Analysing margins charged on medicines related to COVID hospitalisations in Maharashtra

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Disclaimer : The purpose of this study is to document and analyse the situation regarding margins charged to patients by private hospitals during provision of medicines, drawing upon information obtained from a sample of hospitalised COVID patients in Maharashtra. Names of all patients as well as hospitals have been kept confidential. There is no intent whatsoever to affect the reputation of any doctor, hospital, retailer, company, brand, professional association, official body or any other entity, during all processes related to the study and its dissemination. The entire study has been done with the perspective of providing evidence which could help to improve systems for regulation of prices of medicines in India, in wider public interest.

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1. Background

A lthough India is known as the pharmacy of the developing world and ranks third in generic production globally¹, the glaring contradiction is that hundreds of millions of Indians lack access to essential medicines^{2,3}. In 2004 the World Health Organisation estimated that 649 million Indians lacked regular access to essential medicines⁴. This issue is compounded by high out-of-pocket expenditure on healthcare, which is estimated in 2011-12 to have pushed 55 million people into poverty, of which 38 million became poor solely due to their expenditure on medicines⁵. WHO's data on global health expenditures⁶ reveals that India's out-of-pocket expenditure as a

proportion of total health expenditure is significantly higher than the global average, indicating the heavy burden borne by households (65% for India versus world average of around 20% in 2016). According to the National Health Accounts report of 2019-20, pharmaceuticals contribute 43.2% to the total out-of-pocket expenditure (OOPE) on health in India. This makes it the single largest contributor to OOPE, which accounts for an estimated 62.7% of total health spending in the country⁷. This emphasises the critical role that medicine prices play in determining access and affordability to healthcare services, highlighting the necessity for regulation to control drug pricing effectively⁸. The

- 5 Selvaraj, S.; Farooqui, H. & Karan, A. (2018). Quantifying the financial burden of households' out-of-pocket payments on medicines in India: A repeated cross-sectional analysis of National Sample Survey data, 1994–2014. BMJ Open.
- 6 Data from World Health Organization Global Health Expenditure Database.

¹ India Brand Equity Foundation (IBEF) (2017). Pharmaceuticals. IBEF. Retrieved from https://www.ibef.org/download/ Pharmaceutical-January-2017-D.PDF as accessed on 7th Feb 2020.

² Millard, C.; Kadam, A.; Mahajan, R.; Pollock, A. and Brhlikova, P. (2018) Availability of brands of six essential medicines in 124 pharmacies in Maharashtra. Journal of Global Health, 8(1): 010402.

³ Kotwani, A.; Ewen, M.; Dey, D.; Iyer, S.; Lakshmi, P.; Patel, A. et al. (2007). Prices & availability of common medicines at six sites in India using a standard methodology. Indian J Med Res, 125(5):645-54

⁴ World Health Organization (2004). The World Medicines Situation. Retrieved January 17, 2019 from: http://apps.who.int/ medicinedocs/ en/d/Js6160e/9.html.

⁷ Competition Commission of India (2021). Market study on the pharmaceutical sector in India. Delhi

⁸ Roy V, Gupta U and Agrawal A. (2012). Cost of medicines & their affordability in private pharmacies in Delhi. Indian J Med Res 136, November 2012, pp 827-835. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3573605/pdf/JJMR-136-827.pdf

difference between having access to affordable medicines and having to buy overpriced medicines, can translate into the difference between financial well-being and poverty, for a large section of the Indian population.

Drug price regulation in India

Drug price regulation in India has been a muchcontested area, with governments negotiating between public interest and the interests of a powerful pharmaceutical industry. For addressing the issue of drug pricing, the Indian government has implemented the Drug Price Control Order (DPCO) under the Essential Commodities Act, 1955. The latter act authorises the government to fix prices of essential bulk drugs and their formulations. In 1997, the Indian government established the National Pharmaceutical Pricing Authority (NPPA) for implementation of the DPCO. NPPA's role is to fix or revise prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country, under the DPCO⁹. Currently, 887 drugs are under some form of price regulation as per DPCO 2013. These ceiling prices (beyond which the specified drugs should not be sold) are updated every financial year. These drugs are considered critical for public health and are subject to price control to prevent unaffordable pricing. However according to a market study conducted by the Competition Commission of India (CCI), only around 17.7% of the entire pharmaceutical market is currently under price regulation. For the remaining formulations including non-scheduled drugs and new drug formulations that are not listed in the NLEM, there is no effective price regulation, and competition remains an uncertain source of price discipline. Hence although regulatory measures by DPCO and NPPA for drug price regulation are important, the vast majority of drugs marketed in India are effectively escaping from price control.

The exclusion of majority of drug formulations from effective price control often leads to inflated Maximum Retail Prices (MRPs) and high trade margins, imposing a significant financial burden on many patients and families. The absence of price capping for such non-schedule drugs is associated with proliferation of dose formulations and combinations, which may be employed to evade price control measures. Additionally, it is reported that high trade margins enable a large portion to be shared with intermediaries in the medicine trade, as well as often being used to finance less ethical promotional practices focussed on the prescribing medical practitioners. As a result, medical practitioners may tend to prescribe the most expensive brands rather than equally effective, more affordable brands, directly conflicting with the interests of patients.

Retailers' margins in the pharmaceutical market were examined in the CCI market study, which found that the median retail margin was around 28% across different categories, such as analgesics, antibiotics, vitamins, and minerals. The median wholesale margin and retail margin were estimated to be around 9% and 28% of customer price respectively, plus taxes (GST) at 12% of the price to the customer. There have been various representations and complaints regarding high trade margins charged by retailers; it is alleged that there may be huge difference between the sale price at which the company sells to the distributor, and the MRP printed on the product¹⁰. Given this context, demands have been made regarding rationalisation of trade margins on non-scheduled drugs.

Dual power of hospital pharmacies as sellers to 'captive audience' and bulk buyers

Within this overall setting, private hospitals are distinct type of medicine retailers, which can

⁹ Drug pricing in India: regulations to foster innovation, accessibility and affordability (2018). UK India business council. https:// www.ukibc.com/wp-content/uploads/2018/07/UKIBC-Report-Drug-Pricing-in-India.pdf

¹⁰ Government of India (2018). High trade margin report. Ministry of chemicals and fertilisers. Department of pharmaceuticals

powerfully capitalise on their influence over their 'captive audience' of indoor patients to sell medicines at considerably inflated prices.

> Patients are being forced to buy highpriced drugs, medical devices, etc, from hospital pharmacies. This is because patients are in a relatively weaker position compared to hospitals. ... hospital pharmacies have a spatial monopoly on drugs and medical devices. Moreover, hospitals can not only overcharge and force patients to buy products at their pharmacies, but can also negotiate with drug and medical device manufacturers to get lower purchasing prices. This is because hospitals buy these products in bulk, which in turn gives them more bargaining power.¹¹

A patient admitted in a private hospital generally hands over decision making regarding their treatment to the hospital employed doctors. In this situation, in contrast to the dictum 'the consumer is king', the 'consumer is bonded' due to restrictive conditions imposed in the hospital setting.

> Here, patients, like passengers, become a captive audience. This transformation not only reduces patients to passengers or customers, but also removes all the urgency associated with the life-and death situation of a patient. This urgent situation rather becomes a characteristic of the helpless customer, which is to be ultimately exploited by the seller. It also reduces the importance of life-saving drugs and medical devices to mere products being sold in any retail shop.¹²

The NPPA study¹³ in 2018 on medicines and consumables related overcharging analysed the

bills of four major private hospitals in Delhi - NCR. This study found that these hospitals had been making profit margins up to 1,737% on drugs, consumables (like surgical masks, hand gloves, etc.), medical devices and diagnostics. In fact, the inflated prices of these items constituted around 46% of a patient's bill. The study by NPPA found that in order to claim higher profit margins, private hospitals are mostly prescribing and dispensing non-scheduled branded medicines which are outside price control¹⁴. Furthermore, the study highlighted market distortions where hospitals benefit from inflated Maximum Retail Prices (MRPs), without manufacturers receiving any corresponding benefits. It is pointed out that certain consumables (e.g. transfusion sets, gloves, masks etc.), which are not classified as drugs under the Drugs & Cosmetics Act, are not subject to price control or official monitoring at all. This lack of regulation allows hospitals to charge highly inflated prices, contributing to increased healthcare costs for patients. This report from NPPA has also shed light on the practices of certain commercial hospitals, who induce their admitted patients to purchase medicines exclusively from their own hospital pharmacy -

