

Report

Workshop on Competition Issues in the Pharmaceutical Sector in India

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The Competition Commission of India (CCI) organised a workshop on Competition Issues in the Pharmaceutical Sector in India on 27 August 2021. The workshop was conducted as part of the ongoing market study on the pharmaceutical sector in India. The study aims to develop an in-depth understanding of factors that influence competition in the pharmaceutical sector in India. The workshop, held virtually, brought together all relevant stakeholders, including pharmaceutical companies, stockists, chemists, trade association representatives, doctors, sector experts, lawyers, and policymakers to deliberate on the focus areas of the market study from different perspectives.

The workshop comprised an inaugural session and three technical sessions. The themes of the technical Sessions were **Pharmaceutical Distribution: Trade Practices and Competition; Generic Competition in Indian Pharmaceuticals: Price & Non-Price Issues; and Competition in the Pharmaceutical Sector: Role of Regulation and Antitrust**. A summary of the deliberations at the workshop is presented below.

1. Inaugural Session

Mr. S. Ghosh Dastidar, Secretary, Competition Commission of India, opened the workshop with his welcome address.

In his welcome address, Mr. Dastidar highlighted the pivotal role of the pharmaceutical industry in improving the overall well-being of the nation. At the same time, he cautioned that markets by themselves may not deliver optimal outcomes in the pharmaceutical sector owing to the inherent

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information asymmetry between consumers and suppliers of medicines, variability of demand, and the issue of moral hazard. He stressed that any intervention in this sector has to be mindful of these inherent characteristics. Further, he added that, apart from the regulatory controls, competition has an important role in ensuring that the pharmaceutical markets work well so that consumers can benefit from better quality, lower prices, wider choice, and more innovation. Better enforcement of regulation and competition law instruments based on a clear understanding of how competition works in this sector could improve market outcomes, thereby helping strike a balance between short-term static efficiencies and the long-term gains that arise from innovation.

In his address, **Dr. K. Srinath Reddy, President, Public Health Foundation of India (PHFI)**, brought forth the core issues in the pharmaceutical sector from the consumers' perspective. Given the information asymmetry that characterises the sector, he emphasised the criticality of protecting consumers from market imperfections and the role that CCI can play in this regard. Referring to industry practices such as "camouflaged competition" between brands, marked variation in the pricing of the same drugs, etc., Dr. Reddy said that there was a great need for promoting generic competition through quality-assured unbranded generics. He further highlighted the significance of large-scale public procurement in bringing down drug costs. He further discussed how biosimilar drugs and their market expansion would be significantly beneficial.

Mr. Ashok Kumar Gupta, Chairperson, CCI, in his address, underlined the importance of well-functioning markets in the pharmaceutical sector for firms to compete on merits, innovation to thrive, and consumers to benefit from competitive market outcomes. He added that the atypical economics and distinctive features that characterise the sector can, however, attenuate competitive forces, and the ongoing CCI market study is an attempt to take a close look at the factors that influence competition. In the context of price competition in pharmaceuticals, Mr. Gupta highlighted the role that generic drugs can play in creating the competitive pressures required for

bringing down prescription drug prices, thereby reducing healthcare costs and improving access.

While discussing some of the key interim findings of the market study, Mr. Gupta mentioned that, despite the presence of several players in generic formulations, consumers in India ostensibly pay a premium for brands. On this issue of prevalence of branded generics in the pharmaceutical retail market in India, he pointed to the key role that quality expectations and a perception of variation in efficacy across drugs play in fueling brand competition and in diluting the price-reducing effect of generics in India. Besides the quality aspect, he alluded to the significant role that Janaushadhi and the emerging private generic retail chains in the country could play in increasing availability and improving the uptake of generic generics.

Speaking with reference to trade association practices in the distribution segment, such as the mandatory requirement of No Objection Certificates for the appointment of stockists and mandatory charges for Product Information Services which have been found to be in contravention of the provisions of the Competition Act, 2002 in the past, Mr. Gupta stated that the Commission would complement enforcement with proactive engagement with associations across India to create awareness and prevent violation of the Act.

Referring to the critical role that drugs play in health delivery, **Dr. Vinod K. Paul, Member, NITI Aayog**, in his keynote address, highlighted access to drugs without financial hardship and assurance on quality of drugs as the two pillars for achieving the public policy goal of universal health coverage. In view of the fact that spending on drugs accounts for 70% of out-of-pocket expenses on healthcare in India, he emphasised the importance of improving the affordability of drugs.

He pointed to the critical role that CCI plays in addressing market distortions that can affect access and appreciated the Commission's effort in conducting a market study on these aspects. On the issue of drug prices and access to drugs, Dr. Paul discussed the regulatory instrument of trade margin rationalisation implemented by the government for 42 anti-cancer

drugs in India on a pilot basis in 2019. He apprised that cost saving of Rs. 984 crores was accrued for more than 500 brands across 42 formulations on account of capping trade margins. He further mentioned specific instances where margin rationalisation led to 90% price reduction in certain drugs.

Trade margins being one of the focus areas of the ongoing CCI market study, Dr. Paul said that NITI Aayog and CCI could join efforts in this area. He added that feedback received from stakeholders during the course of the market study on the issue of trade margins and margin rationalisation would be useful. He further sought suggestions from industry participants on ways for effective expansion of Janaushadhi. To enhance the trust of prescribers and patients on pure generic drugs, he suggested the introduction of quality mark on generics in India.

Ms. Payal Malik, Adviser, CCI, delivered the vote of thanks. She thanked Dr. Vinod K. Paul for his insightful address and emphasised that the economic characteristics of the pharmaceutical market are well-known, because of which market systems do not self-organise using the forces of free markets. Hence, any system design must be mindful of these inherent characteristics of pharmaceutical markets that will also make the usual parameters of competition inconsequential. Further, drawing from the keynote, she mentioned that, in the aforementioned scenario, the challenge for regulatory architecture is how to spur price competition and also, given the public health agenda of the government in this sector, how these public policy goals could be attained. In addition to public provisioning of services and financing, she pointed out that a key role for the government and regulators is to actively shape the structure of the market using the enabling policy and regulatory levers such that the industry-government partnership could deliver affordable medicines to all.

2. Technical Session I: Pharmaceutical Distribution: Trade Practices and Competition

Technical Session I on “Antitrust Toolkit for Platform Markets” was moderated by Ms. Jyoti Jindgar Bhanot, Adviser, Competition Commission of India. Dr. Preeti Kumar, Vice President, Public Health System Support,

PHFI, opened the session. Mr. Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance; Mr. Dara Patel, Secretary General, Indian Drug Manufacturers Association; Mr. K. G. Ananthakrishnan, Director General, Organisation of Pharmaceutical Producers of India (OPPI); Mr. Rajiv Singhal, General Secretary, AIOCD; Mr. Vaijanath Jagushte, Joint Secretary, AIOCD; Mr. A. N. Mohan, President, AKCDA, Kerala; Mr. Alpesh Patel, President, FGSCDA, Gujarat; Mr. Yash Agarwal, RDCA, Delhi; Mr. Prasad Danave, Joint Secretary, MSCDA, Maharashtra; Mr. Hiren Shah, Jyot Pharma, Bhavnagar, Gujarat; Mr. Sanjay Sharma, Sharma Medicos, Gurgaon; and Mr. Prashant Tandon, CEO, 1mg were distinguished panellists in Technical Session I.

