



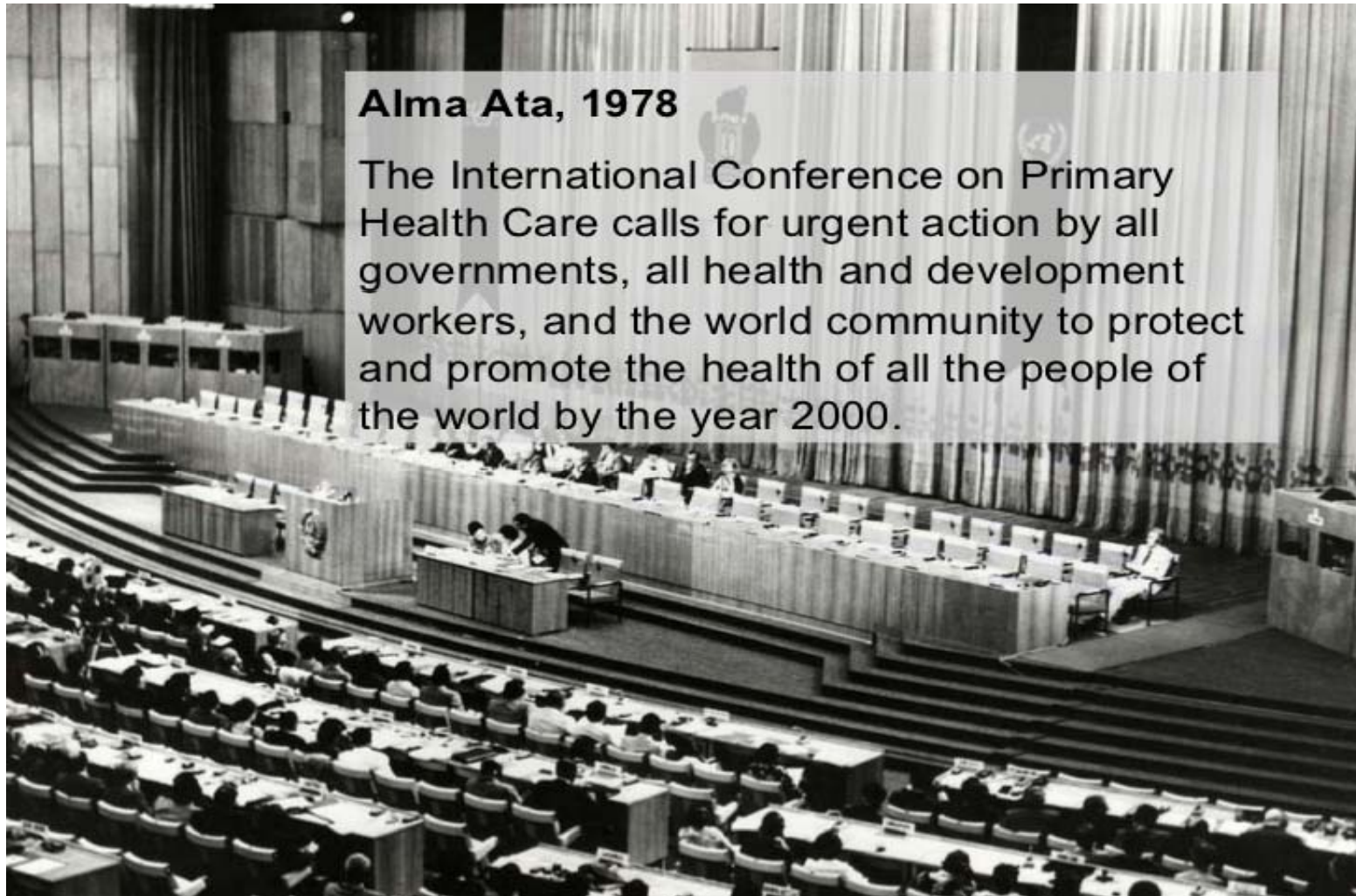
॥सर्वे सन्तु निरामयाः॥

RMSCL– Central Procurement Agency
“Enhancing Access to Essential Medicines”



Dr. Kalpana Vyas
AGM-Logistics
RMSCL

Declaration of Alma Ata (Conference on Primary Healthcare, 1978)



Alma Ata, 1978

The International Conference on Primary Health Care calls for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world by the year 2000.

