INDIAN COMPETITION LAW REGIME VIS-A-VIS HEALTHCARE & PHARMACEUTICAL SECTOR: AN ANALYSIS DURING COVID 19

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ABSTRACT

The core objective of competition law incorporates activities which lead to economic development in the country. Every sector is regulated by the commission while keeping the basic aim of the Act in mind. Health, science and innovation have come to highlight and sharp focus as never before. The fact that COVID 19 has set forth an unparalleled demand in the healthcare and pharmaceutical sector urged to grow an understanding of the interface between competition law and pharmaceutical sector. This outbreak, being an unprecedented global pandemic greatly affected businesses across the globe. The inevitable impact was the halting of economies resulting in an impending economic slump. All major sectors were severely impacted by the pandemic and the resultant lockdown but on the other hand it was a blessing in disguise for the healthcare & pharmaceutical sector.

The present scenario not only focuses on meeting the demands of healthcare but also widens anti-competitive and deceptive practices worldwide. It is this time when the enforcement authorities should adopt stringent and stricter means to detect and penalize such activities which are being performed in the veil of business opportunities coming in way of this sector. To cater the health concerns and to ensure revival of the economic activity back on track the pharmaceutical sector has come to highlight. All set and done, the competition authorities are leaving no stone unturned in scrutinizing the strategic industries to make sure that they do not make profit during such an hour of crisis.

Keywords: Competition Law, Enforcement, Healthcare & Pharmaceutical Sector, COVID 19.

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Introduction

To being ranked the second most populous country in the world to being a major producer of pharmaceutical products, the pharmaceutical industry in India is one of the leading sectors contributing significantly in terms of the country‘s economic growth. With such massive production and export facilities, it is rather saddening to note that the access to healthcare and pharmaceutical products is sporadic in India. Though the fundamental right to health is not explicitly envisaged in the Constitution of India, 1950 it has been recognized as a derived fundamental right under Article 21 of the Constitution of India, 1950 (*N D Jayal v. Union of India,* 2004 (9) SCC 362. Similarly, right to access to quality and affordable medicines forms a vital component of right to health which in modern times frequently gets vitiated midst myriad anticompetitive practices. The anticompetitive concerns in the pharmaceutical industry has brought forth concerns and mounting amount of scrutiny in the developed jurisdictions such as the United States, Europe and the United Kingdom. The regulatory authorities in India have been vigilant to keep a check on such conducts which are devastating to competition in India but there still lies an immense scope of sectoral inquiry to determine, prevent and restrain anticompetitive conducts in the pharmaceutical sector. There are numerous activities influencing the pharmaceutical industry such as price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation policies, biotechnology and safety policies, drug regulation, drug promotion regulation, drug advertising regulation etc. Most of the anti-competitive practices go unscrutinised in India due to a variety of reasons and thus, the urge for competition law to function alongside diverse laws governing the pharmaceutical industry becomes even more crucial since many such practices are regarded as within the routine activities of working of the pharmaceutical industry. As a result, the requirement for a comprehensive re-look becomes prominent.[1]

Globally, India is the largest provider of generic medicines as by volume it occupies 20% share in global supply and looks into supply of 62% of global demand for vaccines.[2]. A significant growth is apparent in the Indian pharmaceutical industry over past few years and is expected to rise 3 times in the next decade. In 2021 India’s domestic pharmaceutical market is estimated at US$ 42 billion and will accelerate to US$ 120-130 by 2030. As per the data released by

[1] Indian Brand Equity Foundation, *available at* https://www.ibef.org/industry/pharmaceutical-india.aspx (visited on January 06, 2021)
[2]Indian pharmaceuticals - A formula for success, *available at:* https://www.investindia.gov.in/sector/pharmaceuticals (visited on February 20, 2021)

Department for Promotion of Industry and Internal Trade the Indian drugs and pharmaceutical sector has brought forth foreign direct investment of nearly USD 17.75 billion between April 2000 and December 2020. In the financial year 2021 the Indian Pharma export has touched US$ 24.44 billion. Indian pharmaceutical sector caters to the supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. As of May 2021, India supplied a total of 586.4 lakh COVID-19 vaccines.[3]

Competition Act is based on three prominent pillars which include Anti-Competitive Agreements dealt under section 3, Abuse of Dominance u/s 4 and Combination and its regulation u/s 5 & 6 of the Act. The commission is under an obligation to identify and prohibit such activities in the healthcare and pharmaceutical sector.[4]

