POLICY NOTE

Making Markets Work for Affordable Healthcare

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Fair Competition
For Greater Good

Competition Commission of India
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The opinions expressed and arguments employed herein do not necessarily reflect the official views of the Commission.

EXECUTIVE SUMMARY

Making Markets Work

Since its inception, the Competition Commission of India (the Commission/CCI) has received 52 cases pertaining to the pharmaceutical and healthcare sector. While adjudicating the matters, the Commission has observed that the pharmaceutical sector is characterised by information asymmetry and supplier-induced demand that significantly circumscribes consumer choice, a condition necessary for well-functioning markets. In the absence of agency with the consumer, various industry practices flourish which do not allow markets to work effectively and efficiently. The Commission also recognises the need for optimal regulation in the sector. Identification of the regulatory gaps/overreach and necessary regulatory reforms is another area of critical importance in the quest of ensuring affordable and quality healthcare through well-functioning markets.

CCI Initiatives in Pharmaceutical and Healthcare Sector

The Commission undertook a series of initiatives focused on the Pharmaceutical and healthcare sector. The Commission collaborated with IIM, Ahmedabad and carried out Competition Assessment of Drug Price Control Order, 2013. It also conducted an internal review of the regulatory architecture governing the Pharmaceutical sector in India; and conducted a Technical Workshop on "Competition Issues in the Healthcare and Pharmaceutical Sector". The workshop was attended by representatives of all stakeholder groups, including pharmaceutical industry, healthcare service providers, civil society organisations, regulators, healthcare think tanks.

Focus Areas

The present Policy Note is the outcome of the above initiatives and discusses the key issues and recommendations for policy/regulatory reform suggested by stakeholders. The note highlights the following four issues:

1. The Role of Intermediaries in Drug Price Build-Up
2. Quality Perceptions Behind Proliferation of 'Branded Generics'
3. Vertical Arrangements in Healthcare Services and Lack of Transparency
4. Regulation of Pharmaceutical sector and Competition

The Note also discusses the role of CCI in addressing the competition issues through enforcement of the provisions of the Competition Act, 2002 ('the Act').

Issue 1: The Role of Intermediaries in Drug Price Build-Up

The Indian pharmaceutical industry currently produces around US $ 33 billion worth of drugs, over 40 percent of which are supplied to other countries. However, 50 to 65 per cent of its people do not have regular access to essential medicines. Also, majority of the healthcare expenditure is out-of-pocket, a significant proportion of which is spent only on medicines. Thus, ensuring affordable drugs is a necessary pre-requisite for bringing down the overall healthcare expenses and to achieve the overall goal of affordable healthcare for all.

One major factor that contributes to high drug prices in India is the unreasonably high trade margins. The extent to which trade margins contribute to the price-build up is discernible from the enormous differences between market prices of drugs and the price points at which states such as Tamil Nadu and Rajasthan provide the same drugs procured directly from the manufacturers under their public procurement and distribution systems. Pecuniary motivation in terms of margin influences which drug is dispensed by traders. 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 trade associations controls the entire drug distribution system in a manner that mutes competition.

Recommendation: public procurement and e-pharmacy

Public procurement of drugs can be an important means for making essential drugs available to consumers at affordable prices. Efficient and wider public procurement of essential drugs can circumvent the challenges arising from the long distribution chain, supplant sub-optimal regulatory instruments such as price control and allow for access to essential medicines at lower prices. Electronic trading of medicines *via* online platforms, with appropriate regulatory safeguards, can bring in transparency and spur price competition among platforms and among retailers, as has been witnessed in other product segments. The Ministry of Health and Family Welfare, Government of India has taken a positive step in this direction by releasing draft rules on Drugs (Sale and Distribution) Rules, 2017 which aims at removing ambiguity on regulations to facilitate sales of drugs

online. It is required that a level playing field is created between online and offline platforms for the sale of drugs.

Issue 2: Quality Perceptions behind Proliferation of 'Branded' Generics

Worldwide, low cost generic drugs are seen as a key competitive force against the patent-expired brand name drugs marketed at monopoly prices, but in India pharmaceutical market is dominated by "branded" generics. Competition between these 'branded generic' versions of drugs is largely based on brand and not on price, thus limiting the effect of generic-induced competition in the market. Although there exists little or no difference in the quality and efficacy of branded and unbranded generics given the same regulatory rigour applied to them, still the branded generics are marketed and prescribed based on the perceived higher efficacy and therapeutic advantage associated with them. Further, both the doctors and pharmacists prescribe and sell these drugs in order to gain incentives and higher margins. It is very well possible that quality consideration may be a reason behind the prescription of branded generics by Doctors. But it is also equally possible this brand proliferation is to introduce artificial product differentiation in the market offering no therapeutic difference but allowing firms to extract rents.

Recommendation: Effective and uniform quality control of drugs and One-company-one drug-one brand name-one price policy

The root cause of brand proliferation is the trust-deficit in the regulatory apparatus for licensing and inspection, which needs to be addressed through consistent application of statutory quality control measures across states 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. Furthermore, the practice of creating artificial product differentiation needs to be addressed through a one-company-one drug-one brand name-one price policy.

Issue 3: Vertical Arrangements in Healthcare Services and Lack of Transparency

The presence of information asymmetry and lack of agency does not allow consumers to make informed choice of service providers and also that of various services

such as diagnostics, procedures etc. provided by the hospitals. Hospitals often have exclusive arrangements with in-house pharmacies, diagnostic labs etc. and may provide multiple services in a bundle or a package. Such arrangements driven purely by efficiencies are reasonable but when guided by private interests of the healthcare providers, result in vitiating the market dynamics. In the absence of well-implemented regulations ensuring transparency and ethical practice, competition between hospitals on the parameters of price, quality or choice is almost non-existent in India.

