuse) or the allegation could not be substantiated by evidence on record⁹. In one such case in the pharmaceutical sector, *Roche* case¹⁰, which is pending adjudication before the Commission, the allegation regarding imposition of unfair prices was made out. Though the Commission ordered investigation for allegations pertaining to non-pricing abuse, with regard to unfair pricing, the observations of the Commission in its *prima facie* order were as follows:

“With regard to the Informants’ allegation on unfair pricing under Section 4(2)(a)(ii) of the Act, the Commission is prima facie not convinced that a case is made out against the Roche Group. Being the innovator, it might have invested huge sums on research and development of Trastuzumab. Thus, initial high prices can be attributable to being the reward for innovation. Further, it subsequently introduced cheaper versions in the market viz. BICELTIS/HERCLON.”

14. Thus, apparently the Commission has intervened sparingly in cases pertaining to excessive pricing and even in cases where contravention has been found on this issue, structural remedies have been devised (as in the *Auto Parts* case) to ensure market self-correction, instead of prescribing what prices would be fair.

2. Drug Price Regulation in India

15. Price controls are considered to be against the principles of competition policy, however, the peculiar infirmities in pharmaceutical industry has necessitated the need for regulating prices of drugs. The distinctive features of the pharmaceutical sector such as ‘information asymmetry’ and ‘supplier-induced demand’ significantly restrict consumer choice, a condition necessary for well-functioning markets. In the absence of agency with the consumer, various industry practices flourish which have the effect of choking competition and which are detrimental to consumer interest. Though such practices may not always violate the provisions of the Act, they create conditions that do not allow markets to work effectively.

16. In India, the prices of essential drugs are regulated by Drug Price Control Orders (DPCOs)¹¹ which are issued by the Government (Ministry of Chemicals and Fertilizers), in exercise of the powers conferred under Section 3 of the Essential Commodities Act, 1955. It enables the Government to declare a ceiling price for essential and lifesaving medicines (as per a prescribed formula) so as to ensure that these medicines are available at a

⁸ Refer to *Aditya Automobile Spares v. Kotak Mahindra Bank*, Case No. 103/2016, available at <https://www.cci.gov.in/sites/default/files/103%20of%202016.pdf>. Also see,

⁹ See *Maharashtra State Power Generation Company Ltd. & ors. v. Coal India Limited & ors.*, Case Nos. 03, 11 and 59/2012, available at <https://www.cci.gov.in/sites/default/files/03%2C%2011%20%26%2059%20of%202012.pdf>.

¹⁰ *Biocon & anr. v. F. Hoffmann-La Roche AG & ors.*, Case No. 68 of 2016, available at https://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf. This case is discussed in detail in Part III.

¹¹ The latest DPCO was issued in 2013 and is referred to as DPCO 2013.

reasonable price to the general public. Price controls are applicable to those medicines which are listed out in the Schedule I of DPCO [*i.e.* the National List of Essential Medicines (“NLEM, generally known as “Scheduled drugs” or “Scheduled formulations” Currently, the NLEM (which was last revised in 2015) contains about 376 medicines.¹²

17. The National Pharmaceutical Pricing Authority (NPPA) is an independent body of experts in the Ministry of Chemicals and Fertilizer formed in 1997 which is, *inter-alia*, responsible for fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers.

18. The new pharmaceutical policy *i.e.* National Pharmaceutical Pricing Policy (“NPPP”), 2012 laid down 3 key principles which are to be followed when controlling medicine prices under the DPCO 2013.

- a) *Essentiality of medicines*: These were to be medicines listed in the NLEM.
- b) *Market-based pricing (“MBP”)*: MBP has been adopted keeping in mind that (i) essential medicines have to be made accessible at affordable prices; and (ii) at the same time growth of the pharmaceutical industry needs to be ensured.
- c) *Price control only on formulations*: 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.

19. MBP marks a departure from the earlier model of cost based pricing which was prevalent since 1995. The DPCO 2013 determines the ceiling price for the NLEM drugs as follows¹³:

- a) Firstly, the base price is set as the average price to retailer for the same strength and dosage of the all the brands having a market share of more than 1%.
- b) Secondly, the retailer margin (currently set at 16%) is added to this base price and the new price becomes the ceiling price announced by NPPA.
- c) Such price ceiling may be revised once in a year in the month of April on the basis of wholesale price index.

