Review Article

iMedPub Journals
http://www.imedpub.com

Journal of Healthcare Communications
ISSN 2472-1654

2017
Vol. 2 No. S1: 42

DOI: 10.4172/2472-1654.100082

Access to Quality Medicines and Health Products in Rajasthan

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Citation: Gurbani N. Access to Quality Medicines and Health Products in Rajasthan. J Healthc Commun. 2017, 2:S1.

Abstract

Access to health stands as fundamental to human rights under UN charter. In India, health spending by the State is very low (nearly 1% of the GDP) and 79% spend on health is out-of-pocket with major spending (about 80%) is on cost of medicines. Almost 30% of the households slide into poverty due to high treatment costs. It is imperative that access to quality essential medicines directly affects the access to health. Though, India is considered as pharmacy for developing countries, yet due to poor regulatory control there is huge price variation in off-patent branded generics, making the affordability at the mercy of prescribers and dispensers. Basically, essential medicines are not costly but are made expensive. By adopting and improving Tamil Nadu model, the Government of Rajasthan has launched a scheme called *Mukhyamantri Nishulk Dawa Yojana* (MNDY), i.e., Chief Minister's Free Drug Distribution Scheme (CMFDDS) for providing free essential medicines to all irrespective of their economic status through establishing an autonomous Rajasthan Medical Services Corporation (RMSC). Utilization of available pricing information of quality medicines along with transparent pooled procurement through prequalification measures for products and suppliers and proper distribution system, RMSC, has made it possible to make free access to medicines, especially underserved population. Educational, managerial and regulatory strategies have been used to promote compliance by stakeholders. Resistance by healthcare providers on pretext of quality of supplies and confusion created in public was countered with proper information, education and communication (IEC) activities. Strong political will with proper administrative and technical support has made it possible to reach the unreached, as a first step towards universal access to health.

Keywords: Healthcare providers; Essential medicines; Chittorgarh model; Healthcare products

Abbreviations: UHC: Universal Health Coverage; IEC: Information Education and Communication; MNDY: Mukhyamantri Nishulk Dawa Yojana; RMSC: Rajasthan Medical Services Corporation

Received: June 07, 2017; **Accepted:** June 23, 2017; **Published:** July 04, 2017

Introduction

Access to health stands as fundamental to human rights under UN charter. Ensuring its safeguards is a major difficulty in developing countries due to several factors like illiteracy, poverty, corruption, non-affordability, medicine shortage and shortage of health workers. In India, health spending by the State is very low (nearly 1% of the GDP) and 79% spending on health is out of pocket with major spending (about 80%) is on cost of pharmaceuticals (which include vaccines, diagnostics, contraceptives, diagnostics, contraceptives, health supplies, devices, etc.) [1,2]. It constitutes the second highest outlay in any given health system after manpower. As these commodities are the interface between a patient and health services, their availability has a direct impact on health. Health science has evolved in all areas, yet pharmaceuticals still play a main role in healthcare and are likely to continue to do so. Therefore, access to essential medicines would be prerequisite to enforce "Right to Health". Almost 30% of the households slide into poverty due to high treatment costs. It is imperative that access to quality

essential medicines directly affects the access to health. As per the UN initiative for Universal Healthcare Coverage (UHC), for a healthcare system to function optimally with access to quality medicines and healthcare products, proper selection and use, affordable pricing, sustainable financing and a reliable supply system must be ensured. According to WHO, two-third of developing nations' population inclusive of India lack orderly access to essential medicines. Despite the accomplishments of the Indian pharmaceutical industry, there is still a greater need to make medicines affordable to people. Medicines are still beyond the means of most people, with the belief that expenditure on medicines makes people poor & sickness leads to poverty. It is undeniable that medicines are overpriced and are beyond the reach of most people thanks to the differential drug pricing and promotion of non-essential drugs. If you analyze the top 300 selling products in the Indian pharmaceutical market, you'd be surprised that only 38% medicines fall under the National Essential Medicines List. Many brands of non-essential drugs that are expensive alternatives without a clear therapeutic gain are in market. These non-essential, irrational, and sometimes hazardous drugs are promoted by the industry, approved by the regulators, prescribed by the doctors and consumed by the unaware patients [3,4].