Dr. Preeti initiated the session by presenting the interim findings of the pharmaceutical market study. She stated that in pharmaceutical trade practice, market distortions can occur at every stage of the supply chain, from manufacturing to wholesale and retail trade. She averred that, in the extensive feedback obtained from different stakeholders, some mentioned the absence of mandatory requirement of No Objection Certificate from trade associations for the appointment of stockists; however, few of the interviewed stakeholders said that the practice continues in some areas of the country. Pharmaceutical trade bodies have often argued that such practices were an offshoot of government committee recommendations such as the Mashelkar Committee, which required trade bodies to act as watchdogs against the supply of sub-standard and spurious drugs. On the issue of levy of mandatory/voluntary PIS charges for launching a product in a market, she stated that it has been a bone of contention. On PIS charges, trade associations have argued against the invocation of provisions of competition law on the grounds that PIS was levied only for the benefit of pharmaceutical companies, after mutually agreeing upon with them. Trade bodies further argued that this practice is voluntary and not mandatory any longer. From the manufacturers' point of view, pharmaceutical companies often lodge complaints of defaulting application of product information, even after significant time lag post payment.

Highlighting the results from the ongoing market study, she stated that the retail margin for drugs was found to be significantly higher by 10%

percentage points over and above the regulatory cap in many instances. She pointed out the significant differences across therapeutic categories, with anti-cancer medicines attracting lesser intermediary margins. She also touched upon the impact of trade margin rationalisation applied to select oncology drugs in 2019.

On e-pharmacies, she stated that this segment was growing, and the coronavirus pandemic added further momentum to it. She highlighted that two major e-pharmacy models were observed, i.e., the marketplace model and the inventory-led hybrid model. The marketplace-based model is essentially where the online pharmacy is an aggregator that connects buyers and sellers. The inventory-led hybrid model involves end-to-end ownership, where the e-pharmacies have an ownership of the inventory in addition to having the responsibility of distribution of the medicines. She mentioned that the issues that need to be addressed in online pharmacies in India include quality and procurement/supply chain management, safeguarding personal information/data, and inter-state enforcement of operability. Online pharmacies could also be developed as an alternate channel for the expansion of generics in India, she added.

Mr. Dara Patel stated that the drug distribution system in India is quite robust, as the pharma industry has existed for more than 60 years and is still progressing. Typically, the distribution system depends on the business and the volume of manufacturer companies as well as their policy on how they want to go about distributing their products and whether they are national/regional players. Depending on the same, there are certain companies who have super-stockists, C&F agents, stockists, and retailers. Some companies also carry out direct selling to hospitals. As far as the regulatory system is concerned, there are checks and balances, especially on trade margins. By and large, the margins are controlled such that it is either 8% and 16% or 10% and 20% for wholesalers/stockists and retailers, respectively, based on price controlled and decontrolled products. If there are super-stockists, they are given a margin of 4–5%, and if there are C&F agents, their margin is 1–1.5% and even 2%. He opined that there is no need for a radical change in the pharmaceutical market, though some checks and balances can facilitate and control the system.

The distribution of medicines has a wide outreach, and due credit is to be given to manufacturers and their distributors and retailers.

Mr. Rajiv Singhal elaborated on the history of formation of pharma trade associations from small villages and districts to that of a pyramid structure, with presence at the national level, such as AIOCD. The reason for the formation of AIOCD, he explained, was the need for a platform to express as well as address the individual trader's concerns. Presently, he said that AIOCD has presence in all 29 states and seven UTs, with a presence in almost all districts and covering 9.4 lakh chemists and pharmacists as its members. He further spoke about how, even though margins are defined on account of huge competition, actual earning of association members is only 2-3%, which can be verified anywhere in the country. He stated that although they have not been declared COVID-19 warriors, they are the "jan-swasthya rakshak," given that they provide services to humanity at large.

Mr. Vaijanath Jagushte stated that chemists and druggists are caretakers of the public at large, especially those who are underprivileged, and every effort is made with the aim of being "pro-public." He mentioned that the pharmaceutical sector is already well regulated and people working therein have to act in compliance with various laws such as the Pharmacy Act, Drugs and Cosmetics Act (DCA), etc. Unless there is full compliance with laws, one cannot enter the drug business. He emphasised that functioning of associations became vital in light of certain issues such as drug quality, expired drugs, safety, proper transport, disposal, etc. It emerged as a platform for small/individual chemists for their grievances. Further, in case of any conflict within the industry, he stated that, upon discussion, solutions have been arrived at amicably.

He added that the primary role of trade associations is to maintain stock in the supply chain in anticipation of demand. Unless demand is anticipated, stock cannot be made available when it is required. He pointed out the peculiar nature of the product, i.e., medicines, that once they get expired after their shelf-life, they cannot be disposed of. Rather, as per the law, all these expired drugs are to be sent back to the manufacturer. The associations see how to maintain the flow of the supply of drugs at every

nook and corner of India. He further added that a pharmacist, unlike a doctor, cannot charge a professional fee from the consumer, given there is no legal provision for the same. However, a pharmacist continues to be the first contact who comes in touch with the consumer and has to be rightly protected. Thus, the remuneration of the pharmacist is included in the margin of the drugs. On the issue of trade margins, he mentioned that hundreds of retailers in the country only get a 5-6% margin as their take-home, while the corresponding percentage for stockists is 2-3% in a month. Thus, the need, according to him, is to find out where the captive market and captive consumption are and where high margins prevail.

With regard to the emergence of online pharmacies, Mr. Jagushte stated that there are four forums where trade associations can appeal: the court, the central government, the Food and Drug Administration (FDA), and CCI. So, on behalf of AIOCD and other trade bodies, they made an appeal to three out of four bodies (except CCI), who deemed e-pharmacies as illegal. He stressed that there should be a level playing field for retail pharmacies and epharmacies.

Mr. Sudharshan Jain stated that the pharmaceutical industry in India has made a big leap from the time of independence, when it was non-existent, to now being the pharmacy of the world. He mentioned that, as an association, IPA focuses on the quality, innovation, and affordability of drugs. Their overall consensus is to provide services to the patient. On the issue of PIS, he pointed out that the practice is no longer prevalent; instead, it is up to individual companies where they want to use the service to supply the information.