There are instances where the patient is forced to purchase consumables such as medicines, syringes etc. at printed MRP from the in-house pharmacy of the hospital when the same is available at significantly lower prices outside the hospital premises. It has also been observed that hospitals commonly reject even recent reports of diagnostic tests conducted outside the hospital and mandates repeat tests from their in-house diagnostic labs. Further with no regulatory framework that ensures and governs portability of patient data, the switching cost for a patient becomes high.

Recommendation: Strong regulatory framework ensuring transparency, data portability and standardisation of diagnostic labs

To help the consumers in making an informed choice about their healthcare services, there should be mandatory declaration of vital data such as mortality rate, infection rate etc. by the hospitals. Further, it is necessary to ensure that the same degree of reliability and accuracy of test results are applicable across labs. There is also a need of strong regulatory framework to ensure that the hospitals put no restriction on purchase of standardised products from open market, accept and initiate treatment based on test reports of outside labs and allow portability of patient data.

ISSUE 4: Regulation of Pharmaceutical Sector and Competition

Regulation of manufacturing, distribution, sale and import of drugs is essential for ensuring safety, efficacy and quality of drugs produced and sold in the country. The regulatory framework that governs these aspects has concomitant influence on the entry of drugs as well as players into the market. Inconsistent application of regulations may lead to irrational entry restriction and/or distortion of the level playing field. Thus, it is important that regulations strike the right balance between preventing sub-standard drugs from being manufactured or sold in the markets while making sure entry is not unnecessarily deterred or made difficult.

In India, there are multiple regulators governing the pharmaceutical sector at the centre and state level. As a result of which 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. There are no statutory timelines prescribed for processing of new drug applications. Further, the dual requirement of treating each biological medicine from a non-originator source as a new drug, with the additional requirement of proving bio similarity, takes so much time and investment that a handful of companies compete thereby softening competition.

Recommendation: Harmonisation of processes through effective centre-state coordination and time-bound approval for new drugs

There is a need to ensure harmonisation of criteria/processes followed by the state licensing authorities and centralisation of training of inspectors to ensure uniformity in interpretation and implementation. It is also imperative to make the approval of new drug time-bound along with detailed guidelines governing each stage of new drug approval process.

Competition Issues and the Role of CCI

CCI will continue to enforce antitrust rules in the pharmaceutical and healthcare sector *via* its instruments of enforcement and advocacy. The focus areas for enforcement will *inter alia* include activities of trade associations in the pharmaceutical distribution chain and the practices in delaying or hampering the introduction of generic medicines upon patent expiry.

Trade associations

The cases before the Commission have shown that the entire supply chain of drugs is self-regulated by the trade associations who regulate entry by mandating a NOC prior to the appointment of stockists, control distribution by restricting/controlling the number of stockists and influence price by deciding the wholesale and retail margins of drugs. The Commission's past interventions have led to some positive outcomes and businesses and business associations have revised their policies and practices to bring them in alignment with the principles of competition.

Generic competition

The Commission is cognisant of the fact that competition by generics is a way to ensure affordable medicines and is also a dynamic force, which stimulates pharmaceutical companies to continue to invest in research and to develop innovative treatments. However, innovator companies are filing for injunction with the aim to pre-empt competition and delay exports of generics. They have succeeded in some cases in getting injunctions from the Courts. The stakeholders are of the view that the CCI should take up the issues of frivolous litigation not only through enforcement but also for discussion with judiciary and other relevant forums.

Finally, two other major issues that affect the healthcare markets and thus warrant policy response are shortage of healthcare professionals in the country and the inadequacy in health insurance. Public health delivery is a complicated policy matter. The focus of this note is not to undermine or question legitimate public policy objectives, but to determine the extent to which choice and competition can improve outcomes consistent with those objectives. The CCI will continue to enforce antitrust rules in the pharmaceutical and healthcare sector to ensure that effective competition is not undermined in these markets. The instrument of competition advocacy would also be employed appropriately to address the causes underlying non-competitive market conditions.

I. BACKGROUND

Over the nine years of enforcement of the Act, the Competition Commission of India (the Commission) has received 52 cases pertaining to the pharmaceutical and healthcare sector. Since inception, the Commission has passed final orders in seventeen (17) cases dealing with cartelisation in the pharmaceutical sector. Of these, three (3) investigations were transferred to the Commission from the erstwhile Monopolies and Restrictive Trade Practices Commission (MRTPC), four (4) were initiated by the Commission on a *suo-moto* basis and the remaining were initiated by the Commission on the basis of information received under the provisions of Section 19(1)(a) of the Act.

The Commission, while adjudicating the matters, has observed that the distinctive features of the pharmaceutical/healthcare sector such as 'information asymmetry' and 'supplier-induced demand' significantly circumscribe consumer choice, a condition necessary for well-functioning markets. In the absence of agency with the consumer, various industry practices flourish which have the effect of choking competition and are detrimental to consumer interest. Notably, 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. For instance, there may not be any horizontal agreement amongst enterprises but marketing and promotional activities of the drug companies may distort competition. Similarly, excessive or "unfair" pricing may be rampant but not attributable to a dominant firm to be able to invoke Section 4 of the Act.

Competitive markets are an effective means to enhance efficiency, reduce prices and improve quality. In India, where private healthcare accounts for almost 74% of the country's total healthcare expenditure[1], it is imperative to identify and address such issues/practices that vitiate market dynamics and deprive the consumers of the benefits of competition in the form of low prices and reliable quality.

The Commission also recognises the need for optimal regulation in the sector. On the one hand, appropriate regulations can pre-empt market-distorting practices and help create pro-competition conditions. On the other hand, regulations may prove to be ineffective or even counterproductive where they undermine competition, erect

[1] IBEF

unreasonable entry barriers or distort the level-playing field between enterprises in the market. Thus, identification of the regulatory gaps/ overreach and the necessary regulatory reforms is another area of critical importance in the quest of ensuring affordable, quality healthcare through well-functioning markets.