I. Intersection between the Pharmaceutical Sector and Competition Law

Like any other sector, the healthcare and pharmaceutical sector too comes within the ambit of Competition Act, 2002. This intersection becomes imperative in times like COVID 19 when the industry like no other was flourishing due to the needs arising to meet the challenge. The key concern of the sector was its involvement in research and development and developing novel and innovative products which are to be protected under the Intellectual Property legislations. Such protection may even lead to monopolies ending in huge profit margins and substantial market power. This attracts the applicability of competition law wherein to boost innovation, protection is provided under the competition act, 2002 however there are specific inclusions too to impose restrictions. The growth of pharmaceutical industry though protected under several IP laws, raises competition law issues and thus, the blanket protection could be detrimental to the interests of the consumers.

The analogy between the pharmaceutical industry and competition law can be complex and intense. The pricing policies and arrangements in particular, have a major role to play while analysing the anti-competitive practices in the pharmaceutical industry. On the legislative front of the pharmaceutical industry, the Drugs and Cosmetics Act 1940 and the rules framed there under provide for framework which govern the marketing, authorisation and pricing of pharmaceutical products in India (including generic drugs). Similarly, it is the Drugs (Control) Act 1950 which governs the manufacture and distribution of pharmaceutical products in India.

[3] Indian Brand Equity Foundation, *available at* https://www.ibef.org/industry/pharmaceutical-india.aspx (visited on February 06, 2021)
[4] Abir roy & Jayant Kumar, Competition law in India 2 (Eastern Law House, Kolkata, 2nd edn. 2014).

Additionally, the National Pharmaceutical Pricing Authority (NPPA) is the regulatory authority under Drugs (Price Control) Order 2013 ("DPCO") and is responsible for drug prices in India. It has been entrusted with the task of fixing, revising and monitoring prices of controlled drugs & formulations in India. However, while the DPCO controls the price of a drug, what it does not exercise control on is the price of close substitutes of the price controlled drug which offers and prompt firms to produce related substitutes and charge higher prices. Thus, the regulatory framework becomes most pertinent for the application of competition law in the pharmaceutical sector.

Further, where the Drugs and Cosmetics Act, 1940 objects at preventing substandard drugs for maintaining high standards of medical treatment and to eradicate the dilution of the necessary concomitants of medical or surgical treatment[5], drug regulation can play a significant role in enhancing or reducing ex ante competition in the pharmaceutical market, including the early entry of generic drugs. In January 2019 the MOHFW notified the Drugs and Cosmetics (Amendment) Rules 2019 which relate to streamlining the regulation of the sale of drugs through online portals or e-pharmacies.

Therefore, it becomes prominently evident that the laws governing pharmaceutical sector must be read in conjunction with those governing competition in the market. And, where a major attribute towards anti competitiveness of actions in the pharmaceutical industry object at profit maximisation and greater trade margins, the intersection of competition law and pharmaceutical industry becomes interesting because of a reason that excessive pricing is arguably the most contentious subjects in the realm of competition regulation which is rarely seen as an independent issue in itself.[6]

Since time immemorial CCI conducted studies to identify the contraventions done by the enterprises. The various studies commissioned in the pharmaceutical sector concluded that there were anti-competitive practices which included boycotts by the trade associations, fixation of trade margins for the sale of drugs or formulations by trade association and the issuance of no objection certificates by the trade associations as a prerequisite for appointing stockiest.

[5] *Chimanlal Jagjiwandas Seth v. State of Maharashtra*, AIR 1963 SC 665.
[6] OECD Policy Roundtables, Excessive Prices, India (2011).

