Prices in the Pharmaceutical Sector and Healthcare Services Market- Study from the Standpoint of Competition and Anti-Trust Regime in India

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Abstract

The Competition Commission of India (CCI) has identified several practices flourishing in the pharmaceutical sector that do not allow consumer agency and choice, and have led to supplier-induced demand as well as drug price build-up. Ensuring affordable and quality healthcare for consumers is the need of the hour. Information asymmetry and supplier-induced demand eventually affect the end consumers' choices and disproportionally raise the health expenditures from the consumers' net disposable income. Recent economic surveys show that India has one of the highest levels of Out-Of-Pocket Expenditures (OOPE) which has directly resulted in uncounted expenditures and extreme poverty. This is why optimal regulation of markets and filling up regulatory gaps has become necessary. Empowering consumers is a task fraught with difficulties since medicine is a highly specialised field wherein any miscalculation in the decision-making process could have dire consequences on the health and well-being of a person.

Anti-competitive practices in the pharmaceutical sector may be categorised into primarily three classes: breaches related to intellectual property rights (IPRs); abuse of competition norms arising from mergers and acquisitions (M&As); as well as collusive and other anti-competitive practices.

Keywords: *Pharmaceutical Sector, Drug Prices, Collusive and anti-competitive practices, Regulation.*

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Introduction

Ensuring affordable and quality healthcare for consumers is the need of the hour in the pharmaceutical and healthcare sectors. Consumers' health expenditures and their choices are affected by information asymmetry along with supplier-induced demand. India has one of the highest levels of Out-Of-Pocket Expenditures (OOPE) in the world[1], as noted in several economic surveys, which has directly resulted in uncounted expenditures as well as extreme poverty. Thus, optimal regulation of markets and filling up regulatory gaps have become pressing needs for the country.

The recent budget for health witnessed a rise of about 16% in absolute terms, between the budget estimates of 2021-22 and 2022-23.[2] However, it still remains stagnant at 0.35% when counted as a percentage of the GDP. This may not be sufficient for catering to the current enhanced resource requirements of the sector. Moreover, this stagnant trend could make it difficult to reach the standard set by the National Health Policy of total public health expenditure being 2.5% of the GDP by 2025[3].

The Indian pharmaceutical industry is the world's third-largest by volume and the fourteenth-largest in terms of its value. From April 2021 to August 2021, India exported US$ 1.37 billion of bulk drugs and drug intermediates. It exports over 40% of its pharmaceutical products to other countries. However, around 50-60% of the population lacks regular access to essential medicines, which majorly constitutes OOPE[4]. Since medicines count for a majority of the OOPE of the population, ensuring affordable drugs is a step that is essential for bringing down overall healthcare expenses as well as achieving the goal of affordable healthcare for all.

In 1997, the National Pharmaceutical Pricing Authority (NPPA) was established under the Ministry of Chemicals and Fertilizers of the Government of India, with the aim of controlling the prices of medicines and ensuring their availability. Recently, the Ministry's Department of

[1]Sanyukta Kanwal, Out-Of-Pocket Expenditure as percentage of current health expenditure across India from 2001-2018, STATISTA India: share of out-of-pocket health expenditure 2018 | Statista (July 29, 2021)
[2] Union Budget 2022-23
[3]National Health Policy, 2017 (https://vikaspedia.in/health/nrhm/national-health-policies/national-health-policy-2017)
[4]ANI, India's Pharma market to grow by 12-14% in three years: KPMG, LivemintIndia's pharma market to grow by 12 to 14% in three years: KPMG | Mint (livemint.com) (19th August, 2020)

Pharmaceuticals authorized the National Pharmaceutical Pricing Authority (NPPA) to regulate the availability and pricing of all the drugs mentioned in the National List of Essential Medicines (NLEM), 2011.[5] Essential medicines are those that satisfy the priority health care requirements of the people. They are classified based on the levels of healthcare, such as primary, secondary and tertiary.

Competition Issues in the Healthcare and Pharmaceutical Sectors

The Competition Commission of India (CCI) has identified several practices flourishing in the pharmaceutical sector which do not allow consumer agency and choice, and have led to supplier-induced demand as well as drug price build-up. In the quest to achieve optimal regulation and well-functioning markets, it has undertaken many initiatives such as workshops, policy notes as well as internal reviews, engaging all stakeholders. The CCI's Market Study on the pharmaceutical sector in India, published on November 18, 2021, identified and summarized many issues with respect to the prices of generic drugs along with competition issues, some of which shall be discussed further in this blog.