Mr. Jain categorically pointed out that Indian drug prices are the lowest in the world and took pride in how the supply of medicines was made at the right price without any impact on quality. However, he cautioned against focusing too much on prices, given that prices affect quality. On the issue of trade margins, he seconded Mr. Vaijanath on the assertion that wholesalers get only 2-3% margins as their take-home. There are about 10,000 formulations and the return is very low. He stated that, concerning trade margin rationalisation, due consideration should be given to the supplies made to the government, given the same should be excluded

while calculating the margin. He suggested that a similar pilot can be conducted for the analgesics market to see if trade margin rationalisation is required in this segment, given anti-cancer segment is distinct compared to analgesics, which is catered to by to around 600,000–700,000 chemists.

On the issue of emergence of e-pharmacies and safety concerns that have arisen, Mr. Jain said that three parameters are crucial in this regard. Firstly, the prescription should be legitimate and there should not be any substitution permission for such prescriptions. Secondly, the privacy of the prescription is paramount, thus, no prescription should be monetised to other companies, and the same requires clear guidelines. Thirdly, there must be clearly laid down rules when it comes to discounting structures and predatory pricing. Everyone is pro-patient, and it is to be ensured that, while using technology to service the patient, one takes care of typical distinctive healthcare issues centred around patients and their privacy.

Mr. A. N. Mohan stated that the various cases before the Commission only concern lapses of implementation of MoUs. He cited one of the initial cases, where a distributorship was terminated on account of some internal feud for which a remedy was devised by a court of law. There are plenty of judgements by various high courts, including the Kerala High Court, wherein it is categorically said that the appointment of stockists is done on manufacturers' wisdom. He concluded by stating that it is not that AIOCD or industry associations are cartelising themselves or monopolising trade for their benefit, or depriving the consumer of their legitimate rights. Rather, the trade associations believe that healthy competition will definitely help all the stakeholders and consumers, but there has to be a level playing field. Lastly, it is constitutional obligation on the part of the government as well as AIOCD to ensure that small chemists also survive in the coming days, as they are the ones instrumental to making the pharma industry a global one.

Mr. Prasad Danave presented the retail side of the scenario. He said that retailers today were the health custodians of the country. On the issue of NOC/LOC, Mr. Danave opined that it is the company that chooses who to give the distributorship to, and the company rightly does so because medicine is not a commodity that can be dispensed in any manner. He

added that due regard must be given to instances where the product has to be transported in a regulated temperature. If a distributor transports drugs but does not take care of such things, then reluctance will exist in any dealings with such distributors.

Mr. Alpesh Patel stated that an association exists to protect the interests of its members, in compliance of laws. He described that the role of AIOCD at the national and state level is to educate its members in respect of various laws such as DCA, Pharmacy Act, DPCO, taxation law, and the Competition Act to ensure compliance. He remarked that, from the distribution perspective, pharmaceutical distribution is a third-party generated business and the company is engaged in marketing through its field staff who, in turn, updates pharmacies and doctors. On the issue of NOC/LOC, he commented that there is no direct role in the appointment of stockists, as the appointment is the prerogative of the company. He raised concerns that to fulfil a company's sales targets, the field staff appoints the stockists, but sales can only be made once demand is generated. In order to address low sales, or slow-moving products which end up getting expired, amounting to a national loss, a policy should be defined for efficient working of such supply chain. He further highlighted concerns in respect to the use of authorised channels in order to avoid any drug-quality issues. In conclusion, he stated that competition has been beneficial for the entire sector, trade associations always act for the benefit of the public, and the pharmaceutical industry as a whole strives to ensure that good quality medicines are available at competitive rates.

Mr. Hiren Shah stated that chain pharmacies purchase directly from company depots/super-stockists, which gives them an edge, and they get good margins, creating problems for proper functioning of the supply chain. Secondly, he suggested that CCI must act against hospitals that are adamant about patients purchasing medicines from the respective hospital's own pharmacy. Further, in respect of pricing/margins, rather than having high MRPs and more discounts, efforts should be made to supply low MRP generics. He concluded by saying that the online pharmacy itself holds a huge opportunity which can benefit patients and other stakeholders, but rather than burning their cash, they should focus on exploring the market instead of exploiting the same.

Mr. Sanjay Sharma spoke about competition in the market and pointed out the difference in margins available to online and offline pharmacies. He further stated that there is no issue of NOC in his area (Haryana). NOC is given to all companies, he added. He remarked on digital start-ups that are utilising their funding to provide discounts and allegedly harming the offline pharmacy business.

Mr. K. G. Ananthakrishnan highlighted that an association does not in any way get into any of the commercial activities of a pharmaceutical company. He reiterated that if a pharmaceutical company wants to appoint a distributor/stockist, it is the prerogative of the respective company to evaluate the same and do the needful. Accordingly, the question of giving any direction on NOC/LOC does not arise at all. On the issue of the PIS system, he spelled out that, since it is a voluntary service, some members opt for the service because they find it to be advantageous on account of its outreach of 400,000–600,000 pharmacies. He went on to discuss his take on trade margin rationalisation and how the methodology of its implementation is not in line with the good intention behind it. He concluded by saying that discussions are ongoing with the Department of Pharmaceuticals and NPPA to look at it in a proper fashion and focus on a patient-centric approach, access, and affordability, as the trade margin rationalisation currently in place is not in line with the primary objective of access.

Mr. Prashant Tandon stated that the cost structure of the trade is high. Trade margins are needed to operate, invest in quality, make sure that pharmacists are available, and for proper inventory management. He averred that e-pharmacies arrange supplies in order to fulfil the customer's need, as there was a need for home-based delivery of medication. As the segment is still in its infancy, there are new players/models coming into the market, which means a significant shift is underway. He went on to elaborate on the various laws under which e-pharmacies operate, such as the IT Act (which covers digital platforms) and DCA (which covers the pharmaceutical aspect) until e-commerce policy comes into place. He assured that e-pharmacies are fully compliant in their functioning. He felt that e-pharmacies need to be compliant, and it is in their own interest

that they follow the law of the land. However, the e-pharmacy model is not yet fully regulated, and thus, it will be a welcome move if they are indeed fully regulated. The distinction is not between online and offline, it is with respect to compliance versus non-compliance. He reiterated that all the companies are operating within the realms of the law, and any issue/violation can easily be investigated.

He concluded by stating that e-commerce guidelines themselves are dealing with various issues/concerns, as the industry itself is in its infancy. The approach to such recognised issues has to be constructive to figure out the path forward, and not merely making tirades and propaganda, which is not helpful. Any synergies between online and offline will ultimately benefit the customers in terms of price and quality.

With regard to checks and balances from an antitrust perspective, he stated that, as per the law of the land, no substitution is allowed, either online or offline. With respect to privacy, it is in the interest of platforms, including offline pharmacies and anyone who is dealing with patient data, to carefully monitor the same. Consumers will not trust platforms that do not take care of their privacy. The issue of predatory pricing is an ongoing discussion. Free market, free competition, and best service to the patient has to be at the forefront.