Most of the drugs, devices and disposables were used and sold by the hospitals from their own in-house pharmacies and the patients were given no choice or opportunity to procure these articles from outside the hospitals where prices are supposed to be lower in most cases because of some 'discounts'.¹⁵

This restriction limits patient choice and prevents them from accessing potentially lower-priced alternatives available outside the hospital premises. This provides a highly lucrative avenue for profit

¹¹ Manu Kanchan, Hospital Pharmacies: Retail Shops within Corporate Hospitals; Economic & Political Weekly March 18, 2017

¹² Ibid, Manu Kanchan, 2017

¹³ National Pharmaceutical Pricing Authority (NPPA), Office Memorandum, 20.02.2018

¹⁴ www.newsclick.in/private-hospitals-making-profits-1737-finds-study

¹⁵ Ibid, NPPA 2018

making by private hospitals, in fact it has been estimated that the pharmacy department alone contributes more than 30% to hospital revenues.¹⁶

The phenomenon of drug profiteering, which has been routinely observed in retail shops and private hospitals, experienced a pronounced exacerbation during the COVID-19 pandemic. A recent study¹⁷ from Maharashtra related to the pandemic reveals that sale of medicines was one major area through which private hospitals charged patients heavily during the pandemic. Out of the sample of hospitalised COVID patients, 76% of the patients had medicine expenditure above INR 50,000 and 66% of the patients had medicines related expenditures above INR 1,00,000. On comparing the proportion of medicine and hospitalisation expenditure, it turned out that medicine expenditure constituted more than half of the total hospitalisation bill in 29% of the episodes.

Drug prices as basis for profiteering during the pandemic

The COVID pandemic is reported to have impacted the affordability and accessibility of various medicines. Particularly during the second wave of COVID, there was a dire shortage of certain medicines, including Remdesivir, Tocilizumab etc.,18 linked with the unprecedented surge in demand. There is also anecdotal evidence of irrational use of medicines with over-prescription, such inflated demand having induced price spikes and even black marketing. There was anecdotal information from certain practicing doctors about overcharging on medicines being used as a 'compensatory mechanism' by many private hospitals, to sustain higher profit margins in the face of official regulation of rates. Given the current lack of systematic evidence focusing on COVID-related medicine overcharging in private hospitals during the pandemic, SATHI has undertaken this study related to selected hospitalised COVID patients from Maharashtra, with the following main objectives:

- Assessment of the overall scale of expenditure on medicines provided in private hospitals, concerning the sample of COVID patients
- Identification of a set of indicator medicines. regarding which further detailed analysis of margins being charged would be carried out
- Analysis of possible high charging on each of these selected medicines keeping in view COVID period regulations in Maharashtra, while comparing the charged prices with prevailing hospital procurement costs.
- Drafting policy recommendations concerning regulation of the prices of medicines provided through private hospitals.

We faced a wide range of challenges in conducting this study, one of the most important being lack of transparent availability of information on margins related to trade in medicines, and procurement prices for various medicines which are availed of by private hospitals. SATHI team dealt with this situation by estimating prevailing procurement rates, through information provided by certain private hospitals as well as from specific medicine distributors in Maharashtra.

¹⁶ Shukla, S - Prescription for Healthcare, Express Healthcare, April 2009, quoted in Mani Kanchan, 2017

Marathe S, Shukla A, Yakkundi D. Overcharging by Private Hospitals during the COVID Pandemic in India: A Patient-based 17 Analysis of Rate Regulation. Int J Med Public Health 2023; 13(1):20-30.

https://m.economictimes.com/industry/healthcare/biotech/pharmaceuticals/crisis-over-shortage-of-remdesivir-fabiflu-to-end-by-18 next-fortnight/articleshow/82340650.cms

2. Methodology

Background of cases selected for the study

n the first (2020) and second (2021) waves of COVID-19 in India, a wide variety of medications were used for treating critical, hospitalised patients. Medicines like Remdesivir, Tocilizumab, Meropenem, Enoxaparin and many higher-end antibiotics, antivirals, steroids, anticoagulants, etc. were prescribed widely in a situation where the boundaries between 'experimental care' and 'excessive / irrational care' were often blurred. Although patients and their caregivers were acutely aware of the expensive and unaffordable nature of treatments being given through private hospitals, they were naturally in no position to question these. It was frequently observed that the scale of bills for medicines were comparable to the scale of already huge private hospital bills.

Anticipating exorbitant overcharging by private hospitals, Maharashtra Government had issued orders in April – May 2020 to ensure rate capping for hospitalised COVID treatment. Official auditors made significant efforts to contain private hospital bills for COVID patients, especially in larger cities, leading to some reduction of such bills. However experiences of overcharging by private hospitals in different parts of Maharashtra remained widespread during the COVID second wave in 2021. Hence the social networks Corona Ekal Mahila Punarvasan Samiti and Jan Arogya Abhiyan conducted a rapid survey in September 2021, to document the scale of overcharging experienced by COVID widows and patient families¹⁹. This participatory survey covered 2579 respondents, including many women who had lost their husbands to COVID, and demonstrated that 75% of the respondents had incurred private hospital expenses which were excessive compared to regulated rates declared by the Government of Maharashtra.

Based on wide publicity to these survey findings and advocacy with the State government, in October 2021 the State Health department initiated a unique process of audit of private hospital bills regarding COVID patients and families who had complaints of overcharging. More than 450 cases

¹⁹ www.thewire.in/health/maharashtra-survey-finds-private-hospitals-routinely-overcharged-covid-patients

registered for this audit process, by submitting their documents like detailed hospital bills²⁰. Along with the mentioned social networks, SATHI team was engaged in the complex process of technically supporting this audit in collaboration with the public health system. In the meantime, SATHI initiated an in-depth study to analyse the experience of 100 hospitalised COVID patients who had faced overcharging, who consented to share information about their episodes, and were in position to provide complete documentation such as hospital and medicine bills. Members of the social networks Corona Ekal Mahila Punarvasan Samiti and Jan Arogya Abhiyan enabled referrals to potential respondents.

Profile of 40 hospitalised COVID cases selected for medicine pricing study

While analysing expenditures by COVID patients in private hospitals, various types of high expenses came to light; expenditure on medicines, nonconsumable materials, disposable materials, and surgical items played a significant role in increasing hospitalisation bills. Given this background, SATHI initiated this detailed study of medicines bills concerning hospitalised COVID patients from the second wave in Maharashtra. These were drawn from the larger group of patients who had submitted medical bills during the overcharging audit process.

In the mentioned study of 100 patients and their experiences of overcharging in hospital bills, we observed various patterns in their medication bills. We primarily identified four types of billing scenarios while examining the excess charging patterns.

- The first scenario involved hospital bills where the entire cost of medicines was listed under a single heading, without any specific details about the medicines or surgical items used during the patient's hospital stay.
- The second scenario included cases where patients received hospital bills according to COVID package rates, without separate,

detailed expenses for each medicine. In these instances, the hospital provided most of the medications, which were included in the standard package. However, patients occasionally had to purchase higher-end medicines like Remdesivir, Meropenem etc. separately, often without receiving receipts.

- 3. In a few cases where multiple family members were hospitalized at the same time, medications were sometimes procured from outside sources. However, it became difficult to attribute the medication expenses to each individual patient, as various bills often got mixed up.
- 4. The fourth category was of patients who had been billed for the COVID hospitalisation episode, while being provided detailed bills for each of the medicines given by the inhouse hospital pharmacy, or by an attached medical store within the premises of the hospital. In some of the instances purchases were made from medical stores outside the hospital, which were not directly associated with the hospital.

Due to lack of availability of necessary information in the first three types of cases, we could not take these patients for study. We selected only certain cases drawing upon patients from the fourth category, where the complete medicine bills were available for the COVID hospitalisation episode. Another criterion for the selection of cases was the total amount of medicine related bills, since we were interested in analysing those cases where the medicine purchases were substantial enough for analysis; we selected such cases where the total spending on medicines during COVID hospitalisation was above Rs 50,000. In this way 40 patients were selected, for whom complete medicine bills were available, and whose spending on medicines during hospitalisation was over Rs. 50,000.