Pricing conduct under the Competition Act, 2002 (CA02) may be examined under three broad categories:

- Anti-competitive horizontal agreements, i.e., collusive price-fixing conduct under Section 3(3) of the CA02[6];
- Anti-competitive vertical restraints, i.e., RPM under Section 3(4) of the CA02[7]; and
- Abuse of dominant position i.e., the unfair and predatory pricing under Section 4 of the CA02.

Anticompetitive Horizontal Agreements

Horizontal agreements are arrangements between enterprises at the same stage of the production chain, and that are generally formed between two rivals for fixing prices, limiting production, or

[5] National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India. [Last accessed on 21-10-20]. Available from: http://www.nppaindia.nic.in/index1.html .
[6]Competition Act 2002 § 3(3)
[7]Competition Act 2002 §3(4)

for sharing markets. There is a presumption in the Act that all such agreements cause an appreciable adverse effect on competition (AAEC).

The CCI typically uses high-combined market shares in the relevant markets as primary indicators for determining whether a horizontal merger is likely to cause an AAEC. Also included in this assessment are factors such as the presence of strong competitors, barriers to entry in the market (such as the presence of patented products), as well as the level of governmental regulation, especially in cases of pharmaceutical mergers.

Anticompetitive Vertical Agreements

Vertical agreements are agreements between enterprises at different stages of the production chain. For example, an arrangement between a manufacturer and a distributor would be a vertical agreement.

Abuse of Dominant Position

An example of this is when the investigative wing of the CCI, in a sub-judice matter before them, found that a dominant super-specialty hospital had been making excessive profits to the tune of more than 500%, on disposable syringes. On this basis, the investigation report concluded that the hospital had abused its dominant position in the market.

Branded Generic Drugs and Competition - Introduction to Branded Medicines and Generic Medicines

Branded medicines are original products manufactured by pharmaceutical companies. These companies are given exclusive rights over the manufactured products and their distribution until the patent of the product expires. While generic drugs are medicines that are replicas of patented medicines, both generic and branded drugs are made in conformance with international standards. Generic medicines are sold by different names, structures, colors, tastes, smells, and so on for the purpose of distinguishing them from branded medicines. Moreover, they are sold under non-proprietary names, helping the market differentiate between proprietary and non-

proprietary products. Generic medicines follow the active ingredients present in branded medicines to manufacture the product and bring it in conformity with the international standard[8].

Prices of pharmaceuticals have a direct bearing on their accessibility and affordability, being the single largest contributor to the OOPE and accounting for an estimated 62.7% of the total health spending in the country. Further, about17.7% of the pharmaceuticals market in India (in terms of value) is under price regulation and consequently, competition plays a dominant role in adhering to the market discipline[9]. Generic drugs or generics also contribute to this by keeping the prices of prescription drugs low, thereby reducing healthcare costs, and improving access by making markets structurally and highly competitive. Branded medicines are significantly more expensive than generic medicines, which account for around 97% of the market. The number of competitors has a notable effect on generic products' price reductions. Generic drugs typically cost less than their brand-name counterparts because manufacturers do not have to repeat the animal and clinical studies that have already been undertaken by the makers of brand-name medications.

Brand Competition of Generic Drugs in India

The pharmaceutical sector in India is characterized by certain trends that have become the factors affecting the brand competition of generic drugs in India.

1. Brand competition, which is premised on product differentiation, governs the market of generics. These generics are supposed to be bioequivalents to the originator, i.e., the patented drugs, and are thus considered homogeneous,
2. What explains the price dispersion observed across brands in the market of the same generic molecules,
3. The significant price difference that exists between unbranded or generic generics and branded generics.

[8]World Health Organisation Background Report 2010, No.35, World Health Organisation
[9]*Supra* 1

Indian Pharmaceutical Market – "A Market of Branded Generics"

Generic Generics vs Branded Generics

Despite being the largest supplier of generic drugs globally and having a pharmaceutical market comprising of generics accounting for around 97% of total drug consumption in terms of value, India only has about 10% of the drugs in the domestic market that are unbranded or generic generics. These generic generics are marketed and distributed as commodity generics, with only their chemical names, and are largely procured and dispensed in public health facilities. The rest 87% of drugs dispensed in India are so-called branded generics, i.e., generic drugs sold with brand names. This phenomenon of "branded generics" is unique to India[10].