Concerns During Covid 19

At the outbreak of the national lockdown the Commission issued a notification whereby all the matters were adjourned and all filings, notifications, submissions and proceedings were suspended. This lockdown led to forced shut down of businesses however only essential services were permitted. The significant change in the market demand and supply needed businesses to coordinate and cooperate certain activities nevertheless such activities should not lead to causing appreciable adverse effect on competition. Any contravention of the provisions of the Act which was done in the veil of COVID 19 was under scrutiny and subject to severe sanctions. Only those business activities were permitted which were necessary and proportionate in addressing the concerns arising from COVID 19.[7] However despite the relaxations offered to the enterprises, the provisions of the competition act are applicable on the businesses even in such harsh times.[8]

To ensure the smooth functioning of economy certain relaxations were provided in the competition rules and regulations so that the enterprises can cooperate with each other. However the enforcement authorities took stringent steps to avoid violations during the crisis. In this vein, the EU's Competition Commissioner, Margrethe Vestager, warned at an online event on 27 March that the COVID-19 crisis is "*not a shield against competition enforcement*" and that the EC will be "*even more vigilant than in normal times if there is a risk of virus-profiteering"*.)[9]

Sec 3 of the Act has explicitly mentioned the prohibitions for the enterprises unless the agreement results in enhancing the efficiency by way of joint venture or promotes research and development. The provisions of the act apply in the same manner unless central government authorizes any exemption in light of public interest at large.[10] To promote and facilitate joint research and development for making test kits, vaccines or the treatment for COVID 19 agreements which enhance efficiencies are not prohibited.[11] The rule of reason test is applied

[7] Available at :https://www.mondaq.com/india/antitrust-eu-competition-/949682/covid-19-competition-act-of-india (Visited on September 15, 2021)
[8] https://www.lakshmisri.com/insights/articles/competition-law-in-the-time-of-covid-19/#
[9] Available at: https://hsfnotes.com/crt/2020/03/30/the-impact-of-covid-19-on-competition-law-in-the-pharmaceutical-sector/(visited on September 26,2021)
[10] Dr. H.K. Saharay, *Textbook on Competition Law* 6 (Lexis Nexis, Gurgaon,2nd edn, 2016)
[11] https://www.lakshmisri.com/insights/articles/competition-law-in-the-time-of-covid-19/#

which helps in outweighing the pro competitive effects over anti-competitive effects.[12]

Competition authorities requested to assess the lawfulness of a co-operation during COVID-19 crisis may face a number of challenges when they are applying some of the common criteria within the limited timeframes presented by the crisis. Some of the main challenges identified are: With the other types of 'co-operation as a response' agreements, an important challenge for competition authorities in relation to 'innovative co-operation' agreements consists in verifying that the exchange of information involved in the innovative co-operation is strictly limited in scope and timeframe to what is required by the objective of the collaboration. In determining the necessity of these agreements, competition authorities may want to look more favorably at agreements that do not include the joint exploitation of the outcome of the R&D projects, provided that they do not significantly affect innovation incentives. Indeed the further away from the market such R&D agreements are, the less likely they will be problematic from a competition viewpoint. R&D between competitors with complementary skills and know-how are also usually less problematic.

E-commerce is a blooming industry and it's way in the Pharma world is creating an attractive revenue stream since sometime. E-pharmacy received a great motivation in this current pandemic while ensuring patients received their medication despite lockdown. The rapid internet penetration creating awareness about health programs and services, online registration process covering functional areas like patient care, lab services, work based documentation & information exchange, medical records, online registrations and appointments, payments, diagnostic reports viewing online, online blood availability, tracking, approval processing for drugs, clinical trials, medical devices, vaccines, etc. is constantly growing leaving the E-commerce sector at unrest.[13]

The role of trade associations is likely to gain much significance in the times ahead as common industry concerns will need to be addressed. There must be strict compliance with competition law by industry bodies to ensure that they do not become a platform for coordination or exchange of sensitive business information in contravention of the Competition Act.[14]The

[12]Available at: https://www.lakshmisri.com/insights/articles/competition-law-in-the-time-of-covid-19/# (visited on September 26,2021)

[13] Covid-19 impact: Pharma industry trends for 2021,available at: https://www.financialexpress.com/lifestyle/health/covid-19-impact-pharma-industry-trends-for-2021/2277793/ (visited on September 30th,2021)

[14] *Available at:* https://www.lakshmisri.com/insights/articles/competition-law-in-the-time-of-covid-19 (last visited on November 21,2021).

concept of MRP acts like a safety net against the exploitative and arbitrary pricing of the traders and therefore the Government has made the face masks and hand sanitizers as "essential commodities" by fixing the maximum price. At times of crisis, the essential commodities are decided on the basis of demand and supply.