As the antitrust regulator of the country, the Commission felt the need for close examination and focused deliberations on these issues, which have serious 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. The important amongst them are mentioned below:

i. The Pharmaceutical sector was selected as a focus sector for conducting competition assessment of regulations; the assessment focusing on price regulation (Drug Price Control Order 2013) was done independently by CCI and IIM Ahmedabad. The findings were presented and discussed in a workshop. The assessment was shared with Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers.

ii. An internal review of the regulatory architecture governing the Pharmaceutical sector in India through the lens of competition was carried out. Building on the work already done by scholars in the area of regulation in the Pharmaceutical sector, the Study aimed to identify the regulatory barriers that may discourage entry, distort level playing field or disincentivise investments and innovations in the sector. An attempt was also made to identify lesser restrictive alternatives, which could address the root causes underlying the problems instead of targeting the symptoms.

iii. A market study on competition issues in healthcare sector was envisaged. However, the Commission later considered direct stakeholder consultation as a more effective and quicker way to understand the issues facing the sector. Accordingly, a Technical Workshop on “Competition Issues in the Healthcare and Pharmaceutical Sector” was organised on August 28-29, 2018 with representatives of all stakeholder groups, including pharmaceutical industry, healthcare service providers, civil society organisations, regulators, healthcare think tanks. The list of speakers is placed at Annexure 1.

The key issues that emerged from these initiatives and the recommendations for policy/regulatory reform suggested by stakeholders are summarised and discussed in this document. The same may be useful for the purposes of policy formulation or amendments in regulations.

II. ISSUES AND RECOMMENDATIONS

ISSUE 1. THE ROLE OF INTERMEDIARIES IN DRUG PRICE BUILD-UP

The Indian pharmaceutical industry currently produces around US $ 33 billion worth of drugs, over 40 percent of which are supplied to other countries.[2] However, 50 to 65 per cent of its people do not have regular access to essential medicines. Also, majority of the healthcare expenditure is out-of-pocket, of which a significant proportion is on medicines alone. [3] Thus, ensuring affordable drugs is a necessary pre-requisite for bringing down the overall healthcare expenses and to achieve the overall goal of affordable healthcare for all.

One major factor that contributes to high drug prices in India is the unreasonably high trade margins. Trade margin is the difference between the price at which the manufacturers sell the drugs to trade (price to trade) and the final price to patients (maximum retail price). The extent to which trade margins contribute to the price-build up is discernible from the enormous differences between market prices and the price points at which states such as Tamil Nadu and Rajasthan provide the same drugs procured directly from the manufacturers under their public procurement and distribution systems.

Table 1. Comparison of Market Prices and TNMSC Prices[4]

Product	Unit of Drug	TNMSC Price	Market Price (in INR)
Aspirin Tab IP	10x10 tabs	12.17	44.42 (Ecosprin)
Paracetamol Tab IP	10x10 tabs	11.69	68.00 (Fapanil)
Paracetamol Syrup IP	60 ml	3.20	19.57 (Calpol)

[2] IBEF
[3] Sakthivel Selvaraj, Aashna Mehta 'Access to Medicines, Medical Devices and Vaccines in India' available at : https://www.researchgate.net/publication/320057825
[4] N Lalitha, Essential Drugs in Government Healthcare: Emerging Model of Procurement and Supply, September 2005

Product	Unit of Drug	TNMSC Price	Market Price (in INR)
Co-Trimoxazole oral Suspension IP	50 ml	4.06	10.00 (Septran)
Co. Trimoxazole Tab IP	10x10	28.37	63.20 (Septran)
Metronidaxole Tb IP	10x10	13.21	36.50 (Flagyl)
Amoxcycilin Cap Ip	10x10	78.47	366.66 (Novamax)
Erythromycin state Oral suspension	40 ml	8.76	25.27* (60 ml) (Novamax)
Tetanus Toxoid Injection IP	5 ml	6.93	
Anti-Rabies Vaccine	3 ml	18.00	294.00 (Aventis)
Ciprofloxacin inj IP	100 ml	7.00	46.89 (cifran)
Gentamycin eye and Ear drops B P	5 ml	3.56	7.51 (gentics)
Atenolol tab IP	14x10	15.26	310.00 (Tenormin)
Ibuprofen tab IP	10x10	13.10	55.55 (Brufen)

Note: Both TNMSC and market prices are inclusive of taxes.
Source: TNMSC L 1 prices for the year 2002-03 provided by TNMSC, and the market prices are the brand prevailing prices collected from a medical shop in Chennai collected during the month of June 2003.

The two main reasons that are attributed to the prevalence of high trade margins are:

a) **Margins as tools of pecuniary motivation**: Pecuniary motivation in terms of margin influences which drug is dispensed by traders. Drug manufacturers offer high margins to the traders for pushing their drugs as against their competitors' products into the market and to the customers. The high margins are a form of incentive and an indirect marketing tool employed by drug companies. Theoretically speaking, marketing and promotional activities might have an informational contribution about products such as medicines, but in the context of India it is now well known that it might not be used by firms as a social good.

b) **Self-regulation by trade associations**: The association of traders (stockists/chemists/druggists) control the entire drug distribution system and govern the various key aspects such as appointment of stockists, discounting practices etc., which mute competition between traders that could otherwise have driven down the final prices to some extent despite the high margins offered by the manufacturers.

Recommendation

Public procurement and distribution of drugs: Public procurement of drugs can prove to be an important means for making essential drugs available to consumers at affordable prices. It helps circumvent the challenges arising from the long distribution chain and number of intermediaries involved in drug distribution and sale. Efficient and wider public procurement of essential drugs can supplant sub-optimal regulatory instruments such as price control and allow for access to essential medicines at lower prices, thereby having a significantly positive impact on overall public health. In this regard, the model adopted by Tamil Nadu Medical Services Corporation (TNMSC) can be emulated by other states as well. TNMSC is an autonomous agency that functions through the Tamil Nadu Transparency in Tenders Act, 1998[5]. The TNMSC, drug warehouses and health facilities are linked through Electronic Data Processing (EDP) units. The TNMSC places purchase orders [6] based on three months base stock and two months pipeline stock. Tamil Nadu model has taken into consideration the WHO's Model List of essential drugs and finalized a list of essential drugs to be procured, upon its institution. The model presents a success story in providing accessible, affordable health care to people through public health facilities. States like Odisha and Kerala are also working in similar direction[7] and therefore it is required that other states also follow similar approach in tackling the problem of drug distribution in the country.