Implications of the Prevalence of Branded Generics for Competition and Pharmaceutical Prices in India

India has the largest number of US FDA-approved facilities worldwide. From August 2019 to July 2020, a market study of the CCI illuminated the presence of 17 brands on average, for each formulation. The number of formulations, brands, and manufacturers varies across therapeutic categories. A relatively larger number of brands are present in markets with a larger number of formulations. While for some therapies, the number of brands created is disproportionately larger than the number of formulations, in niche areas, there are fewer brands in proportion to their formulation numbers[11].

Product Differentiation or Brand Differentiation Brand Proliferation by Pharmaceutical Companies

Branding in the pharmaceutical industry has become extremely important in today's competitive environment. Companies are marketing portfolios of different brands of the same formulation with identical doses and strengths. For instance, a market study of the CCI found 15 companies to be producing two different brands of glimepiride + metformin (tablet, 500mg). In *rosuvastatin* (tablet, 10mg), three brands of the same formulation are being marketed by four companies. In multiple categories, instances of the same company having five to six brands were observed.

[10]High Level Expert Group Report on Universal Health Coverage for India (November 2011) (https://niti.gov.in/planningcommission.gov.in/docs/reports/genrep/rep_uhc0812.pdf)
[11]Sin India, Market Study on The Pharmaceutical Sector in India - Key Findings and Observations (18-11-2021).

Here we clearly see that product differentiation is introduced through brand differentiation even in the cases of generics that are homogenous drugs.

Pricing of Branded Generics

Price dispersion across brands of different companies and price discrimination across brands of the same molecules marketed by the same companies are some trends that have been observed which accelerate the effects of brand differentiation on the pricing of branded generics. There is a considerable price difference between the different brands of a particular generic formulation marketed by different firms. Notable variations in prices can also be observed between brands that are marketed by the same company.

Price and Market Share

The CCI study suggests that market leaders in the sector, even in the presence of a large number of firms and brands, are charging prices that are relatively higher than other market participants. It goes on to suggest that the price charged by the market leader, measured by sales value, remains the highest or among the highest, whereas the prices of the lowest-selling drug remain the least, or among the least.

Price Difference between Branded Generics in the Private Retail Market and Pure Generics in Public Procurement Market

The CCI obtained a study from two major public drug procurers, i.e., Tamil Nadu Medical Service Corporation (TNMSC) and Rajasthan Medical Service Corporation (RMSC), and found that in percentage terms, the price variation between pure generics in public procurement and branded generics in the retail market across 54 molecules ranged from 8% to 190%, with the price difference for 45 molecules being more than 100%.

The above study and data corroborate the market situation in India, which has strong competition in generics at the level of therapy areas and formulations; consumers in India are paying a premium for the brands. The competition in branded generics is based on their quality and the value they create for the respective therapies identified by the consumers. However, the same competition in prices is not expected from the generics because they possess the same active

pharmaceutical ingredients as the originator medicine, and are, therefore, expected to be interchangeable or identical in terms of non-price parameters, such as safety and efficacy.

The Role of Quality in Brand Competition

Do brand names ensure drug quality and do higher prices signal better quality? Is the heterogeneous quality of drugs in India really an issue big enough to warrant quality signaling through brand names and prices?

Before we answer these questions, it is important to understand that the statutory requirements, inspections, and approvals relating to drug quality, remain identical in the country, with the requirement that drug makers must be conforming to Good Manufacturing Practices (GMP) that are made in conformity with international standards. Market players selling top brands seldom get their products manufactured through third parties or contract manufacturing, and the same contractor manufactures for their other competitors. Studies establish that the same companies produce unbranded as well as branded versions of the same generic drugs, at the same plant. Thus, branding can be viewed merely as a way for pharmaceutical companies to create artificial product differentiation and niches even in off-patent drugs to be able to command a brand premium on prices and still sustain high shares in the domestic market.

The alleged heterogeneous quality of drugs, in terms of their safety and efficacy profile, has raised concerns regarding the competition in generics. However, the percentage of actual and those created artificially needs to be understood and analyzed. Branding causes this to happen by enabling niche markets to be created by pharmaceutical companies in order to retain and exercise pricing power. Had there been no product differentiation by brands, price competition would not have been possible since generics are homogenous drugs. A perception of differentiation between higher quality of certain brands and that of a price-quality correlation is created by pharmaceutical companies through their brand marketing, with no real quality differences between the various branded generic versions or between unbranded generic and branded generic versions of the same molecule.

The underlying factors attributing to the primacy of brand competition in generics are – the information asymmetry regarding drugs vis-à-vis the consumers of drugs, the unobservable quality of drugs, and the prescription of drugs by brand names rather than by generic names.