²⁰ www.theleaflet.in/regulation-of-private-hospitals-during-covid-gets-a-booster-of-social-accountability

All the selected cases had been hospitalised during the second wave of COVID-19 in Maharashtra in 2021. Most of these patients had been critically ill, with 30 (75%) having died during the period of hospitalisation and 10 (25%) having survived. (Table 1)

Table 1: Profile of patients included in the study

Status of the patient	No. of patients
Survived	10
Deceased	30
Total number of patients	40

In case of some of these patients, they had undergone treatment in two successive hospitals for treatment of the COVID episode. These 40 patients had undergone a total of 46 hospitalisation episodes (Table 2), this care having been provided by 42 different hospitals which were located in 13 districts across Maharashtra, covering all regions of the state.

Table 2: Number of hospitalisation episodesrelated to sample patients

Number of Hospitalisation regarding sample patients	episodes
One hospitalisation episode	34
Two hospitalisation episodes	6
Total hospitalisation episodes	46

For the selected 40 cases, the period of hospitalisation ranged from 1 day to 36 days. Nearly half of the episodes (21) had hospitalisation period of 7 to 14 days. (Table 3)

Table 3: Number of days of hospitalisation forsample patients

Number of days of hospitalisation in case of all episodes			
Less than 7 days	11		
7-14 days	21		
Above 14 days	14		
Total episodes 46			

In the majority of these episodes (26) medicines had been purchased from an in-house hospital pharmacy, while in some of the cases (16) purchases were made from medical stores outside the hospital, which were not directly associated with the hospitals. (Table 4)

Table 4: Type of pharmacy facility concerninghospitalisation episodes

Type of pharmacy facility concerning hospitalisation episod	accessed les
In-house hospital pharmacy	26
Pharmacy not associated with hospital	16
Both types of pharmacies	4

Criteria for selecting medicines for indepth price analysis

All medicine-related bills were entered into Excel with patient-wise details like date of each bill, name of medicine, quantity purchased, rate per unit if mentioned, discount received if any, taxes if mentioned in the bill, the MRP of the medicine, and the total amount for quantity purchased. Over 6800 rows were generated based on various bills, amounting to total expenditures of Rs. 69,69,289 submitted on behalf of 40 patients. All this entered data was further scrutinized by their type – medicines, surgical items, disposables or consumables. Medicines were further categorized as tablets, capsules, injections, intravenous infusions, ointments, etc. A further step was classifying all the medicine formulations belonging to various brands into a set of Therapeutic Entities (TE), reflecting the underlying single ingredient of each medicine (e.g. Doxycycline) or combination (e.g. Piperacillin + Tazobactam). As expected, most TEs were associated with multiple brands.

Following this a total of 59 TEs were shortlisted for further analysis, to focus on medicines which were

higher priced, or were more frequently used, or in some cases had both features. We selected those TEs where in case of the associated one or more brands, the total expenditure on this medicine in case of at least one patient was above Rs. 2000. Every shortlisted TE was associated with different strengths and brands, and often each particular brand had been prescribed in case of more than one patient. These aspects made the analysis somewhat complex as described further.

S. No.	Therapeutic Entity (TE)	Number of patients in case of whom TE was used
1.	ANIDULAFUNGIN (injection)	2
2.	CASPOFUNGIN (injection)	4
3.	CEFTAZIDIME + AVIBACTAM (injection)	2
4.	COLISTIMETHATE SODIUM (injection)	9
5.	DOXYCYCLINE (injection)	5
6.	ENOXAPARIN (injection)	35
7.	FAVIPIRAVIR (oral)	7
8.	MEROPENEM (injection)	28
9.	METHYL PREDNISOLONE (injection)	25
10.	MINOCYCLINE (injection)	4
11.	PARACETAMOL (infusion)	9
12.	PIPERACILLIN + TAZOBACTAM (injection)	12
13.	POLYMYXIN B (injection)	2
14.	PREDNISOLONE (injection)	6
15.	REMDESIVIR (injection)	30
16.	TEICOPLANIN (injection)	12
17.	THYMOSIN ALPHA (injection)	3
18.	TOCILIZUMAB (injection)	6
19.	ULINASTATIN (injection)	6
20.	VORICONAZOLE (oral)	5
21.	SODIUM CHLORIDE SOLUTION (infusion)	38

Table 5: Frequency of use of high expenditure medicines in case of 40 patients

Finally a set of high expenditure TEs with selected strengths were identified. During this process certain medical experts were consulted who had worked extensively treating COVID cases, helping to identify the most commonly used strengths of medicines used for COVID treatment. Thus 21 TEs were finally shortlisted for detailed analysis. This covered most of the higher-priced medicines, as well as certain medicines which had been prescribed and purchased quite frequently for treating various COVID patients. **We have termed these 21 TEs as 'High expenditure medicines' in the further analysis.**

Those medicines which had lower unit prices, those which were less frequently used, and surgical and therapeutic consumables were kept aside while shortlisting these TEs for detailed analysis.

These 21 high-expenditure medicines together amounted to 62.4% of the total medicine expenditures incurred in case of the 40 selected patients under the study. These 21 medicines were very commonly used in this group of patients; only one patient was found among the 40 patients, where none of these specific high-expenditure medicines had appeared in their bills. Among 27 out of the 40 patients, these 21 shortlisted medicines amounted for more than 50% of their total medicine expenditures. It may be noted that the average of total medicine-related bills for these 40 patients was very high at Rs. 1,74,232.

Estimating hospital procurement rates

As per Maharashtra government notification dated 31 August 2020, **the price charged by hospitals for higher-end medicines which were supplied by them as part of COVID treatment, was supposed to be provided at not more than 10% markup on the hospital procurement rate.** Hence keeping in view the objective of estimating whether excessive charging on medicines had been done by private hospitals, obtaining hospital procurement costs for various brands was the next step. Comparing the Cost charged to patients (CTP) with Hospital procurement costs (specific to different brands as applicable) was done as described below.

Obtaining hospital procurement rates for various medicines was quite challenging. For various hospitals, procurement costs of medicines were based on supplier-hospital transactions, or in some cases direct transactions of the drug manufacturer with larger hospitals. These direct transaction processes were more frequent during the pandemic, which was linked with the quantity of medicines procured by the hospitals on a day-to-day basis, and the fluctuating availability of various brands. These rates availed of by hospitals having in-house medicine departments were not transparently available in the public domain. Hence special attempts were made to obtain the prevailing hospital procurement costs for as many TEs and associated brands as possible, by communication with certain industry insiders, particularly certain small-medium private hospitals in Maharashtra which were willing to share their medicine procurement rates during 2021. These procurement rates obtained from certain small and medium sized private hospitals and specific medicine distributors are a reflection of the prevailing procurement rates for each of the selected medicines and brands in 2021; these have been used as a benchmark for the analysis of medicine pricing. (It is likely that for larger private hospitals, the procurement prices would have been significantly lower due to large bulk purchases, and hence the margins of profit could have been even higher than those estimated in this study.)

Related to the selected 21 TEs, in case of 18 TEs we were able to access the prevailing hospital purchase rates related to associated formulations with various strengths, based on which analysis of margins was carried out. Based on procurement costs made available for 2021, calculations were made regarding the level of margins charged by hospitals concerning the selected key brands related to high-expenditure medicines which were prescribed to COVID patients during the pandemic.

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Findings on medicine pricing and margins related to hospitalised COVID patients

NPPA schedule of price-controlled medicines for 2021. Majority (17 out of 21) of high expenditure medicines were outside the schedule. This situation is likely to have contributed to inadequate regulation of prices for the large number of medicines which fall outside the schedule.

Margins related to pricing of medicines which had been provided by hospital in-house pharmacies, and the margins on medicines which had been purchased from medical stores outside the hospital, were separately analysed. Based on the shortlisted 21 high-expenditure medicines, associated with these we could identify 46 formulations (brands and strengths) which had been supplied by hospital pharmacies, where relevant hospital procurement prices for 2021 were available to us. Analysis of margins was done, comparing the price to patient (as per bill) and price to hospital (as per prevailing hospital procurement rate), for each brand separately, as given in Table 6. We have mentioned brands in anonymised manner (e.g. Brand 1, Brand 2 etc.) to avoid association of particular companies with specific sales margins.