India–'Pharmacy of the Developing World'

India is among the top five bulk drugs producers in the world, ranking 3rd in terms of volume (10% in global sales) and 14th (1.5% in terms of value). India contributes about 20% of the world's drugs production the with one of the most prosperous pharmaceutical industries with over 500 manufacturing plants being US FDA approved which is only second to the United States. There are over 1000 WHO GMP approved companies and the country is widely regarded as the "Pharmacy of the Developing World". The unfortunate irony is that this statistical success has not translated into real availability or affordability of medicines for the masses in India. Indian Pharmaceutical market in general, is free for all players that take advantage of complete asymmetry about the pricing information. In May 2013, a new Drug Price Control Order (DPCO) based on market average price formula replaced the previous cost basis formula. The gap between average wholesale price (which include manufacturer and wholesalers margins) retail prices is huge and is unparalleled to any other industry. Price analysis reveals that this gap is not due to the actual costs of making medicines being high, but rather due to promotional activities of the industry resulting in the retail prices being exorbitantly high which ultimately leads to not only impeding the access to medicines, but irrational promotion of medicines. Most companies, even same companies are selling off-patent product with same ingredients in different branded generics names with different prices **(Table 1)**.

Access to medicines initiatives in India

India is country of many federal States. There are 33 federal States/Union Territories in India ruled by different elected governments of different political parties. Health is under concurrent list of Constitution of India, thereby, both the central government as well as the state governments have roles in management of health with major expectations from State governments as the implementation agencies at grass root levels. It would be beyond the scope of this paper to discuss all prevailing models of medicine accessibility in India, but a state sponsored initiative by the Rajasthan State with population over 70 million is being discussed here highlighting IEC activities for its successful implementation.

Addressing "Availability of Quality Generic Medicines" in Rajasthan

Under the encouragement of Delhi (DSPRUD) initiative "WHO-India Essential Drugs Programme", Rajasthan Society for Promotion of Rational Use of Drugs (RSPRUD) was formed in 1999, which started series advocacy workshops. This facilitated "Rajasthan State Essential Drugs List" in 1999, followed by

Table 1 Comparison of wholesale and Maximum Retail Prices (MRP) of selected few medicines.

S. No.	Name of medicine, dosage form, strength	Average wholesale price to dealer	Printed MRP being charged by retailers
1	Arteether Injection, 150 mg/2 ml	10.45	105.00
2	Aceclofenac 10 Tabs 100 mg+Paracetamol 325 mg	8.75	74.00
3	Amikacin Injection, 500 mg/2 ml	11.00	95.00
4	Ramipril 10 Tabs, 5 mg	6.25	60.00
5	Rabeprazole Enteric coated 10 Tabs, 20 mg	7.25	80.00
6	Protein Powder 200 mg	32.00	195.00

MRPs comparisons of 3 brands of Cetirizine manufactured by the same (Cipla) manufacturer					
Brand Name given by company	Generic name	Prices prior to DPCO 2013 based on cost basis formula		Prices after DPCO 2013 based on average market retail prices formula	
		Rate for retailers or 10 Tablets (stockiest price)	Printed MRP	Rate for retailer for 10 tablets (stockiest price)	Printed MRP
Alerid	Cetirizine 10 mg	28.85	37.50	15.80	20.19
Cetcip	Cetirizine 10 mg	1.88	33.65	2.36	19.01
Okacet	cetirizine 10 mg	1.84	27.50	2.36	19.01

Source: Alkem Lab. Ltd. Rate List for Dealers

"Rajasthan State Standard Treatment Guidelines" in 2008 with subsequent revisions. During this phase two major developments resulted in:

Low cost medicine initiative, evolution based on medicines wholesale prices and printed retail prices information: Efforts to make medicines accessible at affordable prices started as a pilot project in 2006 in one of the 33 districts of Rajasthan, named "Jhalawar" by Dr. Samit Sharma, a pediatrician by qualification, serving as Administrative Officer. This was an "Initiative to establish low cost medicine shops" which eventually evolved as the "Chittorgarh Model"- Making Medicines Affordable" when he became District Magistrate. He devised a mechanism to bring down the prices of medicines and common surgical items to its minimum, so that even the poor can have access to them. Medicines were procured by generic names based on prevailing wholesale prices using a transparent open tender system and were dispensed through Government run Cooperative Medical Stores as Fair Price outlets at maximum 20% margins. It was a district based chain of fair price medicine stores that serve OPDs and Indoor patients of Government hospitals and also general public at dispensaries and Primary Healthcare Centers (PHCs). Such low cost drug and surgical items sale outlets were not subsidized, they were self-sustainable as they were able to generate enough revenue and hence external aid was not required [5]. The purpose of this initiative was to make medicines affordable and accessible to everyone, especially the poor, and the disadvantaged section of the society to limit out of pocket expenses people made on health and to increase the accessibility of drugs. For example- a pneumonia patient who may not have been able to afford injection Amikacin 500 mg as it was sold in the market at about Rs. 70 (printed Maximum Retail Price (MRP) whereas it was priced at about Rs. 7 only in wholesale and this injection could be supplied through these fair price shops at Rs. 8 to 9. Thus, all patients could afford treatment and many more human lives could be saved). This was facilitated by making almost all commonly prescribed drugs available at low cost, ensuring stricter quality control and helped in monitoring, establishing chain of low cost stores in district and covering the rural areas to make them available and accessible to all. However, this initiative was opposed by the prescribing doctors and retailers raising questions on the quality of generic products, although hidden agenda was reduced perverse financial incentives by the pharmaceutical industry. To convince doctors harmoniously to prescribe by generic names and limiting prescription of unnecessary drugs, which costs a lot, seminars and workshops, were organized as face-to-face communication strategy highlighting importance of Rational Use of Medicines (RUM) and conveying necessity of prescribing generics to comply with Code of Ethics. All misconceptions and myths on quality issues were addressed on the basis of similarity of analysis reports on pharmacopeia basis of branded and generic products. To dispel fears about efficacy and quality of generic medicines among people educational awareness programs along with media campaign were also launched, besides putting big display boards outside every fair price co-operative stores and public health facilities illustrating price comparisons of generic products in these stores with prevailing market prices in private retail pharmacies. This compelled private retailers (Pharmacies) to provide generic drugs for sale in almost same price range. As a ripple effect, another 17 districts of the Rajasthan adopted this successful model. This way medicines and surgical items were provided at inconceivably low prices; much below the printed market rate (i.e. MRP) as per illustrative lists under **Table 2**, leading to huge reduction in out-of-pocket expenditure on treatment.