The pandemic has brought the Pharma sector into focus as timely and adequate supply of medicines and healthcare at a reasonable cost has become critical not only in addressing health concerns but also revival of the economic activity. Many of these conduct related cases before the Commission have shown that the entire supply chain of drugs is 'self-regulated' by the trade associations resulting in market distortions. The sector's peculiar structural features with their possible limiting effects on competition and the multitude of cases raising competition law issues, prompted the Commission to take a comprehensive look at the sector from a competition standpoint.[15]

I. Anticompetitive conducts

The practices followed in the pharma industry have wide impact both from the consumer and the market perspective, being a sensitive sector. It is nothing but ironic how consumers in India have little to no choice when it comes to accessing pharmaceutical products. There are various factors and reasons which could be attributed to such little or no choice for the consumers, a prominent one of which could be the high reliance and dependence on the information provided by the pharmacists and doctors. In prescription drug industry, the consumer does not exercise the right to choose but act merely on the instructions where the physician selects the drug and the consumer only pays. The choice of consumer is eliminated and as a result where a consumer visits a private doctor or private hospital, he/she witnesses tied selling of medicine as well as diagnostic tests which are similar to anticompetitive concerns of tying and bundling as are well recognised under Section 3(4) of the Act. These practices are anti-competitive in nature and results in heavy costs being borne by consumers.[16] Evidences of such arrangements in the pharmaceutical industry are many but it goes undetected for the fact that it is considered as a general practice and not a suspicious activity.

[15] *Available at:* https://unctad.org/system/files/non-official-document/ccpb_IGECOMP2021_India_Q1_en.pdf (last visited on December 5, 2021).
[16] Ibid.

The prescription drug industry has flourished in recent times owing to trade margins being allowed by the sector.[17] Drug promotion include a plethora of activities such as those of medical representatives, drug advertisements to physicians, provision of gifts and samples, direct-to-consumer advertisements, periodicals, telemarketing, sponsoring of medical education among many others. It is evident that the blurring boundaries of what constitutes fair practices are of intense debate in issues involving drugs promotion. Thus, practices like these, within the pharmaceutical industry and distribution networks, can well be understood to substantially undermine effective competition and the very view of consumer choice leading to price competition seem to fail in the prescription drug market.

The crucial aspect to be tested is whether the protection vested to pharmaceutical companies assuming a monopoly situation in the market, leading to huge price margins and substantial market power. The CCI in *In re: Vivek Sharma v. Becton Dickinson India Pvt. Ltd. & Max Super Speciality Hospital ('Max' case)*[18] discussed the dynamics of healthcare sector in detail and while assessing dominance laid emphasis on the size, brand name, available resources and R&D as a determining factor which gave the alleged dominant entity an edge over the other players in the market. The view of the Commission is a departure from what it had been consistently following in the past and with this approach, has broadened the lens of scrutiny for conducts which are anticompetitive in nature.

The prevalent trend lacks agency with the consumer, allowing industrial practices to flourish thus, disrupting the efficiency and effectiveness of functioning of markets. Therefore, the idea of a reasonable consumer making wise choices based on prices and availability of substitutes is not akin to the working of the pharmaceutical industry especially where prescription drug market has strong footings.

Furthermore, the provisions of Section 3(3) and 3(4) of the Competition Act, 2002 pertain to agreements entered between enterprises restricting purchase/sale prices, curtailing supply/production of goods and services as well as entering exclusive supply/distribution arrangements, creating tie-in arrangements with the intention of adversely affecting the market. The pharmaceutical companies holding valid patents could enter into agreements with

[17]Competition Law and Indian Pharmaceutical Industry, *available at:*https://www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf (visited on June 28, 2021).
[18] Case No. 77 of 2015 available at: https://www.cci.gov.in/sites/default/files/Case%20No.%2077%20of%202015.pdf (visited on November 28, 2021).

hospitals/pharmacists restricting prices if unregulated by the Drug Price Control Order ("DPCO") and entry in the absence of generic drug manufacturers, as well as inter-se between pharmaceutical companies may lead to possible violations under the Act which might get unidentified. An infamous case decided on these lines which mark the first time where hospital exclusivity agreements were examined and dealt with. In the infamous case of *Ramakant Kini v. LH Hiranandani Hospital*[19] the Competition Commission of India ("**CCI"/"Commission**") found the exclusive arrangement between a hospital and a provider of stem cell banking services to be anticompetitive. It observed that such agreements could create entry barriers and foreclose competition in the stem cell banking services market[20] and therefore, held that the agreement resulted in an appreciable adverse effect on competition ("**AAEC**") in the market for the provision of stem cell banking services, and that it contravened Section 3(1).