Mr. Yash Agarwal stated that e-pharmacies are illegal and there are no provisions under which they are covered. He went on to comment that e-pharmacies do not follow a single rule. While they talk about how this system is successful in the West, they have not been able to capture the ethos that exists in the West. Further, an e-prescription is not clearly defined and there is no provision for it.

He further pointed out that e-pharmacies only ask for a picture of the prescription, which leaves a lot of scope for misuse and drug abuse in this context. He raised caution, as e-pharmacies are allegedly providing discounts and burning cash, which might lead to a retail apocalypse as has already happened in the USA. He also raised concerns with the e-pharmacy space witnessing vertical/horizontal integration. Companies that are integrated will have all the data about the patient. They will thus

have access to doctors, prescribed medicines, pathological and diagnostic tests conducted, and the results.

3. Technical Session II: Generic Competition in Indian Pharmaceuticals: Price and Non-Price Issues

Technical Session II on “Generic Competition in Indian Pharmaceuticals: Price and Non-Price Issues” was moderated by Ms. Payal Malik, Adviser, Competition Commission of India. Dr. Sakthivel Selvaraj, Director, Health Economics, Financing and Policy, PHFI, opened the session. The session had a distinguished panel that included Dr. Ashok Vaid, Oncologist, Medanta Hospital; Dr. Y. K. Gupta, Former Head, Department of Pharmacology, AIIMS; Mr. S. Srinivasan, Founder and Managing Trustee, LOCOST; Mr. Dharmil Seth, Co-founder, PharmEasy; Mr. Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance; Dr. Amit Rangnekar, Chairman, Pricing Committee, IDMA; Ms. Malini Aisola, Co-convenor, All India Drug Action Network (AIDAN); Mr. Ketan Zota, Chairman, Zota Healthcare (Dava India); and Mr. Vaijanath Jagushte, Joint Secretary, AIOCD.

Dr. Sakthivel Selvaraj initiated the session by sharing the interim findings of the market study on the pharmaceutical sector in India with respect to branded generic drugs and their implications for competition. He stated that these findings are based on a range of data sources such as the government procurement database (of various states), retail market sales database, and other regulatory databases (relating to drug quality). He pointed out that perfect competition is seldom achieved in the pharmaceutical sector, where information asymmetry predominates. This allows supplier-induced demand to operate resulting from prescribers acting as the agents of patients and prescribing on their behalf. Producers, in turn, direct their attention to prescribers through heavy marketing strategies, thus influencing prescription practices and restricting choice. As pharmaceutical companies try to retain and create a niche market, they indulge in both vertical and horizontal product differentiation, rendering

price competition a rare occurrence. He said that the uniqueness of the pharmaceutical industry lies in its product differentiation. While drug prices may be determined by the number of players, it is largely influenced by product differentiation. Vertical product differentiation arises from utilising brand promotion. The mean number of brands per formulation is an indicator of brand proliferation, and there are about 17 brands per molecule (although it hides in stark variation within each formulation). There are instances where multiple brands are supplied by a single company, with similar dosage and strength. He further stated that firms also indulge in horizontal product differentiation by tweaking dosage and frequency, or by combining two or more drugs. During the last decade, he pointed out that almost half of the Indian retail market is composed of fixed-dose combination drugs. He then shed light on whether there is price competition in the pharmaceutical industry in the Indian context. Despite brand proliferation, consumers ostensibly pay a premium on brands. He also indicated that the price of retail drugs is usually 25% more than the procurement price.

Dr. Ashok Vaid commenced the discussion by highlighting the diverse backgrounds and affordability for patients. Being a doctor, he believes that doctors face patients from diverse backgrounds. However, the quality and affordability for all patients is not the same. According to him, only 10% of India's population can completely afford the cost of treatment and drugs recommended by doctors. Dr. Vaid was in favour of generic drugs as they are cost-effective, but at the same time, he believes that doctors will collectively be able to recommend them to patients only if it goes through the rigorous evaluation process. A benchmark should be set for all generic drugs. Every generic drug should pass this evaluation test before it can be recommended to patients. An entry barrier should be set in the market which should be the same for everyone.

The cost of research always exists, but someone needs to pay for it. Every country has its procedures and models for research work and how they treat their patients. The biggest challenge, Dr. Vaid believes, is with regard to bio-equivalence, as per which anything from 80–125% is an acceptable limit for treatment. He cited a finding according to which

bio-equivalence and bio-effectiveness may not be the same every time. He concluded by saying that generic drugs are not bad and no doctor would object to recommending it to patients if there is a quality barrier or a barrier to entry and if the quality can somehow be reflected on the carton of the medicine or injections.

Dr. Y. K. Gupta was of the belief that, at the academic level, everyone knows drugs by their generic name and do not talk about the brand name. But once they enter the industry, they tend to forget the generic name and its composition and talk only about brand names. He pointed out that even reputed doctors believe that expensive brands indicate better quality. A generic drug, despite its low price, does not necessarily mean it will be of a lower quality. Similarly, the high price of branded drugs may not indicate good quality.

Dr. Gupta opined that the important part is as to what is actually acceptable and not acceptable under good manufacturing practices (GMP). A doctor can recommend a generic drug to a patient; however, when it comes to the interest of the patients, a doctor would always like to recommend what is best for the patient. He was of the view that one cannot say that a generic drug is of poor quality based on small size sampling, then generalising it for the entire economy. The sample methodology has to be perfect and statistically valid. The restrictive sampling might give false results about the efficiency and quality of a generic drug. According to him, the government of India is also working towards the promotion of generic drugs, as the basic philosophy in India is to provide quality and affordable drugs to everyone in need. Consumers will gain confidence in initiatives undertaken by the government such as Janaushadhi only if the government puts colossal efforts into the quality control of the drugs. The more the efforts by the government towards quality control, the more assurance and faith users will have in generic drugs.

Mr. S. Srinivasan was of the view that there is an Indian pharmacopeia¹ that briefs us about the instructions that one needs to carry out and about the

¹A pharmacopoeia is a book containing directions for the identification of compound medicines and published by the authority of a government or a medical or pharmaceutical society.

limits. Every manufacturer needs to follow the same and only then should a drug be marketed. However, there exist black sheep in the pharmaceutical industry, although in a much lesser proportion compared to before, but their existence cannot be neglected. At the same time, doctors need to familiarise themselves with the politics of drugs and do more research instead of making decisions based on what they believe. He pointed out a finding from an Indian biological report wherein the maximum samples were taken from one company, Pfizer, and 15 of their products were sub-standard. According to him, it is not easy to generalise the results from a single data point. A more detailed study is always required to generalise sample results.