E-pharmacy: Self-regulation and lack of competition in the distribution and retail of drugs are major reasons why drugs are sold at printed prices, which are many times more than the manufacturers' prices. E-Pharmacies are online platforms where consumers can purchase medicines without having to visit brick-and-mortar pharmacies**.** Electronic trading of medicines brings in transparency and can spur price competition among platforms and among retailers, as has been witnessed in other product segments. It also allows the consumer to choose from a range of equivalent drugs for a particular branded drug, which is not possible in the current offline model. All medicine purchases are digitally stored making it easy to track the supply chain, thereby decreasing the risk of counterfeit medicines, drug abuse, and self-medication. Thus, e-pharmacy, with appropriate regulatory safeguards, has the potential to transform the dynamics of drug retail.

[5] A cross-sectional survey of the models in Bihar and Tamil Nadu for pooled procurement of medicines", Maulik Choksi, Habib Hasan Farooqui, Sakthivel Selvaraj, Preeti Kumar

[6] Access to Medicines in India, Sakthivel Selvaraj

[7] Prabal Vikram Singh, Anand Tatambhotla, Rohini Rao Kalvakuntla, Maulik Chokshi, 'Replicating Tamil Nadu's Drug Procurement Model' EPW, september 29, 2012 vol xlvil no 39 E available at : https://accessh.org/wp-content/uploads/2014/07/Replicating_Tamil_Nadus_Drug_Procurement_Model_EPW.pdf

According to Transparency Market Research, the global e-Pharmacy market was around US $29.3 Billion in 2014 and is estimated to grow at a CAGR of 17.7% to reach a valuation of US $128 Billion by 2023.[8]

Due to increasing internet penetration in India, e-pharmacies are likely to be visited by patients that have thus far not been able to conveniently avail medicines. The Ministry of Health and Family Welfare, Government of India has released draft rules on Drugs (Sale and Distribution) Rules, 2017 aiming at removing ambiguity on regulations to facilitate sales of drugs online. The draft comprises six chapters covering process to obtain drug selling license, regulation of sale of drugs through e-pharmacy, roles of licensing authority, essentials of prescription, submission of data on electronic platform, inspection for verification of compliance, conditions for grant of license to sell drugs by wholesale or distribute the same by a motor vehicle, suspension or cancellation of licenses, digitalisation of forms etc.[9]

This is a positive step. However, it is required that a level playing field is created between both online and offline platforms of sale of drugs.

i. **Compliance standards:** At present, the draft sets different compliance standards for online and offline sale platforms. The draft stipulates that e-pharmacies are required to link patient registration number with Aadhaar, verification of doctors and prescriptions etc. which is however not mandatory for retail pharmacies offline. The safeguards mentioned no doubt ensure patient safety. Similar conditions for drug dispensing should also apply to offline pharmacy so that a level playing field is created between the offline and online pharmacies. Further, this will also reduce the problems of self-medication and drug abuse.

ii. **Registration:** The conditions of registration of e-pharmacy are required to be set clearly. The draft does not stipulate clear criteria for registration of e-pharmacies. It is required that rules recognize and explicitly provide the definitions and conditions of registration of the two different models of e-Pharmacy, with marketplace definition being the same as already defined in DIPP Press Note No 3. The requirement on the marketplace technology platform may be the need of a registration, while the retail entity needs to be under license as for all other retail

[8] http://ficci.in/spdocument/20746/E-Pharmacy-in-India-Last-Mile-Access-to-Medicines_v5.pdf
[9] http://pharmabiz.com/ArticleDetails.aspx?aid=104583&sid=1

operators. The conditions of registration for e-pharmacy market place and conditions of license for e-pharmacy inventory based model may be defined separately. Moreover, the scope of e-commerce is beyond state borders. The condition stipulated in draft that a registered e-pharmacy can sell drugs in the territory in which it is registered is having limiting effect in case of e-pharmacy. The rules may allow e-pharmacies to serve entire country. This will help address the problem of drug distribution in entire country. Digitisation and information technology can play a game-changing role in reducing information asymmetry historically prevailing in health care markets around the world, more so in India.

ISSUE 2. QUALITY PERCEPTIONS BEHIND PROLIFERATION OF 'BRANDED' GENERICS

Worldwide, low-cost generic drugs are seen as the key competitive force against the patent-expired brand name drugs marketed at monopoly prices. Generic competition rests on the premise that the generic drugs are equivalent to the patented drug in pharmacopoeia and therapeutic value. There have been studies internationally which have shown that generic formulations are therapeutically equivalent to the originator drug. However, the pharmaceutical market in India is unique in that it is dominated by "branded" generics, which enjoy a price premium owing to a perceived quality assurance that comes with the brand name. Competition between these 'branded generic' versions of drugs is largely on brand and not on price, thus limiting the effect of generic-induced competition in the market.

The Indian market has seen a proliferation of brands and huge price dispersion for brands representing a given molecule. With a regulatory system of drug approval and quality control in place, all brands of the same active pharmaceutical ingredient(s) (API) should yield the same result as they all are presumably subjected to the same statutory approvals and inspections. However, the brand name products are marketed and prescribed based on supposed higher efficacy and therapeutic advantage associated with them.