Starting free drugs distribution in Rajasthan (Reaching the Unreached): Identifying access to medicines as one of the thrust area, around 2010, the Central Government called all States through National Rural Health Mission (NRHM) to adopt and set up logistics and supplies system in lines of Tamil Nadu Medical Services Corporation (TNMSC) [6-8]. Looking at viability and success of this model for making medicines available through cost minimization, the Government of Rajasthan made a policy announcement for providing commonly used essential generic medicines and general health supplies free of cost to all patients visiting government health facilities by establishing autonomous Rajasthan Medical Services Corporation (RMSC) with Dr. Samit Sharma (a medical specialist cum Administrator) as the Managing Director (CEO of RMSC). The scheme was launched on Mahatma Gandhi's Birthday i.e., 2nd October, 2011 with title "Mukhyamantri Nishulk Dawa Yojana (MNDY)" i.e., Chief Minister Free Drug Distribution Scheme (CMFDDS). Under this scheme prescribed essential medicines and health supplies are being made available free of cost to all visiting public health facilities. The benefits under the aegis of MNDY have been extended to the entire 70 million population of the state (irrespective of any economic status). The annual cost burden to State is just INR 3000 million (1 USD=INR 65). A total number of 17527 Drug Distribution Centers (DDC) equipped with manpower, logistics and IT support has been established. Two major focuses under this scheme are: (1) To make medicines and supplies available at all health facilities; and (2) To change prescribing behavior of doctors. For ensuring availability of supplies key steps taken were: (a) Establishment of autonomous centralized procurement Rajasthan Medical Services Corporation (RMSC); (b) Identifying list of essential drugs (EDL) and supplies through a Technical Advisory Committee (TAC) of experts; (c) Procurement of quality products through two-envelope bid (quality and price) transparent process; (d) District Drug Warehouse (DDW) at every district; (e) Laboratories empanelled for quality testing of all supplies before accepting; (f) Proper storage and distribution; (g) Robust transportation system; (i) Innovative software (e-Aushidhi) for inventory management; (j) Transparent and prompt payments system for suppliers; and (k) Availability of sufficient funds. To change prescribing behavior of doctors and healthcare providers following steps were initiated: (a) Sensitization and orientation workshops on Rational Use of Medicines (RUM) in all districts; (b) Instructions for writing prescription on self-carbonated slips with diagnosis, generic names out of EDL as per standard treatment guidelines (STDs), retaining duplicate copy for prescription audit by constituted Drugs and Therapeutics Committees (DTCs), (c) Patient counselling and (d) computerized drug dispensing up to PHCs level.

Major initiatives and salient features under above components have been already discussed elsewhere and are available at the RMSC website (www.rmsc.nic.in). By utilizing available pricing information, bulk and pooled procurement has resulted

Table 2 Chittorgarh cooperative store sale rate comparisons with MRP printed on pack/strip of market products in INR ($1=INR 65).

Generic name of drug	Unit	Chittorgarh cooperative store sale rate (Rs.)	MRP printed on pack/strip of market products (Rs.)
Albendazole Tab IP 400 mg	1 tablet	**1.37**	**25**
Alprazolam Tab IP 0.5 mg	10 tablets	**1.75**	**14**
Arteether 2 ml Injection	1 Injection	**11.72**	**99**
Amlodipine Tab 5 mg	10 tablets	**3.12**	**22**
Cetirizine 10 mg	10 tablets	**1.5**	**35**
Ceftazidime 1000 mg	1 Injection	**64.9**	**370**
Atorvastatin Tab 20 mg	10 tablets	**22.59**	**170**
Diclofenac Tab IP 100mg	10 tablets	**2.75**	**25**
Diazepam Tab IP 5 mg	10 tablets	**1.9**	**29.4**
Amikacin 500 mg	1 Injection	**8.67**	**70**
Name of surgical item			
Blood administration set		12.3	43
I.V. cannula 18		7.48	63
I.V. set		6.61	50
Surgical gloves		7.3	40

Example of huge reduction in treatment costs

When medicines are prescribed by brand name and purchased from retailer shop				**When medicines are prescribed by generic name and purchased from cooperative fair price store**			
Quality of medicines required	**Name of drug**	**Rate per 10 tabs**	**Cost (no. x rate)**	**No.**	**Name of drug**	**Rate per 10 tabs**	**Cost (no. x rate)**
10 Tab	Ciprofloxacin	60.54/-	60.54/-	10 Tab	Ciprofloxacin 500	12.85/-	12.85/-
10 Tab	Nimesulide	25/-	25/-	10 Tab	Nimesulide	2.12/-	2.12/-
5 Tab	Cetirizine	35/-	17.5/-	5 Tab	Cetirizine	1.50/-	0.75/-
Total			**103.04/-**	**Total**			**15.72/-**

in "Economies of Scale" the Rajasthan State government has been able to procure medicines at unbelievable low prices as compared to prevailing market prices **(Table 3)**.