Table 6 : Margins related to medicines provided from hospital in-house pharmacies

Therapeutic entities and associated selected formulations	Strength	Price to patients incl. Taxes (rs.)	Cost to hospital as per market data (rs.)	% margin on prevailing procurement price
ANIDULAFUNGIN Inj.				
Anidulafungin Brand 1	100 mg.	11521	8858.3	30
CASPOFUNGIN Inj.				
Caspofungin Brand 1	50 mg.	13296.3	5808	129
COLISTIMETHATE SODIUM Inj.				
Colistimethate Sodium Brand 1	4.5 MIU	5385.1	715	653
DOXYCYCLINE HYDROCHLORIDE Inj.				
Doxycycline Hydrochloride Brand 1	100 mg.	950	181.5	423
ENOXAPARIN 40 mg Inj.				
Enoxaparin 40 mg Brand 1	40 mg.	427	176	143
Enoxaparin 40 mg Brand 2	40 mg.	425.4	175	121
Enoxaparin 40 mg Brand 3	40 mg.	425.6	269.5	58
Enoxaparin 40 mg Brand 4	40 mg.	425.5	176	142
Enoxaparin 40 mg Brand 5	40 mg.	425.5	242	76
Maximum Retail Price as per DPCO schedule (incl. GST)		456		
ENOXAPARIN 60 mg Inj.				
Enoxaparin 60 mg Brand 1	60 mg.	625	192.5	225
Enoxaparin 60 mg Brand 2	60 mg.	637.8	192.5	231
Enoxaparin 60 mg Brand 3	60 mg.	638.5	192.5	232
Enoxaparin 60 mg Brand 4	60 mg.	638.5	192.5	232
Enoxaparin 60 mg Brand 5	60 mg.	641.7	192.5	233
Maximum Retail Price as per DPCO schedule (incl. GST)		685		

Therapeutic entities and associated selected formulations	Strength	Price to patients incl. Taxes (rs.)	Cost to hospital as per market data (rs.)	% margin on prevailing procurement price
FAVIPIRAVIR Tablets				
Favipiravir Brand 1	Pack of 18 tablets (800 mg and 200 mg)	2560	1828.6	40
MEROPENEM Inj.				
Meropenem Brand 1	1 gm.	685	538.2	27
Meropenem Brand 2	1 gm.	990	385	157
Meropenem Brand 3	1 gm.	1313	385	241
METHYL PREDNISOLONE Inj.				
Methyl Prednisolone 500 mg Brand 1	500 mg.	975	363	169
Methyl Prednisolone 500 mg Brand 2	500 mg.	590	495	19
MINOCYCLINE inj.				
Minocycline Brand 1	100 mg.	2994.8	1693.6	77
PARACETAMOL Infusion				
Paracetamol Inf. Brand 1	1gm. / 100 ml	408	32.8	1145
PIPERACILLIN + TAZOBACTAM Inj.				
Piperacillin + Tazobactam Brand 1	4.5 gm.	490.1	110.9	342
Piperacillin + Tazobactam Brand 2	4.5 gm.	500.0	108.8	360
Piperacillin + Tazobactam Brand 3	4.5 gm.	490.5	93.5	425
Maximum Retail Price as per DPCO schedule (incl. GST)		493.2		
PREDNISOLONE Inj.				
Prednisolone Inj. Brand 1	125 mg.	332.8	99	236
REMDESIVIR Inj.				
Remdesivir Brand 1	100 mg.	3000	2200	36

Therapeutic entities and associated selected formulations	Strength	Price to patients incl. Taxes (rs.)	Cost to hospital as per market data (rs.)	% margin on prevailing procurement price
Remdesivir Brand 2	100 mg.	3490	3025	15
Remdesivir Brand 3	100 mg.	4800	3573	34
Remdesivir Brand 4	100 mg.	899	706.2	27
Remdesivir Brand 5	100 mg.	2450	1925	27
SODIUM CHLORIDE Infusion				
Sodium Chloride Infusion 100 ml Brand 1	100 ml	17.7	11.4	55
Sodium Chloride Infusion 100 ml Brand 2	100 ml	69.3	12.0	478
Sodium Chloride Infusion 100 ml Brand 3	100 ml	37.0	12.0	209
Sodium Chloride Infusion 500 ml Brand 1	500 ml	77.4	18.5	318
Sodium Chloride Infusion 500 ml Brand 2	500 ml	78.9	18.5	326
Sodium Chloride Infusion 500 ml Brand 3	500 ml	79.3	18.5	329
Maximum Retail Price for 500 ml. – Glass as per DPCO schedule (incl. GST)		37		
Sodium Chloride Infusion 0.45% Brand 1	500 ml	180.0	18.5	874
TEICOPLANIN Inj.				
Teicoplanin Brand 1	400 mg.	1856.6	495	275
THYMOSIN ALPHA Inj.				
Thymosin Alpha Brand 1	1.6 mg.	1999	1570.7	27
ULINASTATIN Inj.				
Ulinastatin Brand 1	100000 IU	3566	2310	54
Ulinastatin Brand 2	100000 IU	3865	1815	113
VORICONAZOLE Tablets				
Voriconazole Brand 1	200 mg. x 4 tabs	1181.3	715	65
Voriconazole Brand 2	200 mg. x 4 tabs	1056.4	715	48
Voriconazole Brand 3	200 mg. x 4 tabs	3200	1595	101

Here we can observe that in case of nearly all these brands supplied by various hospital pharmacies, the margins are much higher than that specified by Maharashtra government as part of COVID regulations (maximum 10% markup was allowed). None of the margins charged by various hospitals were compliant with Maharashtra Govt. COVID related regulations. Hence we can state that in case of 100% (46 out of 46) of these higher-expenditure medicines, the patients were overcharged by hospital inhouse pharmacies, since the margins were higher than those specified by Maharashtra government COVID regulations.

Although the DPCO norms are legally applicable only to scheduled drugs, here we have treated these as a general benchmark to assess margins to retailers even for non-scheduled medicines. Keeping this norm in view, only 2 out of 46 margins (4.3%) could be considered within DPCO norms for retailer margins related to scheduled drugs (16% margin allowed for retailer)²¹. This means that the vast majority (95.7%) of margins charged by hospitals were higher than DPCO norms for scheduled drugs. While this near-universal prevalence of high margins charged by hospitals is a matter of grave concern, when we examine the actual scale of high margins in case of these 46 medicines, this is even more serious (Table 7).

In case of nearly half (22 out of 46) of the medicines the sale margins were over 150%, implying huge scale of excess margins. For all these 22 medicines, the involved hospitals charged patients more than two and half times higher amounts, compared to their own purchase costs. The most common category of margins was 201-400% higher sale margins, where hospitals charged patients three to five times higher rates compared to their procurement rates.

It is relevant to note that the trade margins charged by hospitals even for the medicines covered under the DPCO schedule, were significant. The prices charged by hospitals for these medicines were generally at the level or slightly below the level of official MRP. However these MRPs were often much higher than the procurement prices. For Enoxaparin 40 mg. inj. the median margin was 121%; for Enoxaparin 60 mg. inj. the median margin was 231.5%; and for Piperacillin + Tazobactam inj. (4.5 gm) the median margin was 360%. All these medicines in mentioned dosage are covered under the DPCO price regulation schedule. Taking together the 14 medicine formulations in this study which were covered under DPCO schedule, the median margin charged by hospitals was 228%. This indicates that even for

Category of sale margins	Number of medicines	Range of sale margins in category
Less than 50%	11	14 to 48%
51 to 100%	7	54 to 85%
101-200%	8	101 to 169%.
201-400%	14	209 to 360%
400 – 1000%	5	423 to 874%
Above 1000%	1	1145%

Table 7: Categories of	of sale margins	related to hosp	ital in-house	pharmacies

²¹ The Drugs (Prices Control) Order, 2013 states as follows:

Section 7. Margin to retailer – While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.

medicines under drug price control, there are huge margins between the price at which medicines are purchased by hospitals, and the MRPs at which such medicines are generally provided to patients.

Normal saline (500 ml.) is also covered under the DPCO schedule, however we have treated this product somewhat separately from medicines, since this is more in the nature of a regularly provided medical product given in multiple units to nearly all hospitalised patients, rather than a specialised medicine. In terms of its relatively low unit price but nearly universal use in large quantities among hospitalised patients, Normal saline shares some features that are similar to medical consumables. For the brands of Normal saline (500 ml.) where we could compare the margins between prevailing procurement price and price to patient, the margins for hospitals were overall guite high, being in the range of 318% to 329%, showing inflation by over four times compared to the price to hospital.