There are two narratives on the issue: a) in case of branded generic drugs marketed by large MNCs, the quality of drugs is assured and the doctors are acting in the interest of patients while prescribing the expensive branded generics instead of the salt name and

b) though there exists little or no difference in the quality and efficacy of branded and unbranded generics given the same regulatory rigour applied to both, doctors prescribe or pharmacists sell the expensive branded drugs in order to gain incentives and higher margins respectively.

The truth lies somewhere in between. The equivalence of originator drug and generics presupposes stringent and uniform application of the statutory approval, inspection and quality control measures. However, the prevalence of spurious and substandard drugs in Indian markets puts that presumption into question. Given such a situation and given that efficacy of a drug prescribed by a doctor has a bearing on the doctor's reputation, quality concerns may indeed explain the bias in prescription patterns in favour of branded generic drugs manufactured by reputed companies. On the other hand, many reputed drug manufacturers producing branded generics were found to be in the list of manufacturing units having more than 5 not of standard quality drug samples declared in National Drug Survey (2014-2016). This goes to show that while the quality concern is not totally unfounded, the same is not confined only to small generic manufacturers. Thus, the response to the same cannot be to inundate the market with brand-variants representing the same molecule at various price points.

Recommendation

Ensure effective and uniform quality control of drugs: The policy response to the issue must include reforms in the regulatory framework with a view to ensure consistent application of statutory quality control measures across states 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 root cause of brand proliferation is the trust-deficit in the regulatory apparatus for licensing and inspection, which needs to be addressed without any delay. State-of-the-art drug testing infrastructure in every state, centralised training of all state drug inspectors, similar allocation of resources to inspectors will go a long way in ensuring the same rigour in quality control measures across states. Moreover, checking quality at every stage of the manufacturing process, and documenting evidence that Good Manufacturing Practices (GMP) are followed at every step in the process instead of random sampling of commercial drug supplies will ensure all drugs are scrutinised with the same rigour.

One-company-one drug-one brand name-one price: As the Draft Pharmaceutical Policy 2017 has observed, it is not uncommon that the same company manufactures the same salt (pharmacopeial name of the drug) on the same production line but sells it under different brand names at different prices. The widely varying prices for the same drug and the mark ups thereon for retailers, distributors and the stockists do not have any justifiable basis other than to extract the entire consumer surplus. This practice of creating artificial product differentiation for exploitation of consumers, needs to be addressed through a one-company-one drug-one brand name-one price policy.

ISSUE 3. VERTICAL ARRANGEMENTS IN HEALTHCARE SERVICES AND LACK OF TRANSPARENCY

In India, around 60% of the inpatient services are provided by the private sector. The issues of information asymmetry and lack of agency do not allow consumers to make informed choice of service providers and also that of various services such as diagnostics, procedures etc. provided by the hospitals while undergoing in-patient treatments. Hospitals often have exclusive arrangements with in-house pharmacies, diagnostic labs etc. Multiple services are also commonly provided in a bundle or a package. Such arrangements driven purely by efficiencies are reasonable but when guided by the private interests of the healthcare providers, they result in vitiating the market dynamics. Moreover, in most cases there is complete lack of transparency, which makes it difficult to understand the rationale of a particular prescription, procedure or pricing and to identify or question any irrational care or profiteering. Given that a larger section of our population is out of the ambit of insurance, the bargaining power of these consumers vis-à-vis hospitals is nil. In competitive markets, service providers compete on price, quality and choice, which reduces or precludes the possibility of such wrongdoings. However, given the lack of consumer sovereignty and absence of well-implemented regulations ensuring transparency and ethical practice, competition between hospitals on the parameters of price, quality or choice is almost non-existent in India. Three issues that are commonly faced by consumers availing in-patient services are:

Doctor-hospital nexus

The consumers' choice of a hospital is often guided by a doctor's reference and is not based on any objective criteria. Even if one were to make an objective assessment of

a hospital in terms of mortality rate, infection rate, cost of each procedure, *etc.*, that would not have been possible owing to non-availability of any such data. While there is no denying that doctors are best-positioned to select a hospital for a particular secondary or tertiary healthcare need on behalf of the patient, the referrals in certain instances may be driven solely by incentives that are offered to the doctor for such referrals. Thus, the choice of hospital, even based on a doctor's advice, may not necessarily be an informed choice.

Compulsory tying of consumables

The consumables such as medicines, syringes etc. are often to be compulsorily purchased at printed MRP from the in-house pharmacy of the hospital. Many instances have been reported where the same product was available at significantly lower price, i.e. at a discounted price below the printed MRP or at a lower MRP at outside pharmacies but consumers were not allowed to buy the same on the pretext of quality concern. The hospitals would charge the MRP thus retaining the entire margin. It is also reported that hospitals prescribe such products among a set of alternatives available, in which they have the highest margin.

Compulsory tying of diagnostic services

It has been observed that hospitals commonly reject even recent reports of diagnostic tests conducted outside the hospital and mandates repeat tests from their in-house diagnostic labs. The proffered rationale is the lack of reliability and accuracy of the outside reports. The patients thus have to incur diagnostic expenditure again in the hospital in order to proceed with the treatment. Moreover, 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. This problem is compounded by the fact that traditionally the medical data of patient is paper based and it is next to impossible for patient to get access to their data if she intends to switch services of a doctor/hospital.

Recommendation

Mandatory declaration of vital data: In view of the incentive-based referral system that pervade the healthcare landscape, issuing of periodic validated data by the hospitals relating to mortality rate, infection rate, number of procedures etc. could help patients take informed decisions instead of simply following the referral of the GP.

No restriction on purchase of standardised products from open market: The in house pharmacies of the super specialty hospitals are completely insulated from competition as inpatients are not allowed to purchase any product from outside pharmacies. This calls for a regulation that mandates hospitals to allow consumers to buy such standardised products from the open market which are not required on an urgent basis or which do not involve any high degree of quality issue from medical procedure point of view and for the purchase of which patients have the time and scope of exercise their rational choice from open market at lower prices.