Universal Health Coverage



UHC is firmly based on the WHO constitution of 1948 declaring health a fundamental human right and on the Health for All agenda set by the Alma Ata declaration in 1978.

World Health Assembly Resolution 58.33, 2005:

Urged countries to develop health financing systems to:

- ✓ Ensure all people have access to needed services
- ✓ Without the risk of financial ruin linked to paying for care



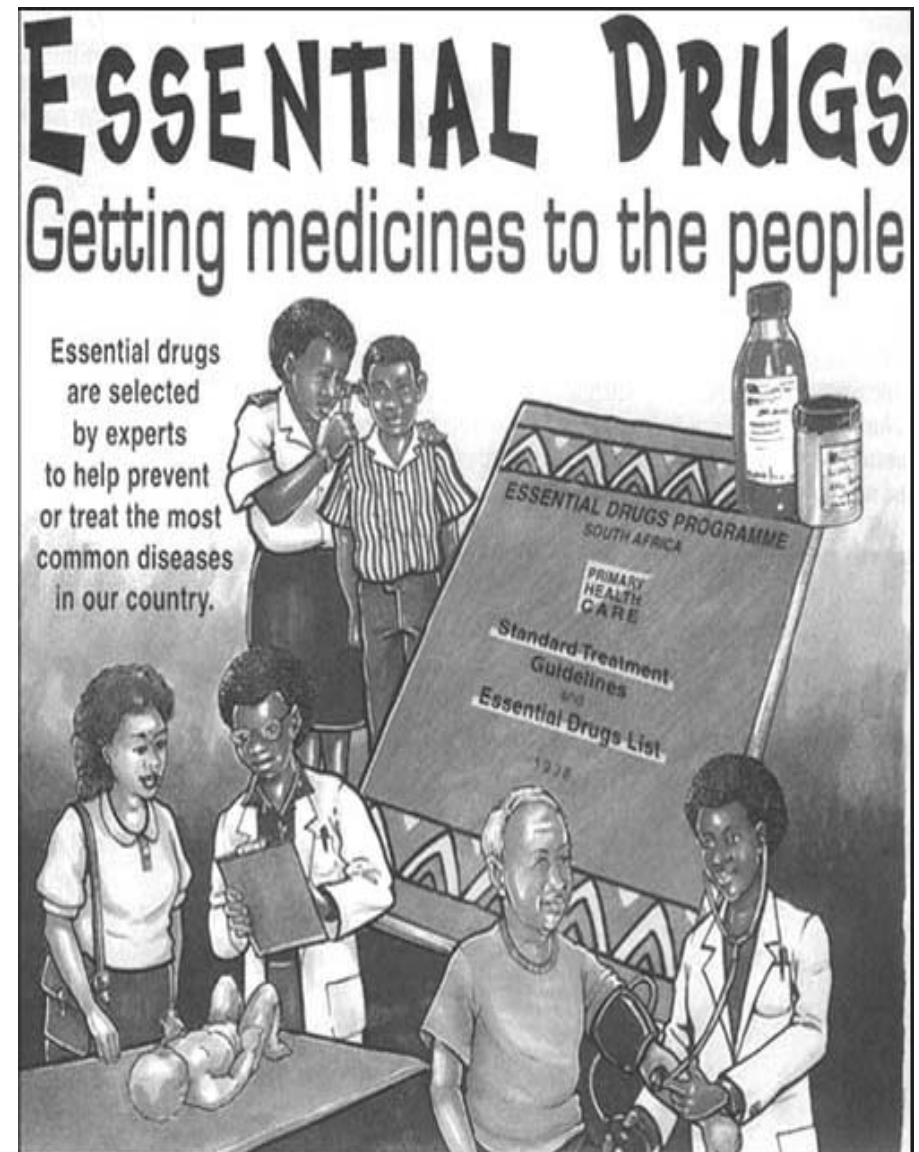
Defined this as achieving **Universal Coverage**: coverage with health services; with financial risk protection; for all