He further added that brands distort the market as they are being promoted by big companies. He cited an example wherein, if a consumer approaches a pharmacist asking for a brand suggested by a doctor and the pharmacist hands over a generic drug, the transaction will be considered illegal, as a pharmacist cannot hand over a generic drug when a brand is prescribed by a doctor. There exists a huge difference between the prices of branded and unbranded drugs. The quality of a drug also depends on the honesty and ethics of its manufacturer, as any negative news about a drug spreads faster than positive news. The rush to harmonise the regulatory requirements in India with the world can sometimes become a barrier for manufacturers and young entrepreneurs; therefore, it needs to be thought through. He also stated that pricing regulation is confined to 15–18% of the domestic pharmaceutical market.

Mr. Dharmil Seth stated that PharmEasy caters to the demands of over 2 million customers in a month. He considers trust to be an important factor for a customer in an asymmetric market. Customers usually rely on doctors for any kind of recommendation, so doctors need to live up to that standard of honesty. The other things that influence a customer while deciding on a drug are the research conducted by him/her at his level (i.e., the research a customer conducts to know the molecules, supply chain, market/store for best drugs) and retailers' insights. Sometimes, instead of approaching doctors, customers seek the retailer's advice and consume the medicine recommended by them. Standardisation should start right

from the manufacturing of drugs. He also said that we cannot have an economy where 25% of the medicines are fake/forged, patients do not have trust in the supply chain, and people that are part of the supply chain are not aware of the product. There should be a checklist that everyone has to go through to ensure strong and effective standardisation. He also shaped the conversation by bringing in the digitisation aspect as to how the digitisation of the supply chain, where all inputs and outputs are managed on a common platform, can help us detect if a product is genuine or not or if there is any leakage in the system. In this regard, he cited a report on how the future supply chain will look and will be able to track 100% supply. He also cited examples of companies which have connected distributors digitally. All the supplies by these distributors are tokenised, which can help avoid leakage and guarantee the legitimacy of a medicine. He believes that the government is surely working towards the quality side but should frame some guidelines to enable customers to make a better and informed decision in this asymmetric market. There should be standard operating procedures (SOPs), high entry barriers, and enough trust in the market.

On being asked about the discounts that e-pharmacies offer, he stated that his company is not the highest discount provider. He considered his company to be more of a tech-enabled company that provides a platform to small medicine shops which, in turn, provides better services and price benefits to the customers. The company does not work towards capital dumping; rather, it tries to generate efficiency in the market.

Mr. Sudershan Jain stated that he considers doctors to be supreme and fundamental to healthcare management, as they know what is best for patients. He shared a few concerns on e-pharmacies. The first is the substitution of prescribed medicines. The emerging technology platforms have a propensity to substitute prescribed medicines with generic substitutes for commercial reasons, he said. These technology platforms are funded by private equity, whose sole purpose is to make profits. Whenever medicine is substituted by these platforms, they provide something that was not intended by the treating physician. The substituted products tend to be of inferior efficacy or quality than those offered by the

leading companies. For reasons of patient safety, tolerability, efficacy, and compliance, it is mandatory in the case of some medicines to ensure that no medicine substitution of any kind takes place. The governing document in the context of prescribing all forms of medicines, the Drug and Cosmetics Act 1945 and rules as amended, does not provide for generic or therapeutic substitution.

Secondly, he opined that e-pharmacy should not engage in tele-medicines. On several occasions, when a patient places an online order but does not have a valid prescription, the patient is supported by epharmacies through e-consulting to generate a fresh prescription without physical verification or without abiding by tele-consulting related government guidelines. This is undertaken by e-pharmacies to encourage the sale of high-margin medicines, which can lead to putting the patient's well-being at risk. Thirdly, the epharmacy, while recommending a medicine, does not take into consideration the medical history of a patient. Doctors may prescribe medicines which do not holistically meet the medical requirements of a patient. Fourth, health-related information and medical record reveal some of the most intimate aspects of an individual's life. This data is important because health information can influence decisions about an individual's access to credit, admission to educational institutions, and his/her ability to secure employment and obtain insurance. Fifth, e-pharmacy platforms operate in an environment of no clear regulation or light-touch regulation that applies to their business. It is therefore suggested that discount regulations should be in place to regulate offers and discounts by epharmacy so that the rights and interests of local chemists can also be preserved. This, according to him, will ensure fair competition in the market by avoiding predatory pricing. Lastly, existing Indian laws do not adequately address concerns relating to privacy and patient health information. It is imperative to keep a check on illegal pharmacies online. A campaign is required in India to create awareness.

According to Mr. Jain, privacy concerns and substitution of prescriptions is fundamental from the patient's perspective. Therefore, it is important to develop a robust regulatory framework governing emerging technologies of e-pharmacy that will prevent the risks/concerns related to patients

and ensure access to safe and effective medicines. The need of the hour according to him is to improve the quality of drugs. The quality should be made homogenous and should be strengthened. A strong regulatory system should also be in place to keep a check on quality.

Dr. Amit Rangnekar initiated the conversation by first comparing the retail market of the USA with that of India. India has a USD 21 billion market while the USA has a USD 480 billion medical prescription retail market. The number of retail pharmacy players in the US market is only three, which account for more than 90% market share, while India has about 1,800 C&F agents, 54,000 stockists, and 8 lakh retailers. India, thus, has a fragmented market where consolidation is inevitable. He then talked about two currently prevailing business models, i.e., the prescription manufacturer model and the generic manufacturer model. Under the prescription manufacturer model, one method is where the manufacturer may sell through his own stockist network (which further includes the retailer model, where drugs are sold at MRP/discount, modern trade pharmacy model, where drugs are sold at a discount on MRP, and e-pharmacy model, where drugs are again sold at a discount on MRP. The second method is where the prescription manufacturer may sell drugs through a generic stockist which go to a retailer who provides deep discount on MRP. The third method is the Janaushadhi model, where the retailer negotiates with the companies on drug prices and there is a deep discount on the MRP. The generic manufacturer model, on the other hand, includes generic retailers or online pharmacies, which reach patients directly and give steep discounts on MRP, ranging from 50-90%.

Based on trade interviews conducted with different companies and associations, Mr. Amit shared the pharmacy sales and reach for the market in India, whose total value is about INR 1,50,000 crore, of which 80% is pure trade pharmacies, with 8 lakh pharmacies and having a value of INR 1,22,000 crore; 12% is trade generics with 8 lakh pharmacies, 18,000 generic pharmacies, and having a value of INR 18,000 crore; 5% is the modern trade pharmacy comprising organised retail chains such as Apollo, Wellness Pharmacy, etc., with 10,000 pharmacies and having a value of INR 7,000 crore; and 3% is e-pharmacies, with about 45 players and having a value of

INR 3,000 crore. He further elaborated that, in the 1980s, drugs constituted 90% of the sales for retail chemists; however, the corresponding figure in 2020 is 60%. Out of this 60%, 48% are pure prescriptions, whereas 12% are substitution/replacement largely governed through bonus offers or generic margins.