Standardisation of diagnostic labs: 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 and hospitals can in turn be mandated to accept and initiate treatment based on test reports of outside labs.

Patient Data Portability: Portability of data will 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. Justice Sri Krishna Committee report also advocates for right to data portability recognising its seamless opportunity for nations' economy. The draft Bill allows data principals to obtain and transfer their personal data stored with a data fiduciary (hospitals in this context) for the data principal's own uses, in a structured, commonly used and machine readable format. Thereby, it empowers data principals by giving them greater control over their personal data. Further, the free flow of data is facilitated easing transfer from one data fiduciary to another. This will in turn improve competition between fiduciaries who are engaged in the same industry and therefore, has the potential to increase consumer welfare in health care sector.

ISSUE 4. REGULATION OF PHARMACEUTICAL SECTOR AND COMPETITION

Regulation of manufacturing, distribution, sale and import of drugs is essential for ensuring safety, efficacy and quality of drugs produced and sold in the country. The regulatory framework that governs these aspects has concomitant influence on the entry of drugs as well as players into the market. Since ease of entry is a necessary prerequisite

for competitive markets, regulatory overreach in this area or inconsistent application of regulations may lead to irrational entry restriction and/or distortion of the level playing field. It is important that regulations strike the right balance between preventing sub-standard drugs from being manufactured or sold in the markets while making sure entry is not unnecessarily deterred or made difficult. This requires clear, objective and transparent principles and norms laid down in the legislation, rules and regulations as well as coherent and consistent implementation of such rules by the implementing agencies.

In India, regulatory control over the quality, safety and efficacy of drugs is exercised through a central legislation called the 'Drugs and Cosmetics Act, 1940' (DCA) and a large body of rules, the 'Drugs and Cosmetics Rules 1945' (Rules) framed thereunder. As regards implementation, there exists a dual regulatory control system. The central drug regulator CDSCO undertakes approval of new drugs, clinical trials, standard setting, import licensing and licensing for manufacturing of certain categories of drugs while the state authorities assume responsibility for issuing licenses for manufacture, distribution and sale of drugs and monitoring of these activities. Two key issues on the regulatory front, relevant to competition dynamics are:

Multiplicity of regulators: Non-uniform interpretation/application of rules

Owing to the dual regulatory structure and lack of effective centre-state coordination, the implementation of the Drugs & Cosmetics Act and Rules is not uniform across the country. This has resulted not only in multiple standards of same products but also different levels of regulatory compliance requirements and diverse degrees of rigour of scrutiny that entry and operations of drug companies are subjected to in different states. This takes away predictability of the systems and can distort level playing field for enterprises.

New drug approval

There are no statutory timelines prescribed for processing of new drug applications under Drugs and Cosmetics Act and Rules as the time taken varies from drug to drug and depends on adequacy of data furnished. Further, the exact requirements of Clinical trials may change from case to case and depend on the extent to which licensing authority is

satisfied about its safety and efficacy.[10]Moreover, the stakeholders are of the view that there is no predictability in the approval process. Entry norms must be non-discriminatory, non-discretionary and be applied in a consistent manner regardless of the identity of the applicant. Any abuse of discretionary power that may facilitate entry of certain drugs and favour the manufacturers of these drugs, not only have the potential to harm public health but also distort the level playing field for the industry as a whole.

Over the past decade, generic drug manufacturers from India have ventured into developing and registering biological medicines, creating an opportunity to use competition as a tool to bring down prices on the most expensively priced treatments in the world.[11] Access to biological drugs in India is however complicated by the complex regulatory process for approval by national regulatory authorities. The term "biosimilars" is a misnomer: most national regulatory authorities insist that competitors not only conduct Phase 1 and 2 trials, but also comparative studies in the final phase, before they receive final regulatory approval. Often, this dual requirement of treating each biological medicine from a non-originator source as a new drug, with the additional requirement of proving bio similarity, takes so much time and investment that barely a handful of companies compete with pharma giants thereby muting competition and resulting in monopoly prices.[12]

Recommendation

A mechanism may be devised under the aegis of the CDSCO that ensures harmonisation of criteria/processes followed by the state licensing authorities and centralisation of training of inspectors to ensure uniformity in interpretation and implementation. As recommended by the Standing Committee, a centralized databank (including data on licenses issued, cancelled, list of sub-standard drugs, prosecutions etc.) may be created to which all the State Drug Authorities should be linked.

The approval of new drugs should be time-bound and detailed guidelines should be brought out for each stage of new drug approval process including clinical trials, consultation with experts, selection of experts etc. A databank may be created including number of new drug applications, number of drugs for which clinical trials were

[10] Prajapati Vishal et al, A Review on Drug Approval Process for US, Europe and India, International Journal of Drug Regulatory Affairs, 2014
[11] Leena Menghaney, Competition is the key to making drugs affordable, Hindu Business Line, May 12, 2017
[12] Ibid

required/waived, number of approvals, rejections, time taken for approval etc. and it may be made available in the public domain to ensure transparency.

III. COMPETITION ISSUES AND THE ROLE OF CCI

The CCI will continue to enforce antitrust rules in the pharmaceutical and healthcare sector to ensure that effective competition is not undermined in these markets. The instrument of competition advocacy would also be employed appropriately to address the causes underlying non-competitive market conditions. The focus areas in enforcement will *inter alia* include activities of trade associations in the pharmaceutical distribution chain to limit competition and practices to delay or hamper the introduction of generic medicines upon patent expiry.