Further ahead, the role of trade associations in any industry and the economy cannot be disputed.[21] These associations or unions facilitate collective decision making and further take up certain functions that cannot be taken up by a single firm.[22] Often times, these associations overstep the competition limitation placed on them and these interactions result in anticompetitive practices with potential impacts on the competition in the market.[23]Pertinently, undertakings cannot take a defence that they were forced into anticompetitive agreements because of the conduct of the other traders.[24] The Commission has been vigilant in its approach while investigating Information alleging anti-competitive practices in pharmaceutical industry. In *M/s Arora Mecical Hall, Ferozpur v Chemists & Druggists Association*[25], penalties were imposed on an individual office bearer of the Chemists and Druggists Association, Ferozpur, for having entered into an agreement to limit supply of drugs and medicines.Similarly, in *Mr. NadieJauhri v. Jalagaon District Medicine Dealers Association (JDMDA)*[26]the union of druggists and chemists in the Jalgaon District, Maharashtra was penalised and the Commission based its decision against the mandatory charging of product information service (PIS) fee to

[19]Case No. 39 of 2012, *available at:*https://www.cci.gov.in/sites/default/files/392012_0.pdf (visited on July 28, 2021).
[20]Ibid.
[21] In *Re: Ravi Pal v. All India Sugar Trade Association (AISTA) & Ors*. Case No. 25 of 2018, *available at:*https://www.cci.gov.in/sites/default/files/25-of-2018.pdf (visited on July 28, 2021).
[22] Ibid.
[23]*M/s Royal Agency vs. Chemists & Druggists Association, Goa & Others*, Case No. 63 of 2013, available at:https://www.cci.gov.in/sites/default/files/632013_0.pdf (visited on August 18, 2021).
[24]*Modena v High Authority*, [1962] ECR 289.
[25]Case No. 60 of 2012,*available at:*https://www.cci.gov.in/sites/default/files/602012_0.pdf (last visited on August 10, 2021)
[26] Case No. 61 of 2015, *available at:*https://www.cci.gov.in/sites/default/files/61-of-2015.pdf (last visited on August 11, 2021).

pharmaceutical companies before the launch of a product into the market as a prerequisite to selling their medicines in the Jalgaon District.[27] While analysing the matrix of this case, the Commission made a reference to *Santuka Associates (P) Ltd. v. All India Organisation of Chemists and Druggists Assn.*[28], where it was held that the anti-competitiveness of public information service charges depends on whether these charges were voluntary or mandatorily payable before the launch of the new drug of pharmaceutical companies.[29]

In India, the Commission imposed a penalty equal to 10 (ten) percent of the average income of the preceding three years of an office bearer of the Himachal Pradesh Society of Chemists and Druggists Alliance ("HPSCDA") for his active involvement in anticompetitive practices carried out by the HPSCDA[30]. In the cases that followed subsequently, the Commission's findings evidently reflect its continued stringent approach against anticompetitive practices while investigating Information filed against the office bearers of chemist and druggist associations.[31]

Ahead of this, it is pertinent to note that collusive conducts take place along the distribution between drug companies, stockists, retailers, Medical Representatives (M.R.) which disproportionately inflates the cost of medicines & the overall treatment. Consumers have little or no choice in such a rigged market and buy what is prescribed by Doctors or what are sold by Chemists which defeats the object of the Competition Act in its entirety.[32]Essentially, a legal test of what constitutes a concerted practice includes that there must be a mental consensus whereby practical cooperation is knowingly substituted for competition- however, such consensus need not be verbal, and can come about by direct or indirect contact between the parties[33]

Oftentimes, the outcome of collusive practices could be myriad, cartelization being a prominent one. Cartelisation has been accelerated by trade associations to set standard prices for stockists

[27]Ibid.
[28] 2013 SCC OnLine CCI 16.
[29] Ibid.
[30]*Rohit Medical Stores v.Macleods Pharmaceutical Limited and Ors.*, Case No. 78 of 2012, available at:https://www.cci.gov.in/sites/default/files/78201227_0.pdf (visited on September 5, 2021).
[31]*Madhya Pradesh Chemists and Distributors Federation (MPCDF) v Madhya Pradesh Chemists and Druggists Association (MPCDA)*, Case No. 64 of 2014 available at:https://www.cci.gov.in/sites/default/files/64-of-2014.pdf (last visited on September 15, 2021).
[32]*Preamble*, Competition Act, 2002.
[33]*ICI v. Commission*, 1972 CMLR 557 and *SuikerUnie v. Commission*, 1976 CMLR 313.