Based on industry and trade interviews conducted with IMS executives and AWACS data, Mr. Amit looked at the contribution from the top 100 cities. The top 100 cities have a business of about 3 lakh pharmacies, which is about 37.5% of all pharmacies. They carry out a business with a value of about INR 90,000 crore. Annually, they do a business of INR 30 lakh per pharmacy. The share of general trade is very high but there is competition from modern trade and epharmacy. Generics are slowly gaining strength. The impact of generics in the top 100 cities is 15% by volume and 5% in value. On the other hand, in 6.5 lakh villages and hamlets, there are about 2.5 lakh pharmacies with an annual business value of INR 10.2 lakh per pharmacy. Generics are dominant here and the margins for generics are high. The impact of generics in the 6.5 lakh villages and hamlets is 90% by volume and 50% by value. Further, according to him, private labels and medical insurance are game changers in this industry. Private labels are preferred due to lower costs, retailer reputation, and service, and the existence of private labels is inevitable in modern trade.

Ms. Malini Aisola laid out areas in policy and practices in the industry that impact affordability and access for customers and patients. She was of the view that despite such a vibrant market, the Indian pharmaceutical industry does not price competitively. When it comes to generic generics, there are broadly two issues — firstly, it has a relatively lower market value and volume, and secondly, the perception that generic medicines of unknown brands are of poor quality due to them being manufactured by small units which are not expected to follow rigorous processes and standards in manufacturing. The attempts for affordable medicines under government stores are nowhere close to meeting the demand, because of which India has free medicine schemes. The most palpable solution to this is the adoption and authorised operationalisation of public procurement schemes under state governments. She pointed out the government's lack

of interest towards quality checks and providing affordable medicines. She indicated that the quality issue not only pertains to small manufacturers or unknown brands, and even big companies that are exporting products go through multiple recalls, abandoning the product in foreign markets. However, there have been no recalls in India. She questioned if this is because of the lack of a regulatory framework in Indian companies. Ms. Aisola was of the view that there should be proactive enforcement of regulations. She considered contract manufacturing to be extensive in India, which should be scrutinised. The regulatory vacuum creates an anti-competitive market. She quoted an example to reflect that a poorly designed regulatory framework can sometimes lead to high prices and legitimise profit earning.

Mr. Ketan Zota was of the view that doctors should always write the generic name with the brand name in their prescriptions. He said his company charges a fixed price for generic medicines and no discounts are provided as the prices are low. The biggest problem a generic pharmacist faces is that their margin is between 15–20%, which does not take into consideration the increase in the capital cost, while the other retailers can survive because they deal in branded (generic) drugs. The margins for distributors also have been 9% for a long time, which ignores the increase in their manpower cost, transportation cost, and other factors. The gap between cost and MRP is increasing and needs to be streamlined so that there is a fixed margin for everyone. MRP should be the same for all the molecules after considering the active pharmaceutical ingredient (API).

Mr. Vaijanath Jagushte considered generic drugs as costeffective. He initiated the discussion by posing a few questions. One, if someone comes to a chemist asking to substitute branded with generic drug, they cannot substitute it as it is against the DCA and is not safe while few market players are still doing it. Two, if a person who can sell medicine at INR 30 even when the MRP is INR 100, then why can the capability of selling it at INR 30 not be mentioned on the medicine. Thirdly, generic generics are supplied by the government at a cheaper rate, but it is questionable whether a retailer can get those products and sell. By providing discounts, companies think they are eliminating competition and driving generic

drug manufacturers out of the market. However, it is to be noted that elimination of competition is a dangerous phenomenon.

4. Technical Session III: Competition in the Pharmaceutical Sector: Role of Regulation and Antitrust

Technical Session III on “Competition in the Pharmaceutical Sector: Role of Regulation and Antitrust” was moderated by Ms. Rema Nagarajan, Journalist, Times of India. Mr. A. K. Pradhan, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO); Ms. Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority (NPPA); Mr. R. Poornalingam, Former Secretary, Ministry of Disinvestment, Government of India, and Former Health Secretary, Government of Tamil Nadu; Dr. Sharmila Mary Joseph, Secretary, Taxes Department, Government of Kerala; Dr. Naresh Trehan, Chairman and Managing Director, Medanta–The Medicity; Dr. Narendra Gupta, Advisor, PRAYAS, Chittorgarh, Rajasthan; Dr. Ajay Bhaskarabhatla, Associate Professor, Erasmus School of Economics, Erasmus University, Rotterdam, Netherlands, and Mr. Ramji Srinivasan, Senior Advocate, Supreme Court of India were distinguished panellists of the Technical Session III.

Dr. Ajay Bhaskarabhatla pointed out that there are two key aspects to be considered while assessing competition in the pharmaceutical industry in India, namely market power and buyer power. Market power concerns pharmaceutical firms while buyer power relates to retailers. He elaborated that market power is the ability of a firm to raise and maintain prices above the level that would prevail under competition. On the other hand, buyer power is concerned with how retailers can affect the terms of trade with upstream firms. He stated that there are hundreds of pharmaceutical manufacturers (suppliers) and more than 9 lakh medicine stores (retailers), thus creating a false impression that a high level of competition is prevalent in the pharmaceutical sector. In this light, he cautioned that both market power and buyer power remain critical issues for CCI. He further added that, while excessive market power and buyer power are both detrimental

to competition, the combination of the two could be even more damaging to competition.

He averred that there are several aspects of price ceiling regulation (Drug Price Control Order (DPCO), 2013) that firms with market power tend to exploit. One is the feature of “incomplete regulation,” wherein some dosage and bundles are regulated but others are not, leading firms to shift demand away from regulated to unregulated dosages and bundles. Second is the feature of “market-based ceiling determination,” wherein prices of brands with more than 1% market share are used to determine the ceiling price, and evidence shows that firms coordinated to inflate the ceiling price. Third is the feature related to issues of “noncompliance,” wherein the cost of non-compliance is low, and enforcement limited, and thus, there is significant non-compliance. The aforementioned three aspects combined with litigation have been used to limit the effectiveness of regulation. At the same time, he added that buyer power has been very active, so DPCO has lower margins for regulated medicines than margins for unregulated medicines. When medicines entered regulation, it stimulated buyer power, such that retailers organised boycotts unless margins remained higher. Buyer power limits competition among retailers and limits entry by pharmaceutical firms. He further acknowledged that, while CCI’s antitrust efforts have highlighted buyer power, it continues to persist today.

Dr. Bhaskarabhatla went on to elaborate on the use of “confidential volume discounts” to illustrate how market power and buyer power “combine” in India. Retailers receive discounts from the manufacturers; however, there is no record of the same. This is market power trying to incentivise buyer power to sell more. Consumers are not aware of the quantum of discounts that retailers get, hence, the term “confidential volume” discounts has been used. In his paper, “Competition, Buyer Power, and Retailer Volume Discounts,” he has examined how competition among suppliers affects volume discounts to retailers in a context featuring significant countervailing buyer power. Using product-level data on wholesale and retail prices, quantity sales, and confidential volume discounts given by pharmaceutical firms to retailers in different regions

in India, it is found that supplier competition increases retailer volume discounts. But the benefits of such discounts are not passed through to the consumers. Furthermore, he finds that confidential volume discounts limited the effectiveness of the 2013 price ceiling regulation on essential medicines in India by raising the price ceiling. He thus stated that when retailers have countervailing power, supplier competition may not be sufficient to lower consumer prices.