Trade association activities in drug distribution

Markets need to be competitive at each level of the supply chain – be it manufacturing, wholesale or retail. The existence of high trade margins in India is indicative of the absence of effective competition in distribution of drugs. The Commission's past interventions have shown that the entire supply chain of drugs is self-regulated by the trade associations. There is a hierarchy of associations in the industry, with the players at each stage of the supply chain having representation in one or more industry associations. The associations typically regulate entry by mandating NOC prior to the appointment of stockists, control distribution by restricting/controlling the number of stockists that can be appointed by Pharmaceutical companies in a particular geographical area and influence price by deciding the wholesale and retail margins of drugs. The Commission's past interventions have led to some positive outcomes. In some cases, mid-course corrections have taken place. Businesses and business associations have revised their policies and practices to bring them in alignment with the principles of competition. The All India Organisation of Chemists and Druggists (AIOCD) issued instructions to all State level chemists and druggists associations requesting them to refrain from indulging in practices, which are anti-competitive. The Commission will continue to be vigilant and intervene where it is deemed necessary to correct trade association behaviour.

Generic competition

Generic competition can ensure access to affordable healthcare. Moreover, competition by generics is also a dynamic force, which stimulates pharmaceutical companies to continue to invest in research and to develop innovative treatments, as they cannot rely forever on their current blockbuster products.[13] However, it has been reported that innovator companies are filing for injunction without providing sufficient evidence of any impending infringement. These relate to generic companies seeking permission from the DCGI under:

i. Form 11: License to import drug for the purpose of examination, test or analysis
ii. Form 29: License to manufacture drug for the purpose of examination, test or analysis
iii. Permission to conduct bio-equivalence study for export purpose

Reportedly, by projecting these permissions as marketing/manufacturing approvals, the innovator companies have sought and succeeded in some cases, injunctions from the Courts. The aim is to pre-empt competition and delay exports of generics. Such litigations not only adds to the cost because of judicial process but may also unnecessarily block or delay the entry of an essential drug in the market.

Traditionally, the patent holders used to block generic companies after applying for regulatory approval. However, now the patent holders seek to block generics at the development stage itself. The innovators block access to pharmaceutical reference products for bioequivalence testing by not providing sample of their products, thereby delaying/denying generic entry. Innovators using distribution safety protocols impede generic/biosimilar drug development; and challenge the marketing approval granted by the drug regulatory authority to prevent biosimilar products. For instance, in India, Roche sued Biocon and Mylan to restrain them from selling their biosimilar of breast cancer medicine Trastuzumab. Roche also challenged the drug regulator for approving the biosimilar.[14]

[13]Contribution By European Commission to the Roundtable on: *Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers at* the Seventh United Nations Conference to review the UN Set on Competition Policy
[14] https://www.biosimilardevelopment.com/doc/beyond-ip-protection-new-tactics-blocking-generic-biosimilar-market-access-0001

The stakeholders are of the view that the CCI should take up the issues of frivolous litigation not only through enforcement but also for discussion with judiciary and the other relevant forums. There is a need to bring in clarity to differentiate between “Marketing approval” and “Test License”. The CCI may coordinate with the DCGI on the issue of whether information relating to product development available with the regulator could be treated as trade secret and thus not to be divulged in response to RTI applications which in turn lead to vexatious litigations and block product development.

IV. SUMMARY AND CONCLUSIONS

The Policy Note discusses the key issues that emerged from the Commission's engagements with stakeholders, enforcement of the Act and competition assessment of regulations. Following are the key issues and the recommendations that have emerged from these initiatives:

Table 2. Key Issues and Recommendations

Sr. No.	Issues	Recommendations
1	**High Drug Prices:** • Drug manufacturers offer high margins to the traders for pushing their drugs as against their competitors' products. • The association of traders control the entire drug distribution system, which mute competition between traders.	• Public procurement of drugs circumvents the challenges arising from the long distribution chain and make essential drugs available at affordable prices. • E-pharmacy brings in transparency and can spur price competition among platforms and among retailers e-pharmacy.
2	**PROLIFERATION OF BRANDED GENERICS:** • Despite therapeutically equivalence of generic formulations to the branded drug, the Indian pharmaceutical market is dominated by expensive "branded" generics due to perceived quality assurance and higher incentives to the doctors.	• The root cause of brand proliferation is the trust-deficit. Hence, reforms in the regulatory framework, with a view to ensure consistent application of statutory quality control measures across states and better regulatory compliance, will build the trust for non-branded generic and ensure equal efficacy. • Practice of creating artificial product differentiation for exploitation of consumers can be addressed through a one-company-one drug-one brand name-one price policy
3	**VERTICAL ARRANGEMENTS IN HEALTHCARE SERVICES:** • The consumers' choice of a hospital is often guided by a doctor's reference and is not based on any objective criteria.	• Issuing of periodic validated data by the hospitals relating to mortality rate, infection rate, number of procedures etc. could help patients

Sr. No.	Issues	Recommendations
	• The consumables such as medicines, syringes, saline water bottles etc. are often to be compulsorily purchased at printed MRP from the in-house pharmacy of the hospital. • Hospitals commonly reject even recent reports of diagnostic tests conducted outside the hospital and mandates repeat tests from their in-house diagnostic labs.	take informed decisions instead of simply following the referral of the GPs. • The hospitals should be mandated to allow consumers to buy standardized products from the open market which are not required on an urgent basis or which do not involve any high degree of quality issue. • All accredited diagnostic labs should meet the same quality standards for getting accreditation. This will ensure the same degree of reliability and accuracy of test results across labs. Further, the hospitals should also be mandated to accept and initiate treatment based on test reports of outside labs. • Portability of patient data will ensure that a patient is no longer locked into the data silos and do not bear additional cost for switching medical services.
4	**REGULATION OF PHARMACEUTICAL SECTOR AND COMPETITION:** • Owing to the dual regulatory structure and lack of effective centre-state coordination, the implementation of the Drugs & Cosmetics Act and Rules is not uniform across the country. • There are no statutory timelines prescribed for processing of new drug applications under Drugs and Cosmetics Act and Rules as the time taken varies from drug to drug.	• A mechanism may be devised under the aegis of the CDSCO that ensures harmonisation of criteria/processes followed by the state licensing authorities and centralisation of training of inspectors to ensure uniformity in interpretation and implementation. • The approval of new drugs should be time-bound and detailed guidelines should be brought out for each stage of new drug approval process including clinical trials, consultation with experts, selection of experts etc.