Since consumers are not in a position to make informed choices and the quality/efficacy of drugs is intrinsically unobservable, they simply follow doctors' brand prescriptions, which are often influenced by aggressive brand promotion by the big pharmaceutical companies. It allows the setting up of high prices, price discrimination, and the extraction of consumer surplus[12].

On the other hand, market studies also show that prescription patterns reflect a preference for brands with known clinical experience of physicians because things like pharmaceutical safety and efficacy are unobservable. In India, the substitution of drugs by retailers/chemists is unlawful; retailers are not allowed to substitute a prescribed brand with another brand containing the same substance. However, prescription by generic chemical names shifts the agency to retailers/chemists, enabling them to exercise their discretion in choosing and dispensing from available brands that offer them the highest margin, without any regard for their efficacy. Due to the non-uniform enforcement of quality standards across states in India, there is a significant quality variance, which has led to an increase in generic competition in the market, based on quality. There is, hence, a dire need for stringent and uniform regulatory evaluation and quality signaling mechanisms for all drugs before they are marketed, which in turn would improve public perception of generic drugs as a whole[13].

The Role of Trade Generics – Branded Generics vs Trade Generics

Studies reveal that generic drugs in the retail trade are a sub-set of branded generics, referred to as "generics" or "trade generics". Branded generics and trade generics have no objective distinctions –however, the marketing channels or business models employed by drug-makers, differ on the matter. Trade generics do not have healthy price competition in the branded generics market, since they are often pitched at higher price points to enhance retailers' margins and incentivize sales. Generics are marketed through brand promotion by medical representatives, prescribed by doctors, and distributed through the conventional distribution channel comprising C&F agents, super stockists, stockists, sub-stockists, and retailers/chemists. On the other hand, trade generics have a higher retail margin and are supplied by pharmaceutical companies directly to chemists, hospital-managed pharmacies, and doctor-run pharmacies.

[12] *Id.*
[13] *Id.*

In India, scheduled drugs under the Drugs Price Control Order (DPCO) attract a statutory trade margin of 24% to 16% for retailers and 8% for wholesalers. However, the DPCO does not specify the same for non-scheduled drugs, which account for around 82.3% of the medicines sold in the market[14]. As pointed out in the CCI study, companies generally follow a margin structure of 10% and 20% for wholesalers and retailers respectively for non-scheduled drugs, while fixing/printing the MRP[15]. Estimates reveal that the median retail margin is significantly higher than the regulatory cap of 16% applicable to scheduled drugs. The data further corroborates the fact that the median retail margin is even higher than 20%, the margin most commonly set by manufacturers for non-scheduled drugs.

Significant costs in the supply chain include transport, storage, overhead costs, and profits associated with each intermediary, i.e., the wholesalers, stockists, sub-stockists, and retailers. Margins attributed to the intermediaries at the wholesale and retail level contribute to the final price paid by consumers. High drug prices are majorly due to these high trade margins. Pharma manufacturers propose high trade margins to traders for pushing their drugs to retailers and consumers over the competitor's drugs. These high margins are indirect tools they use to exploit the market through marketing and promotions. This, in turn, reduces the customer's preference and choice. Moreover, the traders (stockists/chemists/druggists) rule the drug distribution system, reducing the competition between the traders, which could have led to better competition in drug prices, despite high trade margins. Several cases before the CCI have shown that the entire supply chain of drugs is "self-regulated" by trade associations, resulting in market distortions. Therefore, competition between manufacturers on retail margins does not translate to competitive prices for consumers[16].

Effective competition between retailers, inter alia, through price discounts offered to consumers, has the potential to contain the price effects of high retail margins. Given below are some

[14]Sakthivel Selvaraj & Aashna Mehta, Technology: drugs & diagnostics in health, https://www.india-seminar.com/2019/714/714_sakthivel_aashna.htm
[15]*Supra* 11
[16]*Supra* 11, Trade Margin at Para 50.

measures that can be employed to check and balance the quality perception and price competition in generics:

- **Uniformity and effective implementation of existing quality standards**: Differing regulatory and testing capacities lead to different quality standards being followed in practice, in spite of the same rules being applied to all states. A harmonized system of quality standard enforcement is the need of the hour. The Central Drug Standards Control Organization (CDSCO) can ensure uniform and consistent application of quality standards through training, workshops, and designed rules.
- **Transparency:** Transparency at every stage of drug regulation is critical– be it the grant of licenses, inspections, prosecutions for non-compliance, etc., the information from the same can be published on a centralized portal and checked in real-time.
- **Periodic, systematic and scientific testing of drugs**
- **National digital drugs Databank:** A comprehensive, online, centralized drug databank consolidating real-time data on the active pharmaceutical manufacturing companies in the country.
- **Quality control across supply chains and in public Procurement:** Pharma distribution in India is fragmented with wide variation in distribution practices, processes, technical capability, and limited traceability. Pharmaceutical distribution in all developed markets is governed by Good Distribution Practices (GDP). In India, the CDSCO developed and issued draft guidelines for GDP for pharmaceuticals in 2018 in order to establish standards of quality control across the supply chain. While public procurement of drugs is indubitably cost- efficient, the percentage of quality deficient drugs is higher in the samples collected from government distribution outlets, as evidenced by NSQ data.[17]
- **Standard compliance marks for unbranded generic drugs:** To boost the confidence of physicians and consumers when prescribing and using generics, an institutional quality signaling mechanism may be put in place, through the printing of standard compliance marks on unbranded drugs, that meet the quality standards.

[17]Venkatanarayana Motkuri & Rudra Narayan Mishra, Pharmaceutical Market and Drug Price Policy in India, 25 SAGE Journals 30-53 (2020).

- **Awareness**
- **Improved Availability:** JanaushadhiKendrascan play a key role in bringing generic drugs to consumers. Strengthening supply chain management, increasing visibility, and widening the network of JanaushadhiKendrashave emerged as important proposed suggestions in the study for further enhancing the effectiveness of these generic drug stores.

Case Studies Vis-à-Vis Anti-Competitiveness in Prices Pro and Cons of Indian Rules and Policies

1. **Price control:** The price control regime in India is rigorous. While the prices of drugs included in the NLEM are strictly controlled, the prices of other drugs are closely monitored. For drugs that do not form part of the NLEM, companies are permitted to take a 10% price increase over the Maximum Retail Price prevalent in the preceding 12 months. The NLEM is a dynamic document, and new formulations, including but not limited to medical devices, keep getting added and deleted from time to time.
2. **Cost of production:** Though manufacturing incurs some of the lowest costs, the expenses of setting up a new manufacturing unit, or outsourcing to a pre-existing unit, still have to be borne.
3. **Profit margins:** Excessive competition and competitive pricing go hand-in-hand in the market, reducing profit margins. Additionally, with the operation of price-fixation, it becomes impossible to offer medicines at a higher price. The selling price of a medicine can only increase if all the manufacturers agree to increase their prices, thereby increasing the average price.
4. **Distribution network:** India already has an extensive manufacturing and supply chain in this sector. While little or no investment would have to be made in this area, ensuring that one's product is given preference over other generics with the same composition could prove to be the main task.
5. **Innovation vs generic/biosimilar:** A huge factor affecting market entry is whether the entity is an innovator or a generic manufacturer. Innovator companies face the additional burden of competing with debatably non-infringing generic companies, offering their products at sometimes one-tenth of the innovator's selling price. As a consumer market, India does not differentiate between generics and innovators. However, as with every

consumer group, accessibility and affordability play key roles. It is pertinent to note that the revenue share of generics in the market is 70%, while that of patented drugs is 21%.

6. **Return on investment:** This factor needs to be considered before entering a market where there may be several other companies offering the same medicine. In the case of an innovator company, the cost of conducting research in India may be significantly cheaper as compared to other countries. At the same time, the drug so innovated may be subject to fierce competition from generics and/or biosimilars even before its launch on the market. And the price of the innovated drug with respect to the actual cost of production may provide an exorbitant price margin to the innovator.
7. **Foreign Direct Investment:** India allows 100%FDI by an automatic route for greenfield pharmaceuticals; brownfield pharmaceuticals, 74% by automatic route; and the rest (up to 100%) by Government approval.
8. **Make in India Policy:** The Government largely encourages manufacturing and use within India. Another facet of this policy is the necessity to work a patent in India. In case a drug is only imported under a granted patent, it must satisfy the reasonable requirements of the public and should be available at affordable prices, in order to avoid revocation of the patent or the grant of a compulsory licence.
9. **Patent system:** The patent regime in India prescribes a stricter test for patentability in the case of pharmaceuticals, in order to avoid "evergreening", and to ensure that only the actual innovation is rewarded with a monopoly. Section 3(d) of the Patents Act, 1970, provides that new forms of a known pharmaceutical would be granted a patent only if they are found to show enhanced therapeutic efficacy over the known pharmaceuticals through clinical data. Generic and biosimilar versions of patented drugs would also allowed to be subsist if found to be non-infringing on the claims of the patent.
10. **Drug licence:** Any new drug will have to undergo the entire procedure of obtaining a licence from the Drugs Controller. Additionally, due to the absence of patent linkage, data used in the patent application will not be automatically considered for the grant of a drug licence.
11. **Advertising & marketing:** With the D&C Rules imposing a ban on the advertising of drugs, marketing of drugs is challenging, especially for new entrants who are also required to penetrate existing trade channels. The Essential Commodities (Control of

