Speech
of
Chairperson, Competition Commission of India
Workshop on Competition Issues in the Pharmaceutical Sector in India
August 27, 2021

- Respected Member of NITI Aayog and Chief Guest Dr. Vinod K. Paul
- Prof. K. Srinath Reddy, President, Public Health Foundation of India
- Members of the Commission
- Distinguished panellists and participants
- Ladies and Gentlemen

1. It gives me immense pleasure to address you all at this workshop on 'Competition Issues in the Pharmaceutical Sector in India'. For competition enforcement and advocacy to be effective, a clear understanding of markets as well as competition enablers and impediments is necessary. Market studies and sectoral workshops allow us the opportunity to reach out to all stakeholders and gather insights on competition-relevant issues. These studies, which look at sectors as a whole and help ascertain the Commission's priorities, are now an important constituent of our toolkit. It is gratifying to see that the pharma sector study and this workshop have received enthusiastic response from all stakeholders. I take this opportunity to welcome and thank each one of you!

2. The pharmaceutical sector's role in our lives cannot be overstated. The pandemic has brought the criticality of the sector into sharper focus. Getting a molecule from the laboratory to patients is a long and complex journey, and our pharmaceutical industry has made rapid strides in traversing this path and meeting the healthcare needs not only of India but also that of the globe. It is a matter of pride that today, the Indian pharmaceutical industry caters to over 50% of the global demand for various vaccines, 40% of generic demand in the US and 25% of all medicines in the UK. Globally, India ranks 3rd in terms of pharmaceutical production by volume.[1]

[1] Pharma Industry in India: Pharma Sector Overview, Market Size, Analysis...| IBEF accessed on August 10, 2021

3. Given the pivotal role that this industry plays in healthcare delivery, it is imperative that we have well-functioning markets in the sector, where firms can compete on merits, innovation can thrive and consumers can benefit from competitive market outcomes. The atypical economics and distinctive features that characterise the sector can, however, attenuate competitive forces and market discipline. The market study attempted to take a close look at factors that influence competition. Currently in progress, the study has been able to gather useful insights on issues that may directly or indirectly have a bearing on competition.

4. Drug spending is the single largest contributor to out-of-pocket expenses on health in India. Therefore, the intensity of price competition in pharmaceuticals assumes particular significance. Generic drugs play an important part in creating the competitive pressures required for bringing down prescription drug prices, thereby reducing healthcare costs and improving access.

5. The Indian pharmaceutical market predominantly comprises generics, which account for around 97% of drug consumption in terms of value. However, only about 10% of drugs are pure generics, marketed with just their chemical names; 87% of drugs dispensed in India are so-called 'branded generics', which are generic drugs sold under brand names. There are 47,478 brands in the market associated with 2,871 formulations, implying the presence of an average of 17 brands for every formulation.[2] One of the focus areas of the market study was to gauge the implications of the prevalence of branded generics for competition and market outcomes.

6. An analysis of price data for six therapeutic categories, including anti-diabetes, analgesics, cardiovascular, anti-cancer, antibiotics and vitamins-minerals, show significant price variations between different brands of the same

[2] PHFI Research

generic molecule. The price differential was found to be not only considerable between brands marketed by different companies, but in certain instances, notable price variations were observed between brands of the same formulation marketed by the same company. The price charged by the market leader in many formulations was found to be the highest or among the highest. On the other hand, the lowest-selling drugs were often the lowest-priced.

7. Thus, as per the interim findings of the study, despite the presence of several players in each generic molecule, consumers ostensibly pay a premium for brands. Significant price difference for the same generic drugs between the private retail market and public procurement market, further corroborates the same.

8. Stakeholders' views were sought on how brand competition, which is premised on product differentiation, plays out in generics that are supposed to be homogeneous substitutes of originator drugs. This resulted in the emergence of divergent opinions: some attributed it purely to a perception of higher quality of higher-priced brands created by pharmaceutical companies through their marketing efforts despite no real quality difference between different branded versions of the same generic drug. On the other hand, a section of stakeholders was of the view that quality may and does vary across drugs; not all branded versions of the same generic drugs are equally efficacious. According to them, because pharmaceutical safety and efficacy are intrinsically unobservable, prescription patterns reflect a preference for known brands with known quality experience of physicians.