and retailers however it also results in restricting prices. There can be violations of competition law even when the associations are formed to exchange data and information.[34]

In *Sandhya Drug Agency v. Assam Drug Dealers Association Co.*[35] a similar situation arose where the Commission failed to take into account refusal to deal and exclusive distribution agreement entered into by Assam Drug Dealers Association and merely kept itself limited to cartelization as alleged by the Informant. The observation highlights the need for a wholesome analysis in a given case and demands that while the Commission examines or investigates a certain Information put before it for consideration so as to ensure that allied anticompetitive conducts, not reflected in the Information, do not go unattended under the guise of general industrial practice.

Further, where the Competition Act prohibits bid rigging under Section 3(3), it has the potential to artificially inflate the costs of products and adversely affect the efficiency of public spending and importantly lower the benefits that accrue to the consumers.

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 procompetitive 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.

Ahead of this, in *House of Diagnostics LLP v EsaoteSpA*[36] the CCI found Esaoteas the only manufacturer of dedicated tilting MRI machines, holding 100 per cent market share, and thus, the alleged conduct of refusal to perform contractual obligations and unilaterally changing the essential terms of the contract formed the basis of the Commission's observations to hold it in contravention of the Act. Similarly, the Commission base its analysis found contravention with regard to Section 4(2)(c) of the Act against Roche Group[37] and a warranted detailed investigation into the matter.[38]

[34] Ibid.
[35] 2014 Comp LR 0061.
[36] Case No. 9 of 2016
[37] Case No. 68 of 2016, *available at:*https://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf (visited on August 10, 2021).
[38]The investigation is still pending.

Furthermore, it is important also to assess the impact of combinations on innovations. Mergers and acquisitions in innovations markets such as pharmaceuticals, pose a threat for subsequent entry of products by stifling competition at the R&D and product development stage. It is a concern that acquisitions that involve takeover of generic companies may lead to change in priorities of these companies and adversely impact the competition in generic markets. For instance, the review of the 2004 merger between Sanofi-Synthélabo and Aventis[39] was found to reduce competition in three pharmaceuticals in the USA.

The Indian pharmaceutical market has witnessed a rise in collaborations with global companies such as Glenmark Pharmaceuticals, GlaxoSmithKline ("GSK"), Merck and Eli Lilly. Piramal Life Science Ltd (PLS) and Eli Lilly and Company signed landmark new drug development collaboration in 2007.

The case of *HT Media Super Cassettes*[40] was an important judgement in this respect. Though the Commission did not discover 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.

Thus, the Commission ought to correct market failures which would help keep a check on dominant entity's ability to charge abnormally high prices.

Conclusion & Suggestions

Witnessing the scenario a year back, a country should be backed by an innovation ecosystem, a robust infrastructure for producing drugs and pharmaceuticals and preparing a pool of researchers, scientists to act as arrowheads for the future. In order to have easy access to new global markets we have to produce innovative drugs and manufacture generics. To have this happen we need to channelize our regulatory environment and maintain cost competitiveness. Above all, India must look at building next-gen capabilities that will be a differentiator in the

[39] Mergers in the Pharmaceutical Industry: The impact of Mergers on R & D Activities of Large Pharmaceutical Companies, available at:https://core.ac.uk/download/pdf/43559733.pdf (visited on September 20, 2021).
[40] *In Re M/s HT Media Limited & M/s Super Cassettes Industries Limited*, Case No. 40 of 2011 available at:https://www.cci.gov.in/sites/default/files/C-2011-40_0.pdf(visited on September 15, 2021).

decade ahead. This is a time for the Indian Pharma Industry to move ahead full throttle, invest for the future and catapult itself into a new horizon of growth and opportunities.[41]

To encourage the growth of pharmaceutical sector India needs a well defined healthcare model which is unique in its way. India surely exhibited its resilience during the global pandemic and has showcased strength in the pharma sector by ensuring easy accessibility of essential drugs across the countries. The Competition Commission of India also fought back such an obstacle and led to recovery of the economic downturn. The enforcement system should also act as a shield against the anti-competitive practices prevalent in the market. The pharmaceutical industry has shown considerable growth in meeting the demands of the market. The manufacturing sector has been benefitted in catering the needs that new opportunities brought in during COVID 19. We have a robust generic drug sector which is widening its ambit in the foreign markets as well.[42]The pandemic has awaken the country and taught a lesson to be prepared with the right tools to observe such challenges in times of uncertainty. The commission should be equipped with a full proof mechanism to identify unstructured exchange of information which leads to abuse in the market.