Challenges for Change of Behavior of Doctors and Public Education

As expected, serious questions were raised by the medical doctors about quality of generic medicines with additional contention of loss of freedom in prescribing under motivation of pharmaceutical lobbies and doubts were planted in the media as misinformation campaign. To change the prescription behavior of doctors), a number of sensitization and orientation workshops on Rational Use of Medicines (RUM) were organized along with public awareness education programs in all 33 districts of the State to dispel misconception on efficacy of generic medicines as educational intervention. Ensuring availability of all quality drugs under EDL at health facilities and prescription audits by Drugs and Therapeutics Committees (DTCs) constituted at all hospitals were managerial intervention. Specific orders were issued by the highest administrative officer of the State for prescribing by generics as per EDL and STGs were regulatory interventions. To demystify myths of doctors on quality, it was shared that most big pharmaceutical companies are not the original manufacturers, but are marketing companies, as they source their supplies through contact manufacturing, e.g. Torrent, Zydus Cadilla, Indico, IPCA, Micro Lab, Mankind, Lupin, Abott, Wokhardts, Piramal Healthcare, Sun, Cipla, Intas, Sanofi Aventis gets their products manufactured by Akums (unknown to doctors) and same manufacturing company is RMSC supplier. Therefore, there is no question of compromise on quality issues. Further, the State has developed and published Standard Treatment Guidelines (STGs) for rational prescribing with a provision for Prescription audit. Specific orders were issued by the Government to all facilities requesting that carbon copy of prescriptions to be retained to have record for monitoring prescription behavior by the DTCs while dispensing and giving original copy to the patient. Prescribing drugs not included in essential drugs list are required to be justified by the concerned doctor, patients be counselled and dispensing be monitored were additional safeguards.

Public awareness generation

By using NGOs like "Prayas" with support of Action Aid, IEC interventions were encouraged by RMSC to educate public for their entitlement to receive free medicines from the health facilities. Patients are free to call helpline number if they do not get medicines from the health facilities. Various meetings/ seminars, etc. were organized. Following discussions encouraged major empowerment of public: basic understanding of right to health and health equity, health care scenario in the country and in Rajasthan, out-of-pocket expenditure on treatment and its consequences, drug market in the country, regulation of drug prices, difference between generic and branded medicines, etc.

Table 3 Comparison of procurement/tender price of selected few medicines by RMSC with market prices of corresponding branded products and ceiling prices under Price Control Order (DPCO) 2013.

S. No.	Medicines Name	Pack size	Procurement by RMSC INR	Ceiling price DPCO	Printed Retail Price on equivalent brands in INR
1	Diclofenac Sod Tabs 50 mg	10 × 10	14.11	182	Dicloran 219.5, Reactin 225.7
2	Ofloxacin Tablets 200 mg	10 × 10	82.7	526	Oflox 551.5, Zenflox 412.8
3	Cetirizine Tablets 10 mg	10 × 10	10.43	153	Alerid 160.60, Zyncet 160.70
4	Ceftriaxone Injection 1 g	1 Vial	11.86	47.95	Monocef 50.34
5	Cefixime Tablets 100 mg	10 × 10	119.71	826	Zifi 530, Taxim O 866.40
6	Clopidogrel Tablets 75 mg	10 × 10	53.84	644	Plavix 676.14, Deplatt 504, Clopivas 478.8
7	Amlodipine 5 mg Tablets	10 × 10	9.82	233	Amlogard 244.67, Amtas 244.67, Amlopress 244.67
8	Domperidone Tabs 10 mg	10 × 10	12.97	224	Domstal 235.2, Domperi 252.29, Dom DT 235.2
9	Glibenclamide Tabs 5 mg	10 × 10	11.52	103	Daonil 108.7
10	Alprazolam Tablets 0.5 mg	10 × 10	12.94	216	Anxit 226.8, Alprax 255.5
11	Losartan Tablets 50 mg	10 × 10	35.52	462	Losar 484.2, Losacar 498.1
12	Atenolol Tablets 50 mg	10 × 14	16.93	232.4	Tenolol 175.14, Tenormin 17.29
13	Azithromycin Tabs 500 mg	10 × 3 × 3	371.79	1604.7	Azithral 1872, Aziwok 1867, Zathrin 1870
14	Enalapril Tablets 5 mg	10 × 10	16.15	297	Envas 310, Enam 311
15	Atorvastatin Tablets 10 mg	10 × 10	25.6	509	Atorva 534.5, Atorec 534
16	Glimepiride 2 mg	10 × 10	11.67	529	Amaryl 555.47
17	Paclitaxel 260 mg Injection	43.4 ml	637.70	8987.27	Mitotax 9588
18	Imatinib Tablets 400 mg	10 × 10	1729	21332	Imatib 30242, Veenat 20270, Zealata 29123