While not discussed in the Note, the two other major issues that affect the healthcare markets and thus warrant policy response are shortage of healthcare professionals in the country and the inadequacy in health insurance. In India the health workforce serving is meagre in number as compared to developed nations and the available data on

physicians' density in India per 1000 of population is 0.702 only. The availability of doctor is in the ratio 1:1500 in urban areas and one doctor for 2500 people in rural areas, which is extremely low as compared to USA where they have 1 doctor for 250 people. The density of Nurses in India is 1.3 per 1000 of population where the OECD average is 9.1 per 1000 of population. The density of Physicians, Nurses and ANMs (Auxiliary Nurse Midwives) was 13.4 in 2005 as against the benchmark of 25.4 workers per 10,000 of population.[15] The severe shortfall in supply of healthcare professionals in the country warrants a holistic review of the conditions that govern the entry into these professions. The high cost of medical education does not only act as an entry barrier but is also often linked to the unethical and pecuniary motivation driven behaviour that doctors are found to indulge in. The government may address this serious supply-side bottleneck that affect the entire healthcare services ecosystem. In health insurance, the third party administrators need to be regulated efficiently to ensure high operational efficiency, fraud control and better customer service. There is a need to rationalise the number of exclusions, standardised wordings and scope of exclusions. Ayushman Bharat, the National Health Protection Scheme launched on 15th August, 2018, aims to provide insurance cover to at least 40 per cent of India's population which is majorly deprived of secondary and tertiary care. The scheme provides an insurance cover of Rs. 5 lakh per family per year for 50 crores citizens. There is no cap on the family size and age under the scheme, ensuring that nobody is left out. The scheme is indeed a step forward to ensure accessible health care to people in the country.

The CCI will continue to enforce antitrust rules in the pharmaceutical and healthcare sector to ensure that effective competition is not undermined in these markets. The instrument of competition advocacy would also be employed appropriately to address the causes underlying non-competitive market conditions. The focus areas in enforcement will *inter alia* include activities of trade associations in the pharmaceutical distribution chain to limit competition and practices that delay or hamper the introduction of generic medicines.

Public health delivery is a complicated policy matter. The focus of this note is not to undermine or question legitimate public policy objectives, but to determine the extent to which choice and competition can improve outcomes consistent with those objectives.

[15] http://www.gjmedph.com/uploads/R1-Vo5No4.pdf CC

ANNEXURE I

List of Speakers during Technical Workshop on Competition Issues in Healthcare and Pharmaceutical Sector in India

Sr. No.	Name of Speakers
1.	**Dr Vinod K. Paul** Member, NITI Aayog
2.	**Mr Sudhir Mital** Chairperson, Competition Commission of India
3.	**Mr Augustine Peter** Member, Competition Commission of India
4.	**Ms Jyoti Jindgar** Adviser (Economics), Competition Commission of India
5.	**Dr Naresh Trehan** Cardiovascular and Cardiothoracic Surgeon, Chairman and Managing Director, Medanta TM-The MediCity
6.	**Dr Alexander Thomas** President and Founder-Member Association of Healthcare Providers in India (AHPI)
7.	**Ms Rema Nagarajan** Editor-Research, Times of India
8.	**Dr Arun Gadre** National Convener, Alliance of Doctors for Ethical Healthcare (ADEH)
9.	**Ms Malini Aisola** Co-Convenor, All India Drug Action Network (AIDAN)
10.	**Ms Payal Malik** Adviser (Economics), Competition Commission of India
11.	**Dr Raghuraj Hegde** Ophthalmic Plastic and Reconstructive Surgeon, Bengaluru
12.	**Dr Ashok Vaid** Chairman, Medical and Haemato Oncology, Medanta Cancer Institute
13.	**Mr S. Srinivasan** Co-convener, All India Drug Action Network (AIDAN)
14.	**Mr Dharmil Sheth** Co-Founder, Pharmeasy
15.	**Dr Biswajit Dhar** Professor, Centre for Economic Studies and Planning, School of Social Sciences, JNU

Sr. No.	Name of Speakers
16.	**Mr K. M. Gopakumar** Legal Adviser and Senior Researcher, Third World Network
17.	**Dr Malathi Lakshmikumaran** Executive Director & Practice Head of Patents, Lakshmikumaran & Sridharan Attorneys
18.	**Ms Leena Menghaney** Adviser, Medicines Access, Medicines Sans' Frontier
19.	**Mr Yogesh Pai** Assistant Professor of Law, National Law University, Delhi
20.	**Mr Manoj Pandey** Adviser (Law), Competition Commission of India
21.	**Prof. Viswanath Pingali** Professor, Indian Institute of Management, Ahmedabad
22.	**Dr R. K. Vats** Chairman, National Pharmaceutical Pricing Authority (NPPA)
23.	**Dr Sakthivel Selvaraj** Director, Health Economics & Financing Division, PHFI
24.	**Dr James J. Nedumpara** Professor and Head of the Centre for International Trade and Investment Law
25.	**Mr Dilip G Shah** Secretary General, Indian Pharmaceutical Alliance
26.	**Dr S. Eswara Reddy** Drugs Controller General of India, CDSCO, DG-HS, Ministry of Health and Family Welfare, Government of India
27.	**Dr G. N. Singh** Secretary-cum-Scientific Director, Indian Pharmacopeia Commission
28.	**Dr Shailendra Kumar** Director (Drugs), Ministry of Health and Family Welfare, Government of India
29.	**Mr Deepnath Roy Chowdhury** Managing Director, Strassenburg Pharmaceuticals Ltd. and National President, Indian Drug Manufacturers Association
30.	**Ms Prathibha Sivasubramanian** SAMA – Resource Group for Women and Health