

## CCI's Market Study on the Pharmaceutical Sector

On November 18, 2021 the Competition Commission of India (CCI) released its report on “*Market Study on the Pharmaceutical Sector in India : Key Findings and Observations*” (Study).

The CCI, during its decade old enforcement regime, has mostly dealt with anti-competitive vertical restraints stemming from the distribution chain in the pharmaceutical industry. The Study focuses on several aspects of the pharmaceutical industry including distribution channels, role of trade associations, trade margins, online pharmacies and the prevalence of branded generic drugs in India and its implications for competition.

Given that the pharmaceutical sector is heavily regulated, the Study aims to explore the areas of interface between regulation and competition with a view to ascertain CCI's advocacy priorities.

The key focus areas identified in the Study were:

- Competition in generic drugs
- Prevalence of branded generics in India and its implications for generic competition and drug prices
- Pharmaceutical distribution landscape

### Branded Generic Drugs and Competition

The Study notes the growth of the Indian pharmaceutical industry in generic drugs with India being the largest supplier of generic drugs globally. The CCI observes that India's pharmaceutical market predominantly comprises generics with branded generics accounting for 87% of the pharmaceutical market with around 10% being unbranded/'generic generics'.

The market for 'branded generics' is a phenomenon almost unique to India and it has been observed that competition and sales in this segment is driven by retail margins offered to retailers/chemists. Unbranded generics are largely confined to public procurement by government health facilities and constitute a negligible share of the private generic market in the country.

### Pricing and Prevalence of Branded Generics

The Study, in order to ascertain the effect of brand differentiation on the pricing of branded generics, examines price dispersion across brands of different companies and price discrimination across brands of same molecules marketed by same companies. It observes a considerable price difference between brands of a particular generic formulation marketed by different firms. For example, with respect to amoxicillin + clavulanic acid (Tablet, 125/500 mg) the Study notes a substantial price variation between companies selling different brands, ranging from INR 40 to INR 336 for a pack of six tablets. Similarly, the Study also observes a notable variation in price between brands marketed by the same company.

The Study confirms that in the pharmaceutical market in India, product differentiation is introduced through brand differentiation even in generics, which are ostensibly homogeneous commodities and functionally interchangeable.

### Price and Market Share

The CCI observes that market leaders in the pharmaceutical sector, even with the presence of a large number of firms and brands, charge prices that are relatively higher than other market participants, especially those with lower market share. Further, it is seen that the price charged by the market leader, measured by sales value, remains highest or among the highest, whereas the prices of lowest selling drug remain the least, or among the least.

## Price Difference and Quality Between Branded Generics in Private Retail Market and Pure Generics in Public Procurement Market

The Study suggests that despite the seemingly strong generic competition, consumers in India ostensibly pay a premium for brands. For instance, in the comparison between the highest-priced branded generic and public procurement price of unbranded generic, 46 out of 54 drugs (across six therapeutic categories) demonstrate a price difference ranging from 107–197%.

The Study notes that brand competition in the case of patented drugs is based on relative quality and the value that a new drug creates for consumers. In that case, brand name is a means for product identification and awareness creation on the therapeutic merits that a drug offers above and beyond that of the other existing drugs in the same category. However, in CCI's view, the same should not plausibly hold true for generic drugs which, regardless of their brand names, 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 Study finds that one of the major barriers to effective price competition in generics is the perceived variation in the quality of generic drugs. In practice, although low-priced generic copies are available for most originator drugs, asymmetric information about generic quality and penchant for branded medicines undermines price competition. The CCI notes some measures which can help to improve quality standards in generic drugs, such as - (a) the need for uniform and consistent application of quality standards across states; (b) maintaining transparency through a centralized portal for drug regulation; (c) having a robust methodology for sample testing of drug and sample collection; (d) the need for a centralized digital drugs databank; (d) maintaining quality control in handling, storing and transportation of drugs; (e) printing of standard compliance marks on unbranded drugs to boost consumer confidence; (f) creating awareness by launching information campaigns; and (g) the need to improve the availability of generic drugs.

## Drug Distribution and Competition

The Study discusses the distribution network and how competition distortion at any stage of supply chain can act as major hinderance to the supply of pharmaceuticals. The CCI notes the need for continued vigilance in the enforcement of the provisions of the Competition Act to ensure that manufacturing companies, stockists, and pharmacies can enter and operate independently of such collective controls or diktats of associations, which have the potential of limiting competition. The key practices which have been found to limit competition are:

- Mandatory requirement to obtain a 'no objection certificate' (**NOC**) for appointment of new stockists;
- Mandatory charges for 'product information services' (**PIS**); and
- Collective determination of trade margins/association's control over discounts.

While the Study notes that certain NOC and PIS norms help in removing sub-standard/spurious drugs from the market and allow for information dissemination on new drugs, the CCI observes that these issues can be addressed through appropriate regulatory mechanisms. Under its advocacy mandate, the CCI may also take up these matters with central/state drug regulators for deliberation on appropriate pro-competitive regulatory interventions.

The CCI, in the Study, urges trade associations to adopt an effective competition compliance program to ensure that the associations and/or their members do not engage, directly or indirectly, in any anti-competitive practices including, price-fixation; exchange of sensitive information with competitors; allocating geographical areas of market; bid-rigging; creating entry barriers; boycotting etc.

The CCI also discusses the role of online pharmacies and how they enhance supply chain efficiencies. The Study notes that the advantage of this model stems from a truncated supply chain with fewer intermediaries, allowing for higher margin and higher consumer discounts. The key concerns that were raised in respect of online pharmacies relate to

- Discounts offered by these platforms; and
- Concentration of personal health data with a few platforms.

The CCI has not undertaken a detailed assessment of e-pharmacy model and discounts offered through it and has noted that competitive assessment of discounts and any other specific conduct of e-pharmacies having implications for competition will have to be a fact-intensive exercise done on a case-by case basis.

To access the full report on the Study, please see the link made available [here](#).

We trust you will find this an interesting read. For any queries or comments on this update, please feel free to contact us at [insights@elp-in.com](mailto:insights@elp-in.com).

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