Further it is pertinent that for one medicine in this list which was specifically price controlled

during COVID that is Remdesivir - the margins were among the lowest. (We have only studied Remdesivir supplied by hospitals with proper billing, and did not have information about black marketing type inflated pricing which emerged in the periods when demand - supply imbalances were very acute; hence this study does not reflect those hyper-inflated prices.) While the price to patient for different brands of Remdesivir varied more than five-fold, the range of margins for Remdesivir were 15% to 36%, with a median margin of 27% which is much lower than the sales margins for most other formulations which we studied. It can be safely assumed that none of the involved agencies - manufacturers, distributors or retailers including hospitals- were making a loss while selling this medicine which became emblematic of COVID treatment, although they were not making superprofits. We can safely infer that regulation of prices which allows a trade margin to retailers at the level of around 30% is commercially viable, even though it may not be viewed as lucrative by some commercial agencies.

Table 8: Margins related to selected medical consumables provided from HospitalIn-house pharmacies

ltem name	Price Range in Hospital bills (minimum and maximum, Rs.)	Median of prices in hospital bills (Rs.)	Prevailing hospital purchase price (Rs.)	Margins between median prices on hospital bills and prevailing hospital purchase price (%)
Needle (No. 16)	3.60 to 4.40	4	0.63	535
IV set	40 to 270	160	11.6	1279
Oxygen Mask	310 to 650	570	55	936
PPE kit	215 to 800	600	175	243

We also attempted to analyse the prices related to some commonly used medical consumables like needles, IV sets, oxygen masks etc. provided by hospital pharmacies. This analysis was more challenging since standard brands were less prevalent, with considerable diversity of suppliers and often no brand name mentioned. As shown in the table above, there were very wide range of prices at which these items were charged to patients. Based on this information, we estimated the median prices charged to patients for each item. In case of consumables, due to less standard brands we were unable to match hospital procurement prices for exactly the same brand (as we did in case of medicines given above). Hence we obtained prevailing hospital purchase prices for these items from selected small - medium private hospitals, and used these for comparison. As evident from the table above, the estimated sale margins for these consumables was huge, especially for Oxygen masks (936%) and IV sets (1279%). An IV set which may have been purchased by the hospital at around Rs. 12 was sold to patients for amounts ranging upto Rs. 270! For these very commonly used consumable items, we can estimate that some private hospitals charged patients in the range of ten to thirteen times higher amounts, compared to their own purchase prices!

In case of PPE kits the maximum prices chargeable had been officially fixed at Rs. 600 per day, so here the margins were not as high as for the other consumable items. **But here too despite rate capping, these PPE kits were often supplied to patients at more than three times higher rates compared to the purchase prices for hospitals.** These figures are estimates based on available information, and some hospitals are likely to have charged somewhat more or less than these margins, however the overall scale of such very high margins charged on consumables appears totally unjustified.

Further in case of 31 medicine brands used in this sample of hospitalised patients which were

purchased from pharmacies outside the hospitals, the Maharashtra government COVID regulations related to hospitals did not apply. Hence the related margins could not be analysed using the same criterion. Also we did not have access to the price to retail medical stores for these brands, where discounts and prices might be somewhat different compared to procurement prices for hospitals. Overall hospitals tend to have larger scale of purchases, especially bigger hospitals which purchase in bulk and sometimes procure directly from manufacturers. Hence for hospitals the discounts are likely to be overall higher and effective procurement prices might be somewhat lower, compared to those for retail medicine stores.

Another related point which we came to know about from some of medicine wholesalers is that hospitals which purchase larger amounts of certain medicines frequently receive 'perks' or discounts in kind, such as extra free amounts of the same medicine (e.g. if ten boxes are purchased, then one or two added boxes are given free etc.). Such discounts are obviously very difficult to track or analyse, and since they tend to further bring down the purchase price for the hospital, they correspondingly increase the trade margins even more. Given the high MRPs for many non-scheduled medicines, the overall margin between ex-factory price and printed MRPs is often huge, allowing for provision of significant discounts at various points in the trade chain. These 'incentives' induce retailers to procure and sell those particular products in larger volume, where they get higher margins. The entire chain of trading related to medicines is characterised by such 'insider' practices which are not transparent to independent researchers and the general public, but can promote profiteering in various ways.

Discussion and suggested directions for change

s evident from the studies quoted in the background section of this report, the challenge of ensuring rational drug pricing in India is guite complex and multi-dimensional. Significant margins are charged on sales of medicines, linked with chains of profit-making which involve large sections of manufacturers, distributors, retail medical stores, and private hospitals providing medicines to their patients. Private practitioners who may prescribe specific 'preferred' brands to patients in exchange for 'gifts' and promotional incentives from pharma companies, are also often complicit in this complex web of profit-making. All of these influential actors reap benefits in different ways from the trade in medicines, which is generally at the cost of ensuring affordable medicines for patients.

There are well known, huge information asymmetries during doctor-patient interactions, and information distortions at the level of the doctor-drug company interface. The patient does not decide which medicine they will purchase, rather in most cases it is the prescribing doctor who decides the brands to be purchased by the patient; however doctors are themselves prone to influence by powerful drug companies. These knowledge and power asymmetries contribute to the ubiquitous situation of market failure in case of the medicines market. The widespread prevalence of irrational medicines and combinations (which are often higher priced than single ingredients but strongly promoted) adds a further dimension to profit making by the industry, while not being clinically justified.

This entire situation makes effective regulation of the pharmaceutical industry by governments, who must act on behalf of the public, absolutely essential. However the current drug price regime in India based on DPCO based regulation has huge gaps, which are well known and documented. These gaps allow the vast majority (over 80%) of current formulations to remain out of the price control schedule, enabling their manufacturers to largely escape price regulation. This background of overall high profit margins on out-of-schedule medicines is linked with the ability of manufacturers to share significant part of their large margins with medicine retailers, including private hospitals which provide medicines to patients. As seen in this study, the majority (17 out of 21) of the high expenditure medicines which were identified through medicine bills were outside the DPCO schedule.

It is within this broader, complex context, that we need to understand the peculiar character of hospital based pharmacies - which can strongly influence both demand (through prescribing by their doctors) as well as supply (through sale of preferred brands, which may fetch higher sale margins). As mentioned above, hospitals become unique retailers having a 'captive audience' of patients, who are highly vulnerable and hand over decision making regarding medicine purchases to the hospital, which also becomes the seller of these medicines. In this setting, all mythical concepts of 'fairness' of the 'free market' completely evaporate. The buyers (patient and caregivers) have effectively very little choice, except for perhaps exercising the extreme option of exiting from the hospital itself midway during treatment, which is generally unviable for various reasons.

It is with this background that FDA, Maharashtra had issued an order in January 2016 that all hospitals should display a notice to inform patients that they can buy medicines from any authorised pharmacy of their choice, and they cannot be compelled to buy the medicines only from the hospital pharmacy²², which was reiterated by FDA, Maharashtra in Dec. 2022. However this important order was neither adequately publicised, nor was it effectively implemented. It should also be noted that the original orders issued by Maharashtra government in April 2020 for rate regulation on treatment of hospitalised COVID patients, did not cap the margins to be charged by hospitals on medicines supplied by them. It was only in the subsequent order issued in August 2020, where the stipulation was made that private hospitals should charge margins not more than 10% on sale of higher-end medicines and other medical items for COVID patients. However this point was mentioned in the order in rather indirect and less prominent manner, and no specific modalities were defined to practically ensure this important but somewhat technically complex capping of margins during supply of higher end medicines by hospitals.