Through an example, he explained that more competition among pharmaceutical firms (without reforming the trade practices prevailing in the market) simply increases retailer margins, and discounts do not pass through to consumers, particularly so after the regulation. He further added to the discussion by pointing out that it would be naïve to think that the 9 lakh retailers operating across India do not earn enough margins and that it is a livelihood issue. Rather, the data suggests that despite the presence of 9 lakh retailers in India, retailers have managed to work as a single buyer, referred to as a “monopsony” in economics. He added that this single organisation, i.e., AIOCD has tremendous buyer power. Terming the prevalent pricing practices in the pharmaceutical industry as being harmless or inconspicuous would therefore be akin to missing the point, he cautioned. He stated that the reason why everyone is able to agree on a price and maintain it, in other words, able to collude, is that there are institutions from the central level down to the district level, who, without these kinds of instruments (No Objection Certificate (NOC), product information service (PIS), boycotts, or threat of boycotts) help sustain the system prevalent today. The pharmaceutical firms are worried about the buyer power that AIOCD has. Thus, pharmaceutical firms have to work with the AIOCD to adjust their MRP and price-to-retailer (PTR). The point is that AIOCD buyer power remains. Pharmaceutical firms have nowhere to go, and they have to work with the only distribution mechanism available; thus, these firms will ensure the highest of margins.

Mr. A. K. Pradhan stated that regulation of drugs (in terms of prices, intellectual property rights, safety, and efficacy) is directly or indirectly linked to competition in the pharmaceutical market. So far as the regulation of drug safety and quality is concerned, the manufacture/

sale/distribution of drugs is regulated in India under the provisions of the Drugs and Cosmetics Act (DCA), 1940, and the rules thereunder. He elaborated that there are two rules – one relating to drug rules, 1945, and the other set of rules relating to the regulation of new drugs and clinical trials, published in 2019. He further highlighted that the basic objective of the DCA (1940) is to ensure the safety, quality, and efficacy of drugs. However, while regulating the manufacture/sale/distribution of drugs and giving marketing approval/market authorisation, there may be some impact on competition. The manufacturer takes the licence from the state licensing authority for manufacture of any drugs. However, in case of any new drug, they are required to take permission from the office of the Drug Controller General of India (DCGI), and based on the same, they can take a licence from the state. In the DCA (1940), there is no specific definition of branded or generic generics. In response to a question on the mechanism for doctors to complain about drugs (generics) that do not work, Mr. Pradhan mentioned that a doctor may approach any state licensing authority to report an ineffective drug or approach the DCGI office, as DCGI has a system of coordination with the states.

Ms. Vinod Kotwal stated that any regulatory authority functions within the regulatory framework under which it has been constituted. DPCO 2013 or earlier DPCOs were notified under Section 3 of the Essential Commodities Act, she averred. Apart from the same, there exists the National Pharmaceutical Pricing Policy 2012, which gives the broad policy framework to be followed for the pricing of drugs. This policy essentially has three principles related to essentiality, i.e., drugs which are essential. Second is formulation-based, which is a departure from DPCO 1995. Thirdly, there is the market-based method, where the ceiling price is essentially calculated based on marketplace data, where the average PTR is considered for pricing for companies having market share of more than 1%. The first mandate of NPPA is to implement and enforce the provisions of DPCO and simultaneously monitor the availability of drugs and identify shortages (if any and deal with all legal matters which may arise because of the decisions it takes. NPPA fixes the ceiling prices for the drugs in Schedule 1 of DPCO, which are part of the National List of Essential

Medicines (NLEM). The second mandate is the retail price fixation, which is applicable to new drugs applications submitted by companies, and these applications are submitted by any existing manufacturer who is trying to make a new drug in combination with the drug in NLEM. NPPA also gives ceiling prices exercising powers under Para 19, which are extraordinary powers vested with the authority to be taken in public interest. Recently, NPPA exercised its extraordinary powers for trade margin rationalisation. The first pilot was undertaken for 42 anti-cancer drugs in February 2019. Further, these powers have been used to fix the prices of oxygen concentrators via the notification dated 3 June 2021. She pointed out that the drugs, which are under ceiling prices of fixation are around 18-19% of the total universe, whereas the rest are non-scheduled drugs for which NPPA only does the monitoring under Para 20 of DPCO.

Dr. Naresh Trehan expressed his concerns regarding the issue of generic generics that do not work, thus causing a delay in the patient's treatment. He mentioned that there should be a mechanism (in the form of a preventive market survey) to see the quality of drugs that are circulated in different pharmacies or different states, i.e., to check the presence of spurious/ineffective drugs in the market. He cautioned that if a drug licence is granted for four years and, in the meantime, the drug quality drops (for unknown reasons such as price differentials, poor quality of APIs, etc.), then there needs to be a mechanism to prevent the patient from being victimised by early detection of spurious drugs. He highlighted that some surveys point to a significant presence of spurious drugs in the marketplace. He attributed the aforementioned concerns as to why doctors veer towards branded generics or expensive drugs instead of generic generics. Another concern that Dr. Trehan pointed out relates to the delay in access to drugs which are discovered elsewhere (in other countries). He averred that the regulatory mechanism of trials seems to be unattractive to multinational companies, and this problem may also be addressed.

Mr. R. Poornalingam spoke on the topic of "bulk procurement," which is carried out by the Tamil Nadu Medical Services Corporation (TNMSC). He stated that the goal of TNMSC was premised on the idea of setting up a system where quality drugs are ensured for the common man (who accesses

the public health system) at an affordable cost. He regarded TNMSC as being a supply-driven system, where only those drugs are procured that have been prescribed by doctors in Tamil Nadu. Thus, shortage of drugs and excessive purchase of drugs (thus leading to wastage) were prevented by TNMSC by ordering based on real consumption. TNMSC, set up in 1995, was able to address the issue of ensuring quality drugs (generic generics) as it did not rely solely on the good manufacturing practices (GMP) certification issued by the drug controller and rather, undertook a rigorous quality check on its own. As a result, TNMSC was able to supply cheaper drugs despite the upgradation of drug quality. He highlighted that the average per capita out-of-pocket expenditure on drugs is INR 2500 in public facilities in India, which stands in stark contrast with Tamil Nadu's average of INR 110, as per the NSSO 2015 survey. Further, he pointed out that generics supplied by government corporations (like TNMSC) have credibility and demand (due to rigorous quality checks ensured by the government) compared to generics supplied in regular retail shops (where poor-quality control implementation for generics may be done).