9. Irrespective of whether quality is a genuine or a perceived problem, the interim findings point to the key role played by quality expectations and a perception of variations in efficacy across drugs in fueling brand competition and diluting the price-reducing effect of generics in India. Thus, quality regulation is

one of the issues, up for deliberation at today's workshop. We look forward to hearing different perspectives on this aspect as well as on the regulatory pathways that can help build trust and awareness for effective price competition to take off.

10. On the question of supply and availability of generics in the country, the study shows that pure generic drugs are almost non-existent in the private retail network in India. The respondents highlighted that Janaushadhi can play a very important role in increasing the availability of generics in the market. They urged for increased visibility and wider network of Janaushadhi stores. The Janaushadhi model has also led to the launch of generic retail chains in the country. These chains are trying to bring generic medicines directly from manufacturing plants to patients at lower prices. Still in its nascence, if this trend gathers momentum, it has the potential to emerge as a competitive force in the retail market and complement Janaushadhi in improving the uptake of generics in the country.

11. Interestingly, the stakeholder consultation revealed that, in the trade circle, the term generic is used only for a sub-set of branded generics. These drugs, also referred to as 'trade generics', are marketed with trade names and are not distinguishable on the basis of any objective criteria. Reportedly, these drugs are distributed by pharma companies directly to hospitals and retailers and carry significantly higher retail margins compared to their 'branded generic' counterpart in order to incentivise sale, thereby influencing competition at the retail level.

12. Let me now move on to another key focus area of the study—the distribution architecture for drugs and the evolving contours of markets at each leg of the supply chain in India. The Commission has received multiple cases pertaining to the distribution segment of the industry in the past twelve years.

The specific practices that were found to have the effect of muting competition include (i) mandatory requirement of no-objection certificate from the associations for appointment of stockists by manufacturers and (ii) the imposition of Product Information Service charges by associations for the introduction of new drugs in a particular geographical territory.

13. The study made an attempt to gather feedback from industry participants on the current state of affairs *vis-à-vis* these practices. A majority of the respondents informed that the mandatory requirement of obtaining NOCs no longer exists. On the issue of PIS charges, the responses were relatively more diverse; however, a majority stated that it was being now levied on a voluntary basis. The association representatives, while confirming compliance with CCI orders, put forth their perspectives in favour of these practices. According to them, these practices arose from the requirement for trade bodies to act as watchdogs against the supply of sub-standard and spurious drugs into the market. With regard to PIS charges, their arguments centred on the benefits of a centralised information dissemination system to both retailers and pharmaceutical companies. However, this view was refuted by some stakeholders, who considered the charge as a kind of market-access fee imposed by associations and serving no meaningful purpose.

14. Weeding out spurious drugs from the ecosystem and information dissemination on new drugs have significant pro-competitive benefits. However, these are amenable to be addressed through appropriate regulatory mechanisms. Trade associations perform many valuable functions and undertake legitimate activities, which can significantly increase the efficiency and performance of this sector. It is only when they provide a platform for competitors to collaborate and collectively create and enforce norms that have a direct impact on entry, supply, and therefore, on competition, that such conduct warrants antitrust scrutiny.

The Commission shall complement its enforcement with proactive engagement with associations across India to create awareness and prevent violation of the Competition Act, 2002.

15. In the technical session on distribution, we hope to have a holistic discussion on these issues as well as the opportunities and challenges of e-pharmacies from a competition standpoint.

16. I would like to conclude by saying that, as a regulated sector, market conditions in the pharmaceutical sector are influenced by laws and regulations that govern all aspects of the life cycle of drugs. The study has brought out some areas of interface between regulation and competition in the sector. The findings of the study, incorporating the inputs received from stakeholders at today's workshop, will form the basis for ascertaining the Commission's advocacy priorities in the pharmaceutical sector.

17. I look forward to productive discussions in the workshop today.

Thank you!