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CCI brings out policy note on Affordable Healthcare

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Over the nine years of enforcement of the Competition Act, 2002 (the Act), the Competition Commission of India ('the Commission') has received 52 cases pertaining to the pharmaceutical and healthcare sector. The Commission, while deciding on the cases, has observed that information asymmetry in the pharmaceutical/healthcare sector significantly restricts consumer choice. In the absence of consumer sovereignty, various industry practices flourish which have the effect of choking competition and are detrimental to consumer interest. Such practices may not always violate the provisions of the Act, but they create conditions that do not allow markets to work effectively and healthy competition to drive the market outcomes. The response to these issues can, in many instances, take the form of appropriate regulations that can pre-empt market-distorting practices and help create pro-competition conditions.

As the competition authority of the country, the Commission felt the need for close examination and focused deliberations on these issues, which have implications for markets and competition in this sector of critical importance. In pursuance of the same, a series of initiatives has been taken up by the Commission over the years in the pharmaceutical and healthcare sector, which culminated in a Technical Workshop on 'Competition Issues in the Healthcare and Pharmaceutical Sector in India' organised on August 28-29, 2018 in New Delhi with representatives of all stakeholder groups, including pharmaceutical industry, healthcare service providers, civil society organisations, regulators, healthcare think tanks.

The issues identified and recommendations suggested by the stakeholders have been documented in a Policy Note by the Commission titled 'Making Markets Work for Affordable Healthcare'. The key issues and recommendations are as under:

Role of intermediaries in drug price build-up

- One major factor that contributes to high drug prices in India is the unreasonably high trade margins. The high margins are a form of incentive and an indirect marketing tool employed by drug companies. Further, self-regulation by trade associations also contributes towards high margins as these associations control the entire drug distribution system in a manner that reduces competition.
- Efficient and wider public procurement and distribution of essential drugs can circumvent the challenges arising from the distribution chain, supplant sub-optimal regulatory instruments such as price control and allow for access to essential medicines at lower prices.
- Electronic trading of drugs, with appropriate regulatory safeguards, could be another potent instrument for bringing in transparency and spurring price competition among platforms and among retailers, as has been witnessed in other product segments.

Quality perception behind proliferation of branded generics

- Worldwide, generic drugs are seen as a key competitive force against the patent-expired brand name drugs marketed at monopoly prices. In India, the pharmaceutical market is dominated by 'branded generics' which limit generic-induced price competition. The branded generic drugs enjoy a price premium owing to perceived quality assurance that comes with the brand name. Quality consideration may be a reason behind the prescription of branded generics by doctors. However, it is also equally possible that the brand proliferation is to introduce artificial product differentiation in the market, offering no therapeutic difference but allowing firms to extract rents.
- The regulatory apparatus must address the issue of quality perception by ensuring consistent application of statutory quality control measures and better regulatory compliance. Unless the quality of drugs sold in markets can be taken to be in conformance of the statutory standards regardless of their brand names, generic competition in the true sense of the term cannot take off.
- The practice of creating artificial product differentiation for exploitation of consumers may be addressed through a one-company-one drug-one brand name-one price policy.

Vertical arrangements in healthcare services

- In view of the incentive-based referral system that pervades the healthcare landscape, issuing of periodic validated data by hospitals relating to mortality rate, infection rate, number of procedures etc. could help patients make informed choice.
- The in-house pharmacies of super specialty hospitals are completely insulated from competition as inpatients are typically not allowed to purchase any product from outside pharmacies. This calls for regulation that mandates hospitals to allow consumers to buy standardised consumables from the open market.
- All accredited diagnostic labs should meet the same quality standards in terms of infrastructure, equipment, skilled manpower etc. for getting accreditation. This will ensure the same degree of reliability and accuracy of test results across labs.
- There is no regulatory framework that ensures and governs portability of patient data, treatment record, diagnostic reports between hospitals. This acts as a constraint for patients in switching from one hospital to another and creates a lock-in effect. Portability of patient data can help ensure that a patient is no longer locked into the data silos and do not bear additional cost for switching medical services and that doctors/hospitals can have timely access to patient data.

Regulation and competition

- Owing to the multiplicity of regulators governing the pharmaceutical sector at the centre and state level, implementation of regulations is not uniform across the country. This has resulted in multiple standards of same products and also different levels of regulatory compliance requirements.
- A mechanism may be devised under the aegis of the CDSCO to harmonise the criteria/processes followed by the state licensing authorities to ensure uniformity in interpretation and implementation.
- It is also imperative to make the approval of new drugs time-bound along with publication of detailed guidelines governing each stage of new drug approval process.

Finally, two other major issues that affect the healthcare sector and thus warrant policy response are: (i) shortage of healthcare professionals in the country owing *inter alia* to high cost of medical education and (ii) inadequacy in health insurance. Public health delivery is a complicated policy matter. The focus of the Policy Note does not lose sight of legitimate public policy objectives, but endeavours to determine the extent to which choice and competition can improve outcomes consistent with those objectives. Accordingly, the Policy Note is being shared with Ministry of Corporate Affairs, Ministry of Health and Family Welfare, Department of Pharmaceuticals and NITI Aayog. The Commission will continue to enforce antitrust rules in the pharmaceutical and healthcare sector to ensure that effective competition is not undermined in these markets. However, since enforcement cannot address all competition issues in the sector, the instrument of competition advocacy is employed with more vigour to facilitate discussions and make policy changes that are necessary to address the conditions triggering non-competitive market outcomes.