Given this entire background, the findings of this study should not come as a surprise, even though the huge margins charged by several private hospitals on sale of various medicines are quite striking. The phenomenon of high trade margins being charged by medicine retailers, including hospitals, was widely prevalent even before the COVID pandemic, and has continued beyond the pandemic also. However the pandemic situation exacerbated the demand - supply imbalances, and the lockdowns and shortages of certain medicines whose demand surged, created conditions where many hospital pharmacies as well as independent medical stores could charge high margins compared to their procurement prices. Whatever discounts that were being passed on to patients earlier, were now often withdrawn. As shown in this study, these margins were frequently huge, being commonly associated with prices that were inflated at levels in the range of 200 to 400%. There is also an inference that private hospitals 'compensated' for some curbing of their incomes due to official rate regulation during COVID, by higher charging on medicines supplied by their pharmacies²³. The COVID epidemic provided opportunities for extra charging on certain expensive medicines which

²² https://health.economictimes.indiatimes.com/news/policy/maharashtra-fda-ends-monopoly-of-hospital-pharmacies/51224874 See official order at - https://fdamfg.maharashtra.gov.in/SOS/ViewPDF_NOT.aspx?COD=002&ST_CD=MH

²³ Marathe S, Shukla A, Yakkundi D. Overcharging by Private Hospitals during the COVID Pandemic in India: A Patient-based Analysis of Rate Regulation. Int J Med Public Health 2023; 13(1):20-30

were in short supply. A senior physician involved in treating COVID patients, who also owns a private hospital, has stated the following –

Covid was not only a health emergency, but it was also an emergency which exposed our price controlling system. As a physician and hospital owner, I can say that the rate difference between Hospital procurement price and MRP for medicines remains massive. For example, during COVID period Amphotericin-B which was recommended for Black Fungus was in short supply and was sold to patients at Rs. 15,000 for 50 mg. against an MRP of Rs. 7400, while the stockist price was just Rs. 1360. In this way the medicine was sold to patients at over ten times of its price to stockists. It seems we have not become wiser even after the pandemic, although this is the right time for government to drastically bring down the huge profit margins charged on medicines, providing huge relief to patients. (Personal communication by Dr. G.S. Grewal, Former President of Punjab Medical Council and proprietor, SAS Grewal Hospital Ludhiana).

While the COVID pandemic has now receded, the 'permanent pandemic' of profiteering through inflated prices of medicines continues unabated. If one of the many lessons emerging from this pandemic is that super-profiteering on sales of medicines must be effectively checked to protect patients, then a range of policy measures need to be urgently implemented.

Given this entire context, two major levels of action emerge for ensuring affordability of essential medicines, including those provided by hospital pharmacies. **The primary set of measures is related to effectively bringing all required** medicines under rational price control. This would mean that the MRP of each medicine as set by manufacturers would be brought under proper regulation to ensure affordable prices. A secondary set of measures is supplementary and may especially be implemented in the interim period until the DPCO regime is adequately expanded and strengthened, though these measures could also positively shape the larger price control regime. These secondary measures would deal with high trade margins charged by intermediaries in the trading chain, especially hospitals which sell medicines. Given the limited focus of this study on margins charged by hospitals on sale of medicines and consumables, in this report we will briefly reiterate key general measures required for regulation of medicine pricing, followed by some elaboration of specific measures related to containment of margins on sales of medicines, especially during their sale by hospitals.

Some general policy measures required for effective regulation of medicine pricing

Many health activists and experts have commented upon the severe limitations of the current drug price regulatory regime, which need to be urgently overcome through a comprehensive and interrelated set of policy actions²⁴. Discussing these in detail is beyond the scope of this short study. To mention just a few salient points, the wide range of medicines which are used commonly and have rational justification for use, should all be brought under the drug price control schedule. The schedule must be enlarged to include more than just NLEM medicines and should cover entire therapeutic classes rather than just individual medicines, while covering all relevant dosage forms for each medicine. Current loopholes which must be plugged include stratagems to escape price regulation by bringing in expensive 'me-too' drugs in the same therapeutic

24 For deeper treatment of this subject see 'Access to Essential Medicines' by Jan Swasthya Abhiyan at http://phmindia.org/wpcontent/uploads/2018/06/drug_blet.pdf

and 'Medicine Prices and Affordability' by All India Drug Action Network at https://aidanindia.files.wordpress.com/2009/04/drugprices-and-affordability.pdf

category as existing medicines, and modifying the dose content of formulations to evade the schedule (such as marketing Paracetamol 650 mg. which falls outside of the schedule, in preference to the routine dosage form Paracetamol 500 mg. which is under price control). Checking these widespread profiteering-oriented practices would bring down prices of many costlier drugs such as many of those mentioned in this study. Further the market-based price fixation being followed by the NPPA should be replaced with the earlier used cost-based price control mechanism, which could significantly bring down ceiling prices for all drugs covered by the schedule. Ensuring a universally applied foundation of cost-based pricing, combined with reasonable capping of trade margins, would provide a rational framework for drug price control.

We should note that the larger strategy of ensuring access to quality generic medicines is an area linked with both pricing and access, which could have major impacts in terms of bringing down medicine prices for consumers. In addition, irrational medicines and scientifically unwarranted drug combinations should be completely weeded out through effective regulatory measures, to minimise prescribing and usage of such unnecessary though often expensive medications. Any approvals for new medicines should be provided only to those products having a clear advantage in terms of offering better treatment, safety or cost. These measures must be accompanied by effective regulation of unethical drug promotion practices, which majorly contribute to inflated prices along with frequent irrational prescribing²⁵.

Need to curb excessive trade margins during sale of medicines

Within the mentioned larger context of need for effective control of drug prices, we need to view the phenomenon of high trade margins to intermediaries. Unregulated pricing of nonschedule medicines allows manufacturers to provide high trade margins on many medicines to retailers, including hospitals with pharmacies. This creates a perverse dynamic through which more expensive brands and medicines (contentwise equivalent to less expensive standard formulations) may get commercially pushed, because they are accompanied by higher margins to the intermediaries. As noted by the Competition Commission of India –

> one of the key ways in which manufacturers compete to have their products stocked and sold by pharmacies is by offering them high margins. ... Hospital pharmacies and doctor-run pharmacies, as informed by stakeholders, are a key route for the supply of high-margin, high-MRP drugs. In hospitals where purchase of prescribed drugs from hospital pharmacies is in-patients, mandatory for hospital pharmacies are completely insulated from retail competition. ... particularly in such therapeutic categories for which hospital pharmacies are the key dispensers of drugs, and such medications which can be offered only in a hospital setting, margin competition leads to higher price of drugs²⁶.

Paradoxically in these situations competition leads to overall higher, not lower prices! Similarly -

Hospitals often have exclusive arrangements with in-house pharmacies, diagnostic labs etc. and may provide multiple services in a bundle or a package.... 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

²⁵ Shukla A. (2022). Pharma Freebies, Free from Regulation. Economic and Political Weekly, Commentary Vol. 57, Issue No. 40, 01 Oct, 2022

²⁶ Competition Commission of India, Market study on the Pharmaceutical sector in India: Key Findings and Observations, 2021

hospital premises. ... 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 margin²⁷.

Keeping in view these situations, the Department of Pharmaceuticals constituted a 'Committee on High Trade Margins in the Sale of Drugs' which was chaired by Mr Sudhansh Pant, then Joint Secretary, Pharmaceuticals. This official committee observed that:

> The trader gets bargaining leverage and when he is able to sell at the printed MRP, he gets a higher trade margin. Higher MRP therefore provides an incentive to the retailer to sell those brands which have higher MRP printed on them. The patient is always at the receiving end. He cannot decide the bargaining level and most of the times he is guided by the printed MRP. Thus high MRPs is a tool to cheat the helpless consumer. ... There is thus no principle governing the MRPs primarily because there is no control on trade margins, except in the case of scheduled drugs where ceiling/retail price is fixed by the Government. Fixing the MRP is, therefore, free for all and largely arbitrary in which the consumer is the net loser²⁸. (emphasis added)

Within this broader context, the Competition Commission of India has subsequently investigated the specific issue of certain private hospitals in Delhi-NCR charging very high margins to patients on medical consumables such as syringes. In case of Max hospital, it was found that the hospital had been compelling its in-patients to purchase products from its in-house pharmacy, and it was reported that the hospital had earned huge profit margins by sale of different syringes, ranging from 277 per cent to 527 per cent in the financial year 2015-16. The official agency found that huge profit margins were being earned by super speciality hospitals through sale of products to **'locked-in patients'** which amounted to **'abuse of position by the hospital'** by charging **'supra-competitive prices'** for products and services, which included but were not limited to syringes²⁹.