Impact of free drug scheme

The scheme has improved the availability of essential medicines and supplies, considerably reduced treatment cost and out of pocket expenses. Large number of patients, who did not seek treatment till it, gets very serious for non-availability of money, has started availing health care. Emphasis on RUM saved patient from heavy load of unreasonable and unnecessary drugs which are the cause of rising drug resistance and other iatrogenic morbidities and money saved in turn can be used to improve nutrition and condition of other social determinants of health in the country. The impact can be briefly put together as: Increase in access and equity of the underserved, and reaching out to the unreached, savings to Government, smiling patients and thousands of lives saved.

External evaluation by WHO and PHFI

A baseline evaluation study has been jointly commissioned by the WHO and Public Health Foundation of India (PHFI) of this free medicines scheme as external and independent evaluation. In total 157 healthcare facilities sampled of which 112 were public (various levels) and 45 were private facilities across 10 districts of the state. 160 medicines under different therapeutic category from EDL were identified and segregated based on availability of such drugs at different levels of care. Data from a random sample of prescription slips were captured on the day of the facility visit (roughly 20-30 slips per facility) for prescription audit. During the survey analysis two parameters were estimated, namely; Average number of medicines prescribed per encounter and Proportion of generics, antibiotics, injections, fixed drug combinations and syrups prescribed with findings as under [9-11].

Indicators	Quantity/ Percentage
Average no. of medicines per encounter (prescription slip)	3.29
Percentage of medicines prescribed by Generic name	98.29
Percentage of antibiotics prescribed	28.9
Percentage of injections prescribed	7.1
Percentage of prescription slips with syrup prescribed	9.3
Percentage of prescription slips with vitamins prescribed	3
Percentage of single drugs prescribed as against fixed drugs	89.02

Availability of medicines in Rajasthan (on survey day) stock-outs of medicines in 112 government facilities across 10 districts of Rajasthan were surveyed using a structured questionnaire and found overall availability of supplies at PHCs, CHCs and district hospitals as 71, 69 and 88% respectively. This WHO and PHFI Study findings have revealed.

Reduction in out-of-pocket expenditure (OOP) and increased per capita health expenditure: The per capita health expenditure before the free-MNDY scheme was estimated to be Rs. 5.70 which now stands close to Rs. 50.

Increased utilization of public health facilities: Another positive spin-off from this initiative is the rapid increase in outpatient visits and considerable increase in inpatient admissions.

Decreased absenteeism: As medicines are available free now, absenteeism appears to have reduced considerably, putting pressure on the health system infrastructure to improve further.

- Ensured Availability of Medicines.
- Positive influence on prescription/dispensing patterns.

- Sound Quality Assurance System.
- Efficient Procurement Processes and Fair Procurement Prices at RMSC.
- Robust e-Aushadhi Application Software.

Conclusion and Way Forward

Synergy of strong political will, technical expertise and clear administrative approaches coupled with proper IEC, managerial and regulatory interventions can successfully bring a positive change towards enhancing access to quality medicines toward Universal Access to Health. Utilization of the available appropriate and accurate pricing information and adoption of clear, transparent and pooled procurement with proper distribution network for safe and effective medicines is always possible. All people should get Safe and Effective medicines. It appears that in due course all states would follow NRHM directions and not only replicate good models, but would come out with further improvement to support Universal Healthcare Coverage.

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