Where the distribution of drugs in India has witnessed a paradigm shift in the current years, the pharmaceutical market presents an interesting saga of extent of competition in the prescription drug market. More particularly, where pharmaceutical sector is characterised by information asymmetry and supplier-induced demand that significantly circumscribes consumer choice, it brings forth need for a broader and mindful scrutiny such that affordable drugs which forms a necessary pre-requisite for bringing down the overall healthcare expenses could be ensured. The existing issues petition for optimal regulation in the pharmaceutical industry to achieve the overall goal of affordable healthcare for all. Furthermore, where India is working towards robust innovation landscape awareness, innovation facilitators such as human capital investment in research and development, safety-legal environment, regulatory environment to provide truly world class biopharma research, it is essentially important the regulators undertake a vigilant approach to check the appreciable affects which could follow as a result of such developments. It becomes essentially vital to identify the regulatory gaps/overreach.

[41] Indian Pharmaceutical Industry 2021:future is now, available at: ey-ficci-indian-pharma-report-2021.pd (visited on September 30th, 2021)
[42] The Indian Pharmaceutical Industry, available at: https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/2021-04_The-Indian-Pharmaceutical-Industry.pdf (visited on September 30th, 2021)

Necessary regulatory reforms are another area of critical importance in the quest of ensuring affordable and quality healthcare through well-functioning markets.

Furthermore, it is an undisputed fact that competition has the potential to reduce prices for medicines and drugs, particularly for the essential medicines. Essentially, with the advent of newer retail and online pharma in India, the change the sector has witnessed and would witness in near future is significant which could be attributed to the ingress of organized players in the market. Thus, while the competition legislation purports at striving to preserve competitive conditions and promoting market forces to self-correct even where there is irregularity, the greatest conundrum is to balance consumer welfare with entrepreneurial interests in the pharmaceutical sector. Arguably, competitive effects associated with the introduction of generic drugs have the potential to promote consumer welfare, affording medicines at cheaper rates and stimulating competition in the market.

To strike a balance between the regulations and competition is vital given the unique characteristics of the pharmaceutical market. It is pertinent to make certain that the regulatory mechanism does not adversely affect the incentive to innovate in the sector such that consumer welfare in the long run is ensured. Similarly, a trade-off between the regulations and competition is required to balance the short run and long run incentives to the enterprises. Also, differential pricing or negotiated pricing between the innovator and the government might be the way forward. Also, incentivizing pharmaceutical companies to produce drugs that are meant for India specific problems (through patent extensions, subsidizing R&D, etc.) might be a way forward.

To conclude, the issue of price-quality paradox needs mention. Enormous investments are required for standard quality and this is reflected in the price. As prescription insurance is absent in India hence this high price drastically reduces affordability. There are many side effects if the medicines are of substandard quality. The problem of irregular access to medicines is eliminated and that consumers shall not invest too much on medical expenses since healthy competition in the market economy shall provide for competitive prices, benefiting consumers both in the present and future. Thus, a dedicated approach would allow disentangling many issues in pharmaceutical cases under the competition regime.

Suggestions & Recommendations

1. Legitimate co-operation should be allowed between the competitors in the interests of

consumers. Such co-operation should ensure least restriction on competition taking into account such extraordinary situation.

2. The commission should conduct market study of the pharmaceutical sector and identify the lacunas and problem areas which can be rectified in normal times and readiness can be made for such unforeseen contingencies.
3. Workshop should be conducted on regular intervals so that the concerns of the stakeholders can be properly documented.
4. There should be MOUs and co-operation with other competition agencies to foster best practices in dealing with conducts during such crisis. The rich experience will help the authorities to deal with such times easily.
5. Competition advocacy should be promoted so that the healthcare and pharmaceutical sector can be well regulated.