More recently in 2022 the Competition Commission of India conducted another investigation in Delhi – NCR and it was reported that 12 super-speciality hospitals of major chains in the region **'abused their positions of dominance'** by charging **'unfair and excessive prices'** on items including medicines, medical devices, and consumables.³⁰ As per the report syringes and surgical instruments were priced higher as compared to other consumable vendors. Although medicines were not sold beyond maximum market prices, the hospitals made large profits since they were procured at lower rates.³¹

Hence we can see that the general issue of high prices of medicines has a range of interlinked determinants, which need to be addressed through effective and comprehensive implementation of a greatly strengthened and expanded Drug Price Control Order regime. Within this larger context, the high trade margins charged by intermediaries, especially medicine retailers are a matter of major concern. And further within this setting, in the words of CCI the 'abuse of position' by many private hospitals related to their patients, is a special

²⁷ Competition Commission of India, Making Markets Work for Affordable Healthcare, 2018

²⁸ Department of Pharmaceuticals, Report of 'Committee on High Trade Margins in the Sale of Drugs', 2016

²⁹ www.business-standard.com/article/economy-policy/cci-to-probe-pricing-practices-at-super-speciality-hospitals-indelhi-118090501166 1.html

³⁰ www.moneycontrol.com/news/business/indias-largest-hospital-chains-abused-dominance-through-excessive-pricing-finds-cciinvestigation-9219251.html

³¹ www.freepressjournal.in/business/private-hospital-chains-in-delhi-caught-jacking-up-prices-in-competition-commission-of-indiasreport

kind of market distortion. This compels patients to purchase consumables and medicines from the hospital's own pharmacies at often higher prices, which deserves separate attention.

Policy options for regulating trade margins in sale of medicines

The need to regulate trade margins during sale of medicines has been recognised globally. A review of 27 European countries revealed that pharmacy sales margins were controlled in all 27 countries, while 21 of these countries also regulated wholesaler markups.³² WHO has developed guidelines regarding pharmaceutical pricing policies, which state that regulation of mark-ups particularly in settings where there have been no price control strategies, may lead to lower prices of medicines. Further regulation of mark-ups may be technically less complex to implement than other policy **options** as it requires relatively limited information about costs and the supply chain, and can be done with modest enforcement capacity. Based on such considerations, WHO recommends a range of measures on regulation of trade margins including the following³³ :

- As part of an overall pharmaceutical pricing strategy, countries should consider regulating distribution chain mark-ups (i.e. regulation of distributors and wholesalers).
- As part of an overall pharmaceutical pricing strategy, countries should consider regulating retail chain mark-ups and fees (i.e. regulation of pharmacies, dispensing doctors, and dispensaries).
- If mark-ups are regulated, countries should consider using regressive mark-ups (i.e. lower mark-up for higher-priced products) rather than fixed percentage mark-ups

 In systems where discounts in the distribution chain occur, countries should consider regulation of discounts and should make them transparent.

It is relevant to note that the **Sudhansh Pant** - chaired committee of Dept. of Pharmaceuticals (2016) has provided a set of specific recommendations in the Indian context³⁴ which are broadly parallel to the WHO guidelines. These include the following recommendations -

- Putting a cap on trade margins to control exorbitant trade margins which fleece consumers.
- Trade margins of all drugs including stents and orthopaedic implants, whether scheduled or non- scheduled, ethical or non-ethical, generic or branded generics need to be capped so that the fleecing of consumers may be avoided.
- Capping of trade margins should be with reference to the Price to Trade (PTT)³⁵. Margins are to be calculated backward by putting a cap on them.
- Capping of trade margins on medicines in various categories is proposed as following –

S. No.	MRP of single unit of medicine in Rs.	Maximum trade margin as a % of MRP
1.	Upto Rs. 2	No capping of trade margin proposed
2.	More than Rs. 2 upto Rs. 20	50%
3.	More than Rs. 20 upto Rs. 50	40%
4.	Above Rs. 50	35%

³² Douglas Ball, WHO/HAI Project on Medicine Prices and Availability, Working Paper 3: The Regulation of Mark-ups in the Pharmaceutical Supply Chain, 2011

³³ World Health Organization, WHO Guideline on Country Pharmaceutical Pricing Policies, 2015

³⁴ Ibid, Department of Pharmaceuticals, 2016

³⁵ Price to Trade (PTT) is defined as the price at which the Manufacturer/Importer sells the medicine to first point of distribution, such as distributor or stockist.

- It is not recommended to put any cap on formulations with an MRP of upto Rs. 2 per unit, so that the apprehension of small value formulations going out of market may be ruled out. There should be higher trade margin cap for lower value drugs, and lower margins for higher value drugs.
- The benefit of any bonus offer should be passed on to the consumer by revising the margins as mentioned above proportionately. For example for a bonus offer of 1 + 1, the maximum trade margin in % terms will be halved.

The WHO guidelines (2015) and the Dept. of Pharmaceuticals (DoP) committee (2016) recommendations form an excellent basis for regulating medicine price margins in India. In fact implementation of the DoP committee (2016) recommendations is now long overdue in India, given further experiences of super-profiteering through excessive margins on sale of medicines and consumables, as revealed in the NPPA study on Delhi hospitals (2018), as well as in this study related to hospitalisations in private hospitals during the COVID pandemic in Maharashtra. Based on the DoP committee (2016) recommendations, the Alliance of Doctors for Ethical Healthcare has demanded³⁶ that the trade margins on medicines should be capped at a maximum of 30% difference between the factory price and price to the consumer.

In the absence of these important recommendations being implemented, certain kinds of ad hoc actions were taken in certain Indian states during the COVID pandemic, in an attempt to reduce excessive inflation of medicine prices by hospitals during the crisis situation. We have already mentioned the order by Maharashtra govt. mandating a cap of 10% margin on higher end medicines provided for COVID patients. Besides this, the West Bengal Clinical Establishment Regulatory Commission (WBCERC) issued the following Advisory³⁷ during the COVID pandemic:

WBCERC ADVISORY-14 (22 August 2020)

- 1. It is common knowledge of all, the medicines are now readily available of any brand in the State at a discounted price. Some of the traders would also offer discount to the extent of 20%. However, the clinical establishments are charging the in-house patients on M.R.P. for the medicines supplied by them either on their own or through the pharmacy operating in their premises.
- 2. The Commission thus feels, the clinical establishments must give at least 10% discount on all medicines and 20% discount in case of consumables supplied directly by them or through the pharmacy situated within their premises and/or tied up with the said clinical establishment. (emphasis added)

This is an interesting advisory since it clearly recognises that the MRPs mentioned for medicines and consumables are generally inflated, and that hospitals often receive large discounts from wholesalers or traders when they procure these items. Although the legal tenability of such an advisory, making discounts to patients mandatory might be debatable, the underlying intent is clear. The idea is that a part of the large discounts on medicines and consumables being enjoyed by the hospitals should be passed on to patients to provide them some relief from high prices. The underlying logic resonates with the WHO recommendation on regulation and transparency of discounts mentioned above.

³⁶ www.moneycontrol.com/news/trends/doctors-body-pitches-for-capping-for-30-percent-trade-margin-for-all-drugs-inindia-9341591.html

³⁷ West Bengal Clinical Establishment Regulatory Commission, Advisories and Relevant Orders, Guidelines to the Clinical Establishment of West Bengal, 2021

Specific measures to protect patients from profiteering related to medicines and consumables provided in hospital settings

As mentioned already, this short and somewhat exploratory study has focussed on the pricing of medicines charged by private hospitals to their patients. While being cognisant of the wider range of policy reforms which are definitely necessary to effectively regulate and rationalise medicine pricing, here we suggest a few immediate or short-term measures which should be implemented as soon as possible, to protect patients from overcharging on medicines and consumables provided by private hospitals.

1. 'Unlocking' patients: Changing the hospital scenario from 'locked-in consumers' to patient autonomy

As noted by official bodies like NPPA and CCI, the need to ensure freedom of patients to purchase medicines and medical products from the source of their choice is non-negotiable. From a consumer rights point of view, coercing patients and their caregivers to purchase medicines only from the hospital where they are admitted is not permissible. In an important judgment dealing with such a situation in context of a patient admitted in a corporate hospital in Jaipur, the National Consumer Disputes Redressal Commission (NCDRC) clearly opined –

"We know that the corporate hospitals purchase the medicines, surgical items, consumables, in bulk. Certainly huge margin is available, while procurement. ... The corporate hospitals should not be commercial / business centres for profiteering from the exploitation of such critical patients, who have to pay skyrocketing hospital bills....