Tenets of UHC

- Prioritize the poor and vulnerable sections of society
- Increase financial risk protection through reliance on public funding
- Reduce, out of pocket expenditure at the point of service
- Increasing efficiency of health systems

Essential medicines

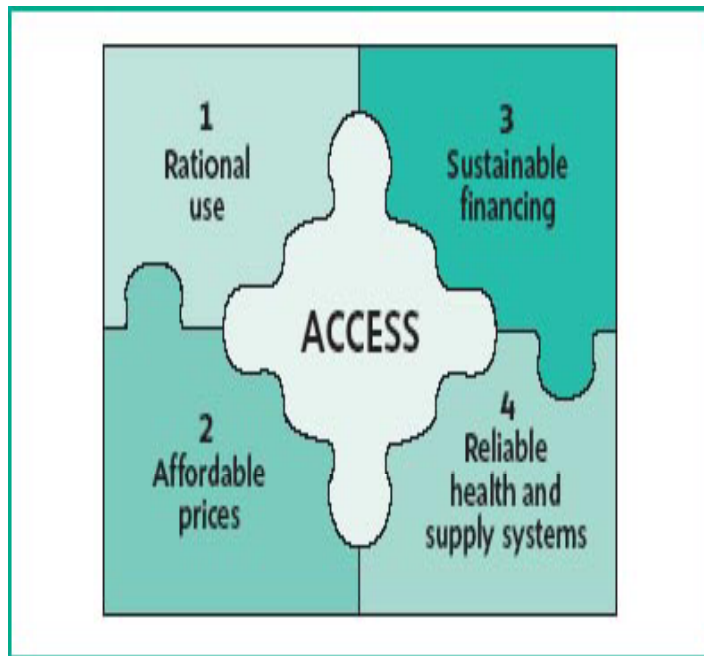
- Essential medicines are *those that satisfy the priority health care needs of the population.*
- They are selected with due regard to *public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.*
- Essential medicines are intended to be available *within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.*



KEY FACTORS INFLUENCING ACCESS TO ESSENTIAL MEDICINES



In addition to general problems of health systems performance, four medicines-specific factors have to be in place to ensure that medicines are accessible to people whenever and wherever they are needed -



- **Rational medicines selection processes** should be in use, based on national or local essential drugs lists and treatment guidelines;
- **Prices should be at levels affordable** by governments, health care providers and consumers;
- **Fair and sustainable financing** for the medicines component of health care should be ensured through adequate funding levels and equitable prepayment mechanisms, such as government revenues or social health insurance, to ensure that poor people do not face proportionally higher costs than the better off; and
- **Finally, reliable health and supply systems** need to be in place, incorporating an efficient and locally-appropriate mix of public and private service providers.

Failure in any one of the above processes jeopardizes people's access to medicines

Some alarming facts



Issue of access to essential medicines is a big challenge being faced by our country –

- 65% of the Indian population lacks regular access to essential medicines. *(39 percent of the world's population without access to medicines lives in India)*
- The expenditure on health is the *second most common cause for rural indebtedness*
- Over *23% of the sick don't seek treatment* because they are *not having enough money* to spend.
- *Expenditure on medicines* constitutes about *70% of the total health care cost*.
- Over *40% of hospitalized patients* have to *borrow money or sell their assets to get themselves treated*.
- As a result of *single hospitalization 24% of people fall below poverty line in India*.