Dr. Sharmila Mary Joseph stated that pharmaceutical pricing falls under the domain of NPPA, and pricing of drugs is regulated by DPCO, 2013, which is currently in vogue. This order draws its powers from the Essential Commodities Act, which underscores the point that affordability of medicines is essential. Further, she added that the price control order of 2013 is based on the principles of market-based pricing. DPCO caters to only a small section of the medicines which are in use in the country because it caters only to prices which are included in the NLEM. This implies that hardly 20% of the medicines fall under price control. For the remaining medicines, i.e., unscheduled medicines which are not in the NLEM, the prices are not controlled or not determined by NPPA. However, NPPA does exercise some regulation in the sense that the prices of the unscheduled medicines should not exceed 10% of the prices of the previous year. This is monitored by NPPA through the offices of the drug control departments of different states. Further, the pharmaceutical pricing authority has devised a software/database (the integrated pharma data management software) through which the data regarding the prices of

both scheduled and non-scheduled medicines are being monitored by the authority. She further added that most of the pharmaceutical companies have, by now, registered their details and names of the various products that they sell/manufacture.

In response to a question that the hospitals might be placing orders only for drugs with the highest MRPs, Dr. Sharmila stated that NPPA's basic mandate is to prescribe and fix the ceiling price of scheduled drugs, not non-scheduled drugs. She pointed out that DPCO 2013 and 2015 included many more medicines compared to DPCO 2011 that are routinely used. Even then, a large number of medicines fall outside the purview of NLEM and do not come under the pricing regulation of NPPA. The medicines which are prescribed through the public system to public hospitals are mostly those that come under the purview of NLEM. She further mentioned that a recent amendment to DPCO was promulgated by the Department of Pharmaceuticals (DOP) in 2019, where the section for exemption from the pricing of new drugs was amended in 2019. As per the original paragraph of DPCO of that particular section, the exemption from price control for a period of five years was allowed only for new medicines which were indigenously manufactured in India or for which R&D was done in India. But by virtue of the order of DOP in January 2019, this exemption was provided for medicines which were manufactured outside India as well.

Thus, protection for patented medicines from price control was provided through this amendment. There is, however, some ambiguity as far as this amendment is concerned because this exemption is valid for a period of five years from the date of commencement of commercial marketing in India. The ambiguity is because the amendment does not specify whether the date is the date of market authorisation/date of start of manufacturing elsewhere or in India/date of import to India. Hence, some clarity is required on this aspect along with clarity on whether the applicant is required to apply to NPPA to get this exemption.

Dr. Narendra Gupta stated that, in 2011, when the Rajasthan government constituted the Rajasthan Medical Services Corporation (RMSC), many of the senior government doctors expressed their displeasure to the government for introducing generic medicines for the public, citing the

quality of these medicines as questionable and even as being inferior/ineffective. They felt that even if such a system is adopted, it should be adopted at the peripheral level, such as villages/districts, but it should not be introduced in medical college hospitals that provide tertiary care. However, the government collected considerable data to check on the same issue and cited the TNMSC model, which was successful. It decided that this scheme would be uniformly applied at all levels of hospitals, including medical college hospitals. The RMSC model has been in place since then, without any complaints that generic medicines are not effective for treatment of patients. Hence, he pointed out that it is difficult to understand why the dichotomy between generic generics and branded generics is being created specifically in terms of one being superior in quality compared to the other. He further added that while the concern of generics supplied by regular retail shops being of poor quality (compared to generics supplied by government corporations is valid, even some branded generics may be of spurious quality.

Mr. Ramji Srinivasan spoke on the regulatory challenges faced by the pharmaceutical industry. Given how large the scale of the industry is, he stated that it is interesting that there is no rule/regulation governing chemists other than the fact that they are to register themselves under the Pharmacy Act. It is remarkably informal and self-regulated, where there are 9 lakh retailers across the country (including at the village and district levels). He commended the self-regulated system of the pharmaceutical industry and mentioned that it seems to have worked well to provide drugs required by the common man.

Over a period of time, he stated that CCI has found, and in some instances, justifiably, that it is an external force that may seem to prevail in terms of organisation and in terms of ensuring availability/nonavailability of medicines. Principally, there were three allegations that were looked at and investigated by CCI, one of which is whether or not there was the action of retailers or organisations in providing what is called the product information service (PIS). A PIS note, if published, was asked to be sponsored by a few manufacturers, and therefore, it was made available. This was challenged to say that this actually prescribes/circulates/

maintains certain pricing, and therefore, the retailers playing into the hands of the manufacturers insofar as the maintenance of basic pricing is concerned. Thus, CCI held that PIS should not be published. However, the appellate overturned this decision and said that PIS only serves to provide information to every chemist about the drug prices of these manufacturers.

The second allegation relates to district associations at the federation level insisting on an NOC for a stockist to be appointed by a manufacturer. Therefore, the question was that, before the company started distributing the drugs, they must obtain the NOC of the local association. This was held to be a bad practice by CCI. The appellate court stated that this is not in the nature of an NOC. The whole thing emanated from the government's own action, which encouraged the association of chemists to regulate and provide for some sort of information dissemination and make sure that expired/poor quality goods were not sold. This, therefore, required oversight at the local level, and on this basis, there is the requirement that it be decided as to how many stockists should operate in a particular area. The requirement of a pharma company to have more than one stockist in an area is fine; however, a requirement of more than 10 stockists in a particular town may not be justified (given that sales may not warrant such requirement) and may rather be an outlet for expired drugs/drugs of suspected quality. Also, it is questionable whether this offers the manufacturer an opportunity not to take back expired goods. Thus, NOC, which was founded on good principles, seems to have been abused.

The third allegation related to fixing the trade margins. The question that arises is that the government itself fixed margins because small chemists have to survive in the market, as the same drug is being manufactured by multiple companies. So, it is not as if there is a problem at the retail level. But studies reveal that there is an incentive for certain manufacturers to keep higher margins. But fixing trade margins, which is statutorily done by the government, is a means to provide an economic incentive for the retailers to be able to provide some sustenance for themselves, otherwise these retailers would start indulging in suspect practices.

In his concluding remarks, Mr. Srinivasan highlighted the new challenges for the pharmaceutical sector, the first among them being e-pharmacies. Secondly, what kind of margins should or should not be allowed. Thirdly, whether trade margins should be abolished. Fourth, in the place of product information booklets, what information are we making available to retailers and consumers.

The workshop saw engaging discussions on three themes — (i) competition issues in respect of distribution of drugs, the role and functions of trade associations, and the opportunities and challenges for e-pharmacies in India; (ii) implications of the prevalence of branded generics in India for competition and drug prices; and (iii) regulatory pathways for promoting competition in the pharmaceutical sector.

The insights gained from this workshop and from the market study will inform and contribute significantly to the design of the pharma market in India to attain the objective of affordable medicines for all.