... we are of the opinion that the hospital authorities exercised undue influence and compelled the Complainants to pay excess price. This amounts to unfair trade practice. Therefore, considering the facts and circumstances, we are of the opinion that the hospital authorities exercised undue influence and compelled the Complainants to pay excess prices. The right of the complainant / patient cannot be curtailed by preventing the complainants to exercise their option to purchase the medicines or injections from the market³⁸."

In this particular case, the NCDRC ordered the concerned hospital to refund 50% of the excess amount charged by them on medicines which were available at lower cost outside the hospital, since the patient had been made to purchase them from the hospital itself at higher rates. The Competition Commission of India has similarly clearly recommended that no such restrictions should be placed on patients regarding the source from which they purchase medicines -

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 ...³⁹ (emphasis added)

³⁸ Judgement by NCDRC in Revision petition no. 2448 of 2013, dated 22 July 2014. Available at: www.casemine.com/judgement/ in/590a01354a932663936c9a89

³⁹ Competition Commission of India, Making Markets Work for Affordable Healthcare, 2018

As mentioned above, Food and Drug Administration (FDA), Maharashtra has already issued two rounds of circulars (in 2016 and 2022) mandating that all hospitals should display a notification that '**Patients are not compelled to buy medicines from the hospital pharmacy only. Admitted patients and their relatives are allowed to purchase medicines from any registered medicine retailer of their choice'.**⁴⁰

It is now high time that across the country, **Health** departments as well as State FDAs should promptly issue such orders ensuring 'Right to choice for patients' covering all private hospitals, ensuring the mandatory display of such information and related implementation. There is also need to actively monitor observance of such orders, which would freely allow patients to procure medicines from the source of their choice without any compulsion. Combined with this, very wide publicity needs to be provided regarding this provision to ensure that every person, every patient and caregiver is aware of their rights in this regard. The best antidote to major information asymmetry is ensuring some degree of parity of information among the involved parties. Any hospitals found violating these provisions should be subjected to exemplary penalty, and complaint redressal mechanisms for dealing with such issues need to be set up, or existing forums could be strengthened in each state. Those who promote marketisation of medical care in India should note that such compulsion amounts to making the patients and caregivers bonded to the hospital, and defies even basic market logic, whose first principle is freedom of consumers to choose.

2. The best disinfectant: Allowing the sunlight of transparency to shine on medicine pricing:

Sunlight has been termed as the 'best

disinfectant'; similarly public transparency is regarded as one of the best measures for checking malpractices. As noted repeatedly, the current trade environment in medicines in India is shrouded in opacity linked with 'insider practices'. Very few have access to key information like the landing price or exfactory price regarding various medicines and consumables, the current margins charged at various levels, and various forms of discounts and incentives which are provided especially to retailers including pharmacies. Today concerns hospital about transparency in medicine pricing are a global phenomenon, with the need for openness being expressed in various forms:

Drug pricing transparency has been a topic of debate throughout the health care system.

Similar to transparency of hospital prices and costs, drug pricing transparency would hold manufacturers accountable for the prices being charged for medications. ...

The issues of rising drug prices and pricing strategies are complex. The solution to the problem requires that all parties, including the pharmacy and manufacturers, be transparent about pricing and the reasons for higher prices.⁴¹

A comprehensive document published by OECD mentions the following:

Price opacity has become commonplace in pharmaceutical markets as actual transaction prices paid by purchasers are increasingly disconnected from public or 'list" prices ... confidentiality is undermining the confidence of both payers and patients about the industry ... Confidential prices prevent the general public

⁴⁰ For the FDA, Maharashtra Jan.2016 circular see https://fdamfg.maharashtra.gov.in/SOS/ViewPDF_NOT.aspx?COD=002&ST_ CD=MH

⁴¹ Kaitlyn N. Dana, John B. Hertig and Robert J. Weber, Drug Pricing Transparency: The New Retail Revolution, Hosp Pharm. 2017 Feb; 52(2)

from scrutinising public expenditure, and undermine the accountability of reimbursement and coverage decisions⁴².

While these arguments for improving transparency of medicine pricing in more developed nations have emerged in health system settings different from India, the underlying concerns are parallel to the Indian situation. Although this is a complex and multi-dimensional area requiring further research and discussion, a few basic processes could be promoted to improve transparency. Firstly, information should be publicly available about the range of margins on medicines and consumables which are charged by hospitals and medicine retailers. This should be done in form of a public information process, which would encourage hospitals and retailers to provide discounts especially in situations where they enjoy very large margins. Secondly, various branded medicines should mention the Price to Trade (PTT) along with MRP which would provide patients an estimate of the margins being charged by the intermediaries who operate between themselves and the manufacturer. Thirdly, making general availability of such information could create public opinion and social momentum for legal regulation of margins and overall strengthening of DPCO regulation. Fourthly, public health officials and political decision makers should be aware of the broad ranges of margins and critical issues related to margins on medicines, enabling them to take more informed decisions about medicine policy and procurement.

MRPs should not mean 'Manipulated, Raised Prices': Regulation of trade margins on medicines

As discussed above, the WHO guidelines (2015) provide a broad set of principles, and the Dept. of Pharmaceuticals (DoP) Committee report (2016)

has laid down a detailed framework for regulation of margins on medicine prices. This specifies the margins to be charged by all intermediaries added together, which is in addition to the Price to Trade defined by the manufacturer. For lowpriced medicines where the unit cost is within Rs. 2 there is no capping of margins recommended, but for all higher priced categories the margins are supposed to be capped at 35% to 50% levels, with the margins being brought to lower levels for the more expensive medicines. It may be argued that the role of intermediaries like private hospitals is basically maintaining certain inventory and providing the medicines to patients, and they are not supposed to be profiteering in this process. In the current DPCO regime, the margin allowable for drugs under the DPCO schedule for retailers is 16%, and for wholesalers is 8%. Given this situation, the combined margins for wholesalers and retailers even for non-schedule medicines may be kept within 30% markup above the Price to Trade allocated by the manufacturer.

The operational message is that until such time that the DPCO regime is expanded to include most of the existing formulations, the trade margins on all medicines and consumables should be capped at reasonable level (say maximum 30%-35% markup for wholesalers plus retailers including hospitals) at earliest, to protect patients from exorbitant margins which are frequently being charged at present. It is very important to include medical consumables (like IV sets, needles, syringes, oxygen masks etc.) in this regulation since especially in hospital settings, these are often appearing as the basis for excessive charging to patients. The entire perverse chain of supplier driven price distortions would be curbed to large extent if trade margins on all medicines and consumables are effectively capped.

While the issue of high margins on medicines is long standing, as shown in this study the experience of

⁴² Eliana Barrenho, Ruth Lopert, Exploring the consequences of greater price transparency on the dynamics of pharmaceutical markets, OECD Health Working Papers No. 146, 2022

excessive charging during the COVID epidemic has added sharpness to this problem; today this especially deserves urgent and effective policy action. We have suggested above a few immediate and short-term steps which could be taken to rationalise the margins charged on medicines, especially by private hospitals. These are proposed as short-term measures, which could contribute a few pieces towards solving the larger, complex puzzle of high medicine pricing in India. Yet these must be contextualised within the larger overall policy scenario which urgently demands major expansion, strengthening and reform of the entire DPCO regime as mentioned earlier.

While this short study has focussed on medicine pricing, there are major policy areas related to medicines in India which we have not touched upon; although these are very important, they lie beyond the modest scope of this study. These include policies related to ensuring access to medicines, both in the public health system (such as issues related to medicine budgets, procurement and distribution systems) and in the private sector (such as promotion of quality generic medicines, and outlets like Jan Aushadhi stores). The entire area of ensuring consistent and universal quality of medicines is another important area which needs attention, especially keeping in view certain recurrent lapses in regulatory systems which have led to serious consequences. Further there is the entire concern regarding rationality of medicine prescribing and usage, which is related to frequently excessive and unwarranted consumption of medicines, having major economic and health related consequences. We hope that all these interrelated domains related to medicines - pricing, access, quality and rationality of use - would be viewed in integrated manner, and could become major social and political priorities, propelling action by governments linked with greater awareness in society, in the near future. Spending on medicines, especially during hospitalisation, should no longer remain a huge budren which pushes millions into poverty in India every year. Action on medicine related policies should become an integral component of the larger movement towards Right to healthcare and Universal healthcare, which are undoubtedly an outstanding priority for the people of India today.

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