Govt. Expenditure on Health

- The situation in India is exacerbated by the lack of public spending on health care and the resultant financial burden individuals must bear to pay for care.
- *The government of India spends around 1% of GDP on health, among the lowest levels of public spending in the world (Kumar et al. 2011).* (That figure has not changed significantly with government spending on health care rising to 1.3 percent of GDP according to the Economic Survey of India 2015-16.)
- In the absence of robust public spending, individuals have had to fill the gap with private expenditures accounting for some 78 percent of health spending (Kumar et al. 2011)

Access to medicines: still elusive to a large segment of India's population



Despite India being referred to as
“**pharmacy of the global south**”
access to medicines is still elusive

Position of India Pharmaceutical Industry

In terms of volume - 3rd

In terms of value - 14th

In terms of generic production - 4th

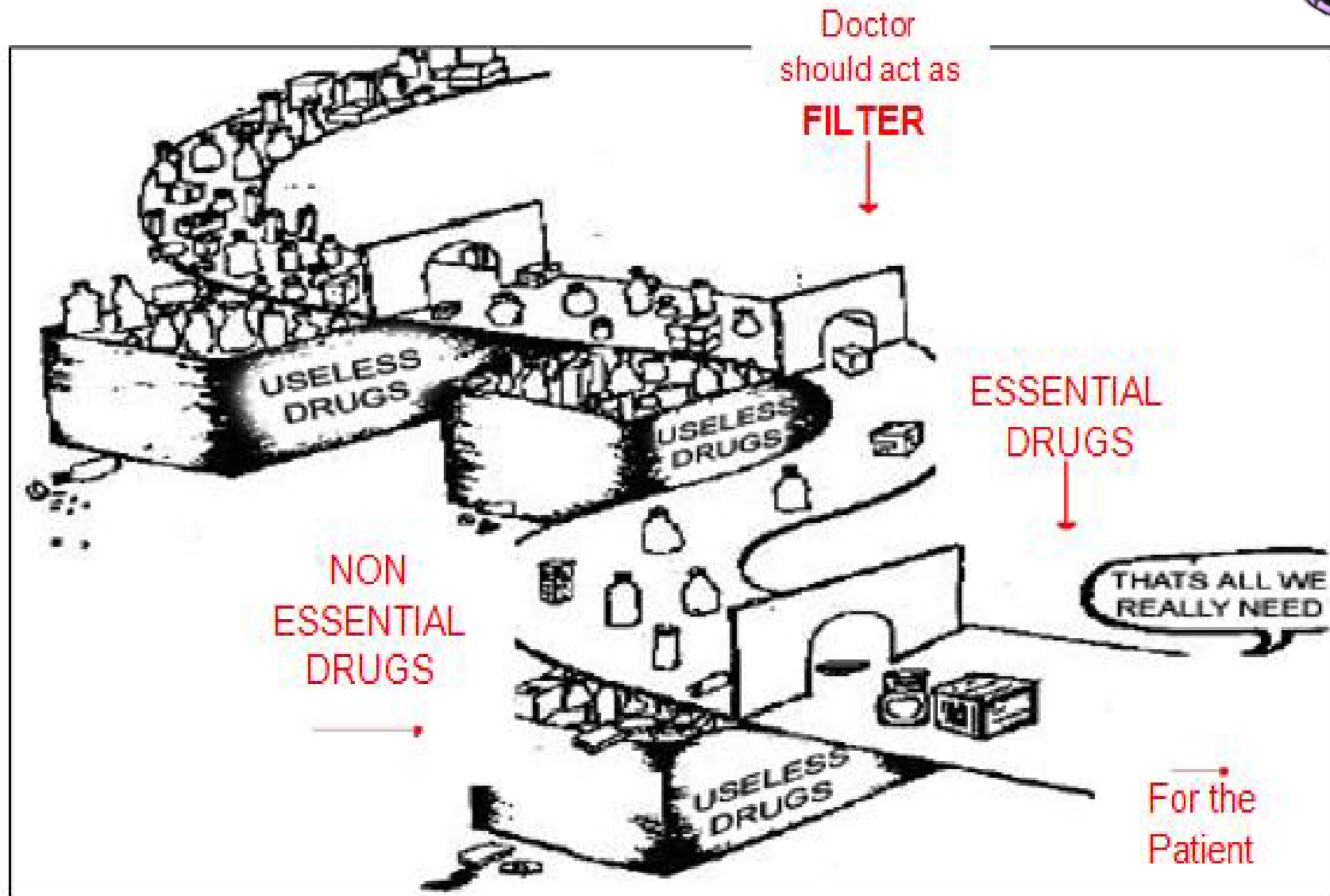
In terms of export value - 17th



Key Barriers to Access to Medicines

1. Gross inadequacy of government spending on healthcare
2. Inefficient procurement systems
3. Inefficient medicine distribution mechanism
4. Unaffordable market prices
5. Irrational prescription and use of medicines
6. Tilt of market mainly towards branded drugs

Promotion of Non essential drugs





Implications of Unethical Promotion and Irrational Use of Drugs :

THE SUFFERING

- 1. MEDICINES BECOME UNAFFORDABLE**
- 2. INAPPROPRIATE MEDICATION**
- 3. RISK OF ADVERSE EFFECTS**
- 4. RISK OF ANTIMICROBIAL RESISTANCE**
- 5. TRANSMISSION OF DISEASES THROUGH UNSAFE INJECTIONS**
- 6. DRAIN ON FOREIGN EXCHANGE**

SOLUTION ???



LOW COST GENERIC DRUGS

Quality drugs at affordable prices.



ESSENTIAL DRUGS LIST (EDL)



STANDARD TREATMENT GUIDELINES (STG)





