CCI RELEASES ITS FINDINGS OF THE MARKET STUDY ON THE PHARMACEUTICAL SECTOR IN INDIA

1. BACKGROUND

1.1. On November 18, 2021, the Competition Commission of India ("**CCI**") published the findings of its market study ("**Study**") on the pharmaceutical ("**Pharma**") sector in India.[1] While the Pharma sector is a regulated sector,[2] the Study was initiated in October 2020, with the objective to understand the factors that influence price competition in the Pharma sector. Based on secondary research, stakeholder consultation and empirical analysis, the CCI identified the priority areas for competition enforcement and advocacy in the Pharma sector, namely: (i) prevalence of branded generic drugs in India and its implications for competition; (ii) the role of trade margins; (iii) the role of trade associations; and (iv) online pharmacies.

2. CCI's FINDINGS

2.1. The key competition concerns as well as some of the CCI's suggestions for the identified priority areas, as noted in the Study, are as follows:

A. Prevalence of Branded Generic Drugs in India and its Implications for Competition

2.2. Given that generic drugs are homogeneous and interchangeable to the originator products,[3] competition centers mainly on price. However, the Study found that brand competition overrides price competition where the generic drugs are marketed with distinct brand names. Hence, the market leaders in each category of generic drugs charge higher prices than their competitors. The Study also found that *inter alia* prescription of drugs by brand names rather than by generic names[4] was one of the reasons for the sale of unbranded generic drugs being restricted to government procurement agencies rather than the open retail market.

2.3. In order to dispel concerns about drug quality and move competition in generics from non-price to price, the Study suggested: (i) the promotion/ facilitation of generic entry; (ii) prescription by generic drug name; and (iii) substitution between generics by pharmacies. In addition, the Study *inter alia* suggested the following:

(a) Uniform and effective enforcement of existing quality standards across different States by equipping the regulators with adequate personnel having requisite knowledge and skillset, state-of-the-art infrastructure, and sufficient resources.

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[1] Available at: https://www.cci.gov.in/sites/default/files/whats_newdocument/Market-Study-on-the--Pharmaceutical--Sector-in-India.pdf.

[2] The Pharma sector is regulated under the Drug and Cosmetics Act, 1940 and the rules made thereunder and is enforced by the Drug Controller of India. Further, the National Pharmaceutical Pricing Authority constituted *vide* Government of India Resolution dated August 29, 1997 acts as an independent regulator for pricing of drugs to ensure availability and accessibility of drugs at affordable prices.

[3] In terms of their therapeutic attributes.

[4] Owing to the perceived quality issues of generic drugs.

(b) Better transparency to bridge the information gaps regarding grant of licences, inspections, prosecutions for non-compliance, etc., through real time data/information published and available on a central online portal. Further, the introduction of an easily accessible, comprehensive, online and centralised drug databank consolidating real-time data on active Pharma companies in the country along with their products, manufacturing and marketing entities to help address information asymmetry in the Pharma Sector.

(c) Periodic, systematic and scientific testing of drugs through sample collection and testing through a scientific and statistically robust methodology to curb spurious drugs.

(d) Ensure quality control by following good distribution practice (**GDP**) as witnessed in developed countries. It was recommended that draft guidelines for GDP issued by the Central Drugs Standard Control Organization should be promoted and implemented.

(e) Ensure standard compliance marks for unbranded generic drugs as an institutional quality signaling mechanism, which may provide necessary confidence to the physician community to prescribe generic drugs.

B. Role of Trade Margins

2.4. The Study found that Pharma manufacturers compete *inter-se* for stocking and selling of their products by offering financial incentive to pharmacies in the form of high trade margins.[5] While this incentive allowed new manufacturers or manufacturers with limited product portfolios to enter and expand their market shares against the incumbents, it did not translate into lower price for the consumers. The stakeholder feedback further revealed that these hospital and doctor-run pharmacies were the primary route of supply for the high margin, high MRP drugs. Given that in-patients are often mandated to purchase prescribed drugs from hospital pharmacies, they are insulated from retail competition. Thus, while there is competition on trade margins between Pharma manufacturers, in the absence of effective competition at the retail level, Pharma manufacturers had no incentive to compete on the final price paid by the consumers.

2.5. As effective competition between retailers (through price discounts offered to consumers) may contain the price effects of high retail margins, the CCI stated that it will continue to deter and prevent: (i) collective determination of trade margins by industry; and (ii) any concerted attempt to fix, restrict or discourage offering of discounts by chemists and stockists. Further, the Study suggested exploring rationalisation of trade margins through regulatory intervention of the National Pharmaceutical Pricing Authority ("**NPPA**") to curb high trade margins.[6] However, given that: (i) the CCI's role does not extend to fixing the prices/ determining what the appropriate price of products should be;[7] and (ii) there is a

[5] Trade margin is computed as the difference between the retail price of drugs and cost price of manufacturers (ex-factory price).

[6] The NPPA, under the provisions of the Drug Control Price Order (**DPCO**), regulates the trade margin of scheduled drugs and has capped it to 24%, with 16% reserved for the retailers and 8% for the wholesalers. However, the DPCO does not specify the same for non-scheduled drugs, which allowed companies to fix a margin structure of 10% and 20% for wholesalers and retailers, respectively.

