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

23 November 2021

#### **Background**

Within close to a year of initiation of its market study into the pharmaceutical sector, on 18 November 2021, the Competition Commission of India (CCI) released its findings in its report titled '*Market Study on the Pharmaceutical Sector in India: Key Findings and Observations*'.<sup>1</sup>

Statistics reveal that the CCI has received 43 cases involving the pharmaceutical sector. The relentless flow of incoming cases in this space prompted the authority to examine the sector with the aim to understand discounts, margins, prevalence of branded generic drugs, wholesale and retail level distribution policies, role of trade associations, impact of e-commerce and online pharmacies on price and competition, among other aspects.

Given the CCI's emphasis to consider a 360 degree view of the industry, various stakeholders, such as pharmaceutical companies, stockists, chemists, trade associations, doctors, sector experts and regulators were consulted to gain an in-depth insight into the issues plaguing the sector.

#### **Key Observations and Findings**

(i) *Brand competition trumps price competition:*

The CCI recognised the role of generic drugs in bringing down drug prices, thereby reducing healthcare costs and improving access. In its view, competition in the generic drugs space should typically centre on price, as generics are homogeneous and interchangeable to the originator product and are chemically and functionally identical.

The following observations are noteworthy:

- Despite the domination of generics, with the presence of multiple manufacturers for each formulation, brand competition *outweighs* price competition.

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<sup>1</sup> Competition Commission of India, *Market Study on the Pharmaceutical Sector in India: Key Findings and Observations*, dated 18 November 2021, available at: [http://cci.gov.in/sites/default/files/whats\\_newdocument/Market-Study-on-the-Pharmaceutical-Sector-in-India.pdf](http://cci.gov.in/sites/default/files/whats_newdocument/Market-Study-on-the-Pharmaceutical-Sector-in-India.pdf).

- A considerable price difference exists between brands of a market leader when contrasted with the prices of other market participants, especially those with lower market share.
- Brand differentiation in terms of a perception of different levels of quality and trade margins offered to incentivise chemists are key drivers of brand competition in India's markets for generics.
- The perception of difference in the quality of drugs by different manufacturers also feeds into brand differentiation.

Recommendations:

Observing that the enforcement of quality regulations was not *inter alia* uniform across states leading to different quality standards being followed, the CCI has provided a multi-pronged approach and harmonised regulatory recommendations to address the lacking uniformity in drug quality across the spectrum. To achieve this, the report *inter alia* recommends:

- The Central Drugs Standard Control Organisation (CDSCO) to create awareness on quality issues, build capacity, and harmonise training and practices across the country for consistent application of quality standards;
- Creation of a central portal to facilitate transparency on grant of licenses, inspections, prosecutions on non-compliance, etc.;
- Quality control across the pharmaceutical supply chain guided by good distribution practices;
- Standard compliance marks for unbranded generics;
- Quality controls in public procurement by implementing strategies through pooled / centralised procurement systems and layered quality checks; and
- Establishment of national digital drugs database to address information asymmetry by creating an online, centralised drug databank by consolidating real-time data on active pharmaceutical manufacturing companies in the country, therapeutic class wise / formulation-wise approved branded / unbranded products along with their manufacturing and marketing entities which may be created, and made accessible to regulators, industry, physicians and consumers alike.

(ii) High margins to lure stockists with no retail price competition:

The report noted that pharmaceutical manufacturers compete to have their products sold by retailers / pharmacies through high margins, particularly in trade generics. Other significant findings in the report are:

- While retail margins act as an incentive mechanism and may allow new entrants with limited product portfolios to enter and expand their market shares against established incumbents with wider product portfolios, it does not translate to lower prices for end consumers.

- Setting high margins does not necessitate lowering of the manufacturers' price, as it may be adjusted by increasing the final price of the product.
- The sufficient flexibility allowed to manufacturers for manoeuvring MRPs (for drugs outside the Drugs (Prices Control) Order, 1995 (DPCO)) - to accommodate margins which drive competition - indicate muted price competition between manufacturers possibly resulting in a systemic upward pricing pressure, eroding the benefits of generic competition.
- The prevailing chemist centric approach of setting margins was seen to not be aligned with consumer interest. The report remarks that this mechanism is another means of allowing exploitation of agency problems and information asymmetry that riddles the sector while keeping price competition at bay.

Recommendations:

The report opines that effective competition between retailers *inter alia* through price discounts offered to consumers can address price effects of high retail margins on final prices. Based on deliberations with stakeholders, the CCI among others, recommended a regulatory trade margin rationalisation scheme (with price caps) designed to exclude undesirable effects, such as enhanced sale of drugs when the entire therapeutic class is not covered; or increased sale of higher priced drugs which have better financial incentives.

(iii) Online v offline modes of distribution:

The report recognised the steady rise of market share of online pharmacies and observed that while data and digital technology can improve access to and efficiency of healthcare delivery, concentration of data with few platforms raise concerns over collection, storage, security, and sharing of such data.

It further asserted that competition law in India is wide enough to enable the assessment of any competition harm that may be caused by disproportionate collection / use of data by digital entities with market power.

Recommendations:

- To safeguard patient privacy and protecting sensitive personal medical data, the CCI expressed the need for necessary regulations to be enforced until India legislates its data protection laws; and
- It recommended self-regulation by online pharmacies to adopt measures in relation to collection, use, and sharing of data and privacy.

(iv) Best practices for trade associations:

Echoing its decisional experience, the CCI emphasized that: (i) mandatory requirement of No Objection Certificates (NOC) for appointment of stockists; and (ii) mandatory payment of Product Information Service (PIS) charges for introduction of new drugs by pharmaceutical companies, have been held to be anti-competitive by the CCI in several cases.

The report noted that when trade associations provide a platform for competitors to collectively create and enforce norms that have an impact on entry and supply, and therefore, on competition, such conduct would warrant competition scrutiny.

*Recommendations:*

The CCI urged such trade associations to adopt an effective competition compliance programme to disengage in any anti-competitive conduct prohibited under the Competition Act.

**Comment:**

This report marks the second study (however, more in-depth) that the CCI has conducted following its recommendations in a 'Policy Note' on 'Making Markets Work for Affordable Healthcare' in October 2018.<sup>2</sup> The CCI expects that the insights gained will inform and contribute significantly to the design of the pharmaceutical market in India to help attain the objective of affordable medicines for all.

Notably, this report comes in the wake of a slew of market studies that the CCI has commenced under the aegis of its advocacy initiative which seeks to study hot sectors either witnessing an uptick in probes for potential market failures (such as digital markets / e-commerce) or defined by rapid technology driven transformations (e.g. telecom, media and entertainment, film distribution, and over-the-top (OTT) streaming platforms).

Be that as it may, considering the sensitivity of the healthcare industry and impact on common lives, tackling competition issues within its realms remains an enforcement priority for the CCI and one can only expect the CCI to be even more watchful of market participants' conduct in this space.

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<sup>2</sup> Competition Commission of India, *Making Markets Work for Affordable Healthcare*, Policy Note, dated October 2018, available at: [https://www.cci.gov.in/sites/default/files/POLICY\\_NOTE.pdf](https://www.cci.gov.in/sites/default/files/POLICY_NOTE.pdf).