20. Further, the list of essential medicines (NLEM) is not static but is dynamic due to many reasons such as changing disease burden (*i.e.* the proportion of population afflicted by that disease); antimicrobial resistance; and development of newer and better medicines. Accordingly, NPPA regularly revises the list of essential medicines covered in NLEM.

21. The prices of medicines which are not covered in the Schedule I of the DPCO, 2013 are also monitored by NPPA. As provided in the DPCO, 2013, no manufacturer shall increase the maximum retail price of a non-scheduled drug more than 10 per cent of maximum retail price during the preceding twelve months.¹⁴ However, there is no control on the launch price of non-scheduled medicines, which are fixed by the manufacturers themselves at the time of launch.

¹² See, <http://cdsco.nic.in/WriteReadData/NLEM-2015/Recommendations.pdf>.

¹³ Clause 4, DPCO, 2013, available at <http://www.nppaindia.nic.in/DPCO2013.pdf>.

¹⁴ Clause 20, *Id.*

22. Optimal regulation in the pharmaceutical sector necessitates balancing of static and dynamic efficiencies so as not to undermine investment incentives while ensuring that consumers' interest is protected. Though appropriate regulations need to create pro-competitive environment by averting anti-competitive practices, counterproductive regulations may undermine competition or create unreasonable entry barriers. Thus, striking a right balance is of utmost relevance. As the antitrust regulator of the country, the Commission felt the need for focused deliberations on these issues, which have serious implications for markets and competition in the pharmaceutical sector. Towards this end, a Technical Workshop on "Competition Issues in the Healthcare and Pharmaceutical Sector" was organized in August, 2018, with representatives of all stakeholder groups, including pharmaceutical industry, healthcare service providers, civil society organisations, regulators, healthcare think tanks. The policy note from the said workshop is expected to guide regulatory redesign to ensure affordable, quality healthcare through well-functioning markets.

3. Indian competition enforcement experience against excessive pricing in pharmaceuticals

23. There are various challenges associated with intervening in excessive pricing cases, foremost being an assessment of benchmark 'fair price', followed by dilemma associated with trade-offs between static and dynamic efficiency. These challenges proliferate manifold when the case arises in pharmaceutical sector, all the more when the prices of innovative medicines for critical diseases are under scrutiny. Such medicines are a result of years of research and development, generally preceded by series of failed attempts leading to high costs of failure. Thus, applying traditional standards (e.g. price-cost comparison) may wither dynamic efficiencies and disincentivise future research and development.

24. Till date, the Commission has not found a contravention on account of excessive prices in pharmaceutical sector. One of the cases, which is pending investigation involves the issue of excessive pricing of medical syringes. Another case (*Roche*), though had an allegation of unfair pricing, the Commission ordered investigation only with regard to non-pricing abuses. Both these cases are discussed briefly herein below.

3.1. In re: Vivek Sharma v. Becton Dickinson India Pvt. Ltd. & Max Super Speciality Hospital ('Max' case)¹⁵

25. A social worker filed information before the Commission against Becton Dickinson India Pvt. Ltd, manufacturer of disposable syringe under brand name 'Emerald', and Max Super Speciality Hospital alleging that Becton Dickinson manufactures disposable syringe for Max Super Speciality Hospital for their in-house pharmacy located within the hospital network and the same is marked at a higher price compared to MRP of same product in the open market.

26. The Commission, while forming a *prima facie* view, observed that Max hospital is providing healthcare services in super speciality category *i.e.* services in relation to a particular disease, forming a distinct product, and assessing the condition of competition for supply, the relevant market delineated as '*provision of healthcare services by super speciality hospitals in Delhi*'. In terms of size and resources and brand name, Max Hospital

¹⁵ Case No. 77 of 2015.

prima facie was found to be dominant in this relevant market. The Commission observed that requiring patient to buy disposable syringes from the Max Hospital takes away the option of a patient/consumer to purchase the same product from open market at a cheaper price. Therefore, the matter was referred to the Office of the Director General (DG) to investigate the issue of imposition of unfair price in sale of disposable syringes. Recently, *vide* order¹⁶ dated 31.08.2018, the Commission broadened the scope of investigation by including other super speciality hospitals (along with Max Hospitals) who are indulging in the impugned practices of charging high prices and restricting the patients not to buy from open market. The relevant excerpts from the order dated 31.08.2018 are reproduced below:

“Though the monopoly of OP-2 (i.e. Max Hospital) in the aftermarket of pharmaceutical and other consumables in healthcare services for in-patients by itself is not an issue for the purposes of the Act; however, abuse of that position by OP-2 by charging supra-competitive prices from the locked-in in-patients for the products and / or services including but not limited to syringes in that aftermarket needs to be explored. It is common knowledge that this practice of exploitative pricing from the locked-in patients is followed with impunity by most of the hospitals. Though the information in the present matter was received with respect to the alleged abusive conduct of OP-2 only in the sale of syringes, the scope of investigation may be broadened by the DG by including other super speciality hospitals who are indulging in the aforesaid practices not only with respect to syringes but also with respect to other products such as medicines, surgical tools etc.”

3.2. Biocon & anr. v. F. Hoffmann-La Roche AG & ors (‘Roche’ case)

27. On an information filed by competing biosimilar drug manufacturers (*namely* Biocon Limited and Mylan Pharmaceuticals Private Limited), Commission decided to investigate Roche and its two group firms, multinational pharmaceutical company, for alleged anti-competitive conduct with respect to its biological cancer drug, Trastuzumab. The allegation comprised of pricing as well as non-pricing abuses. Though the Commission found a *prima-facie* case of contravention of the provisions of the Act, the investigation direction was only with regard to denial of market access because of the abusive strategies adopted by Roche *e.g.* denigrating the image of the biosimilars. With regard to the allegation of excessive pricing¹⁷, as stated earlier, the Commission was of the opinion that being the innovator, Roche might have invested huge sums on research and development of Trastuzumab and initial high prices can be attributable to the reward for such innovation. This case is presently under investigation.¹⁸

¹⁶ See CCI’s order at <https://www.cci.gov.in/sites/default/files/Case%20No.%2077%20of%202015.pdf>. This matter is currently under investigation.

¹⁷ Biocon and Mylan alleged that the Roche’s products are excessively priced when compared to the price of their biosimilars.

¹⁸ Aggrieved by the investigation order under Section 26(1) of the Act passed by the Commission, Roche approached the Delhi High Court challenging the said order of the Commission. The matter is currently pending in the Delhi High Court.

3.3. Other cases dealt by CCI in the Pharma Sector

28. Besides, the Commission has also dealt with various cases involving anti-competitive practices by State-level or regional trade associations in the distribution of pharmaceutical products. The supply chain of pharmaceutical drugs is complex and includes many intermediaries before the drugs reaches the end-consumer, making the sector vulnerable to anti-competitive practices. The practices which have been found foul of the provisions of the Act are mandatory requirement of 'No Objection Certificate' (NOC) from the association for appointment of stockist or wholesaler; fixation of trade margins by the associations below which the stockists/wholesalers were not allowed to sell the drugs; compulsory approval from association for introduction of new drugs or new dosages of the existing drugs in the market (PIS charges) *etc.*

29. Through its various orders in different cases, the Commission has held that the aforesaid practices to be anti-competitive in nature and therefore, ordered the associations to cease and desist from engaging in such practices. The Commission also imposed penalty/fines on chemists and druggists associations and, in some cases, also on pharmaceutical companies along with their office bearers/officials.

4. Conclusive Remarks

30. Excessive pricing, which is a sub-set of unfair pricing under the Indian Competition law regime, is a cognizable issue only when administered by a dominant firm. Given the challenges associated with assessment of benchmark 'fair price', followed by regulatory dilemma of associated trade-offs between static and dynamic efficiency, the Commission has rarely intervened in cases exclusively involving excessive pricing as the primary allegation. Even in cases where intervention has been made, the Commission has been averse to devising any pricing remedies. Rather attempts have been made to correct market failures which would keep a check on dominant entity's ability to charge abnormally high prices. A case involving excessive pricing by super-specialty hospitals is presently under investigation. The outcome of the said case is expected to disentangle many issues on excessive pricing in pharmaceutical cases under the Indian competition regime.