Unethical Practices in Marketing of Drugs) Order, 2017, further restricts incentives to medical practitioners and bars the unethical marketing of drugs.

12. **Research opportunities:** India offers an exceptional platform for contract-based research and development. With a massive pool of human resources and scientists, conducting research in India is a promising endeavour for new entrants.
13. While revising its drug pricing policies, the Government needs to balance its core responsibility to protect the health and welfare of the Indian people as well as the nation's interest in sustaining the continued development of world-class Indian life sciences capabilities. It is vital that the citizens of India, particularly the common man, have access to affordable medicines for treating common and important disease conditions. This should be the core mission of any government.

In re: Vivek Sharma v. Becton Dickinson India Pvt. Ltd. & Max Super Speciality Hospital ('Max' case)[18]

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

The Commission, while forming a *prima facie* view, observed that Max hospital is providing healthcare services in a super-specialty 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 having been delineated as "the provision of healthcare services by super-specialty hospitals in Delhi". In terms of size and resources and brand name, Max Hospital *prima facie* was found to be dominant in this relevant market. The Commission observed that requiring a patient to buy disposable syringes from the Max Hospital takes away the option of a patient or consumer to purchase the same product from the open market at a cheaper price. The matter was

[18]Competition CommissionofIndia,CaseNo.77of2015

thereby referred to the Office of the Director General (DG) for investigating the issue of imposition of unfair price in sale of disposable syringes.

Vide the order 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 same impugned practice of charging high prices and restricting patients from buying from open market. It also directed the Director General to conduct further investigation for assessing the conduct of these super-specialty hospitals, indulging in abuse of their position in the after-market once the patients are admitted to hospitals and are forced to purchase products from the hospital pharmacies at higher prices. The CCI held that the concept of "aftermarket abuse" should be used to define the relevant market as "*the market for healthcare services/facilities in the after- market for the in-patients in super-specialty hospitals*". It further observed that Delhi may be taken to be the relevant geographic market, and the scope of the investigation should be broadened to cover all the aftermarket healthcare products and services provided by super- speciality hospitals across Delhi to their in-patients.

Biocon & Anr. v. F. Hoffmann-La Roche AG & Ors. ('Roche' Case)[19]

Upon information filed by competing bio-similar drug manufacturers, namely Biocon Ltd. and Mylan Pharmaceuticals Pvt. Ltd., the Commission decided to investigate Roche and its two group firms, the 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 the denial of market access due to the abusive strategies adopted by Roche, e.g., the denigrating the image of biosimilars. Biocon and Mylan had alleged that Roche's products were excessively priced when compared to the price of their biosimilars. The Commission was of the opinion that being the innovator, Roche might have invested huge sums on the research and development of Trastuzumab, and the initial high prices could be attributed to being the reward for such innovations. Aggrieved by the investigation order under Section 26 (1) of the Act passed by the

[19]CompetitionCommissionofIndia,CaseNo.68of2016

Commission, Roche approached the Delhi High Court challenging the said order of the Commission. The matter is currently pending in the Delhi High Court[20].

Competition Concerns

It is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including in India. An issue of vital importance, however, is that consumers of the formulations are very often not the decision-makers. They are, for the most part, guided by the instructions from their doctors and pharmacists. The significant role assumed by the doctors and pharmacists in influencing drug sales leads to manipulation of the system with drug companies, more often than not, seeking to exploit this influence. Such practices often result in patients being misled into purchasing more expensive medicines, or the prescribing of irrational (or combinations of) drugs, which may lead to medical complications, sometimes even death. This distorted guidance on the part of the doctor deprives patients of the best possible healthcare.

Empowering consumers is a task fraught with difficulties since medicine is a highly specialised field in which miscalculations in the decision-making process may lead to severe, and sometimes even irreversible effects on health.

[20] *Id.*