[7] (i) Case No. 10 of 2021, *Confederation of Indian Alcoholic Beverage Companies and another v. Kerala State Beverages (Manufacturing and Marketing) and another*, CCI order available at: https://www.cci.gov.in/sites/default/files/10-of-2021.pdf (Para 63); (ii) Case No. 12 of 2019, *Indian Chemical Council v. General Insurance Corporation of India*, CCI order available at: https://www.cci.gov.in/sites/default/files/12-of-2019.pdf (Para 11); (iii) Case No. 21 of 2020, *Automotive Tyres Manufacturers Association v. General Insurance Corporation of India*, CCI order available at: https://www.cci.gov.in/sites/default/files/21-of-2020.pdf (Para 17); and (iv) Case No. 68 of 2012, *Manjit Singh Sachdeva v. Director General, Directorate General of Civil Aviation and another*, CCI order available at: https://www.cci.gov.in/sites/default/files/682012_0.pdf (Para 3).

possibility of certain distortionary effects[8] of this regulatory tool, the Study suggested conducting pilot studies across different therapeutic categories to test the feasibility of trade margin rationalisation.

C. Role of Trade Associations

2.6. The Study noted that trade associations have the potential to limit competition by exercising collective control over entry and supply of Pharma, given their repeated contravention of the provisions of the Competition Act, 2002 ("**Act**"). The CCI had previously penalised and directed them to cease and desist from indulging in certain anti-competitive practices,[9] such as: (i) mandatorily requiring a no-objection certificate ("**NOC**") for the appointment of stockists by manufacturers, which had the effect of limiting stockists in a particular geographical territory; and (ii) mandatorily levying product information service ("**PIS**") charges for the introduction of new drugs in a particular geographical territory.[10]

2.7. While the stakeholder feedback suggested a significant positive impact of the CCI's directions to discontinue the practice of the mandatory NOC and PIS norms, the Study urged trade associations to adopt effective competition compliance programmes to ensure that the associations and/or their members, directly or indirectly, do not contravene the provisions of the Act.[11]

D. Online Pharmacies

2.8. The Study noted that even though online pharmacies were relatively new in India, this segment witnessed rapid growth with the pandemic providing a significant impetus to online purchase of products, including drugs. As such, the key concerns in this segment related to: (i) discounts offered by the online pharmacies; and (ii) concentration of personal health data with a few online pharmacies (in light of their integrated end-to-end offerings, spanning across teleconsultation, diagnostics, drugs, etc.).

2.9. In relation to the discounting practices, the Study noted that they can be pro-competitive when: (i) offered by new entrants to overcome the incumbency advantage; and (ii) offered on account of efficiency gains. Nonetheless, the competitive assessment of discounts or any other specific conduct of online pharmacies being a fact-intensive exercise would have to be conducted on a case-by-case basis.

2.10. In relation to concentration of personal health data, the Study noted that the competition laws of India are wide enough to examine any competition harm that is likely to be caused by disproportionate collection/use of data by digital entities with market power. Further, until the country legislates its data protection law, the Study suggested that the online pharmacies should adopt self-regulatory measures

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[8] These effects include: (i) substitution of drugs under margin control with those out of its ambit when the entire therapeutic class is not covered under the rationalisation scheme; and (ii) the likelihood of increase in the sale of higher-priced drugs, owing to the retailers' or hospitals' interest in selling drugs which fetch them maximum financial incentive in absolute value.

[9] (i) Case No. 64 of 2014, *Madhya Pradesh Chemists and Distributors Federation v. Madhya Pradesh Chemists and Druggists Association and others*, CCI order available at: https://www.cci.gov.in/sites/default/files/64-of-2014.pdf; and (ii) Case No. 65, 71, 72 of 2014 & 68 of 2015, *Alis Medical Agency v. Federation of Gujarat State Chemists & Druggists Association and others*, CCI order available at: https://www.cci.gov.in/sites/default/files/65%20of%202014%2C%2071%20of%202014%2C72%20of%202014%20%26%2068%20of%202015.pdf.

[10] A minority of participants of the stakeholder feedback indicated that the practices may still be in force in some form in pockets.

[11] To *inter alia* prevent anti-competitive practices, such as: (i) price-fixing, (ii) market partitioning such as allocation of customer groups or territories between competitors; (iii) bid-rigging; and (iv) exchange of sensitive information such as prices and discounts, or price-related contractual terms, ongoing bids or plans to bid for business, business plans or commercial strategy, production planning or output levels, etc.

in the areas of collection, use, sharing of data and privacy to safeguard patient privacy and protect sensitive personal medical data.

3. INDUSLAW VIEW

3.1. Given that healthcare, economy and welfare of a country have a direct correlation, the Pharma sector has been a focus area for the CCI from its early days. The focus is evident from the fact that the CCI has examined approximately 43 cases in this sector till date. Additionally, in the short lifespan of 12 years of the CCI, the instant the Study is the second instance where it has examined issues plaguing this sector; the first being in October 2018.[12] With the advent of the coronavirus pandemic, ensuring the robust working of the Pharma sector has taken a front seat for the government and regulators alike. Against this backdrop, the Study comes at an opportune time to extensively discuss and address the extant competition issues in relation to distribution, pricing and availability of drugs. To tackle these plaguing issues, the Study has made insightful recommendations to secure the long-term competition interests in the Pharma sector.

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[12] Available at: https://www.cci.gov.in/sites/default/files/event%20document/POLICY_NOTE_0.pdf?download=1.