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# UPDATE

## ERGO
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## MAKING MARKETS WORK FOR AFFORDABLE HEALTHCARE

23 November 2018

Recently, the Competition Commission of India (CCI) released a policy note titled *Making Markets Work for Affordable Healthcare* (Policy Note).

The Policy Note asserts that the CCI, over the course of its adjudicatory experience, had observed information asymmetry and supplier-induced demand in the pharmaceutical / healthcare sector resulting in circumscribing consumer choice. The key issues and recommendations discussed in the Policy Note are set out below:

- **Key Issues and Recommendations**

  - **The role of intermediaries in drug price build-up**

  *Issue*

  - Unreasonably high trade margins (defined as the difference between the price to trade and the maximum retail price) drive drug prices up, and exist for two reasons:
    - Manufacturers offer them as incentives to traders; and
    - Associations of stockists / chemists / druggists act as gatekeepers for the entire supply chain and regulate the appointment of stockists, discounting practices, etc.

  *Recommendations*

  - Replace price control with public procurement to provide essential medicines at lower prices.
  - Regulation to encourage / promote e-pharmacies, which enhance transparency and consumer choice.

  - **Quality perceptions behind the proliferation of 'branded' generics**

  *Issues*

  - Dominance of branded off-patent generic drugs which command price premiums due to the perception of greater quality.
  - Brand-name products are prescribed and dispensed in greater amounts either because they are perceived to be more efficacious, or because doctors and pharmacists gain higher margins and incentives for prescribing or dispensing them.

*Recommendations*

- Strengthen and harmonise the drug regulatory system to build consumer trust in off-brand products and ensure that the quality of generics is at par with branded drugs.
- Prohibit artificial product differentiation (i.e. the marketing of a single drug through multiple brands at varying price points) through a one-company-one-drug-one-brand name-one-price policy.

- **Vertical arrangements in healthcare services and lack of transparency**

*Issues*

- Patient referrals may be driven solely by incentives given to doctors by hospitals.
- Hospitals tie high-margin consumables supplied by in-house pharmacies to inpatient care, despite the availability of cheaper substitutes at external pharmacies.
- Hospitals tie diagnostic services to treatment by rejecting external test reports, thereby also increasing switching costs for patients.

*Recommendations*

- Mandatory declaration of vital data (mortality, infection rate, number of procedures).
- Regulation to allow consumers to buy standardised consumables in the open market rather than from in-house pharmacies at hospitals.
- Quality standardisation for diagnostic labs, which would help bolster regulation requiring hospitals to accept external test reports and initiate treatment on their basis.
- Patient data portability, i.e. regulation allowing patients to obtain and transfer their personal data stored in the hospitals in a structured, machine-readable format.

- **Regulation of the pharmaceutical sector and competition**

*Issues*

- Non-uniform application of drug regulation due to multiplicity of regulators and a lack of co-ordination, leading to multiple standards governing the same products.
- Unpredictability in the new drug approval process due to a lack of statutory timelines, high discretion and additional constraints on novel biological drugs.

*Recommendations*

- Training of state licensing officers must be centralised and harmonised, and a centralised databank on licensing should be created and linked with the states.
- New drug approvals must be time-bound and transparent through a publicly available database and governed by detailed guidelines for each stage of the approval process.

➢ **Competition issues and the role of the CCI**

The CCI has in the past identified, *inter alia*, two focus areas for enforcement which are set out below.

- Trade association behaviour in the pharmaceutical supply chain:
  - The existence of high trade margins indicates the absence of effective competition in drug distribution.
  - However, the CCI has noted that some degree of course correction has taken place following its earlier interventions.
- Activities that hamper or delay generic market entry after patent expiry:
  - Innovators filing for injunctions with insufficient evidence of impending infringement.
  - Denial of access to sample products.
  - Frivolous litigation (e.g. Roche's challenge against the approval of Mylan/Biocon's Trastuzumab biosimilar).

***Comment*:**

*The CCI's interest in the healthcare and pharmaceutical sector shows no sign of waning, and the Policy Note indicates that the CCI does not intend to adopt a light-touch approach. The Policy Note also appears to be consistent with recent trends in merger control as well as enforcement, particularly considering the ongoing investigation in respect of super-specialty hospitals in New Delhi and recent orders against Gujarat-based trade associations and drug manufacturers.*

*While several recommendations contained in the Policy Note (e.g. public procurement, e-pharmacies, patient data portability, etc.) can only be implemented by other arms of government, the CCI appears to have already demonstrated its intention to co-operate with the appropriate agencies (e.g. in the form of discussions with the Drug Controller General of India and the Department of Pharmaceuticals) to realise outcomes that it sees as desirable for robust competition.*

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