In Rajasthan, the journey towards “Enhancing Access to Essential Medicines” was started in year **2006** by making them available at cheaper prices

through opening of –

- Medicine Stores operated by Co-operative department
- Life Line Drug Stores run by Medical Relief Society



- District Collectors tried at their own level to create the awareness among the masses to go for generic drugs. Uniform success was not noticed across the state. **Sustenance of the supplies and sale at right prices was an issue.**
- In 2010 Jan Aushadhi centres were opened to ensure supplies at the hospitals but they could not succeed and **non-availability of drugs led to doctors, not prescribing it any more.**
- So “Mission Generic drugs” faced a major setback.
- Doctors/pharmacy shops/company reps were all hands in gloves to make it non-functional.

In all, Generic drugs faced resistance

How to ensure generic drugs for all???.



Ensuring Availability of **FREE GENERIC MEDICINES**

CHALLENGE was really big and impossible



- 342,239 Sq. Km area
- 70 million population
- 33 Districts/249blocks
- Approx. 17648 institutions

Way out – To purchase drugs by Generic name & Take price advantage of “Economies of Scale”



- Budget announcement for year 2011-12 talked of “Free Medicine Scheme” for all.
- Formalities were completed and the RMSCL was incorporated under the companies Act of 1956 as fully owned and managed enterprise of the state Govt on **4th May 2011**.
- Certificate of Commencement of Business obtained on 13th June, 2011.
- Mukhyamantri Nishulk Dava Yojana was rolled out across the State on **2nd October, 2011**.
- Political willingness towards generic drugs continued in the state even after the **change of the government – budget allocation has been sustained**.



Earlier Scenario – Pre MNDY

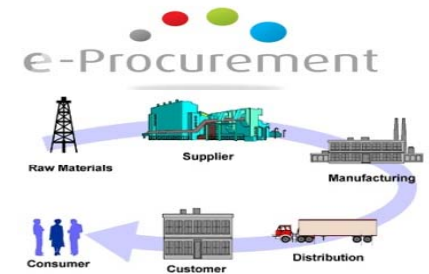
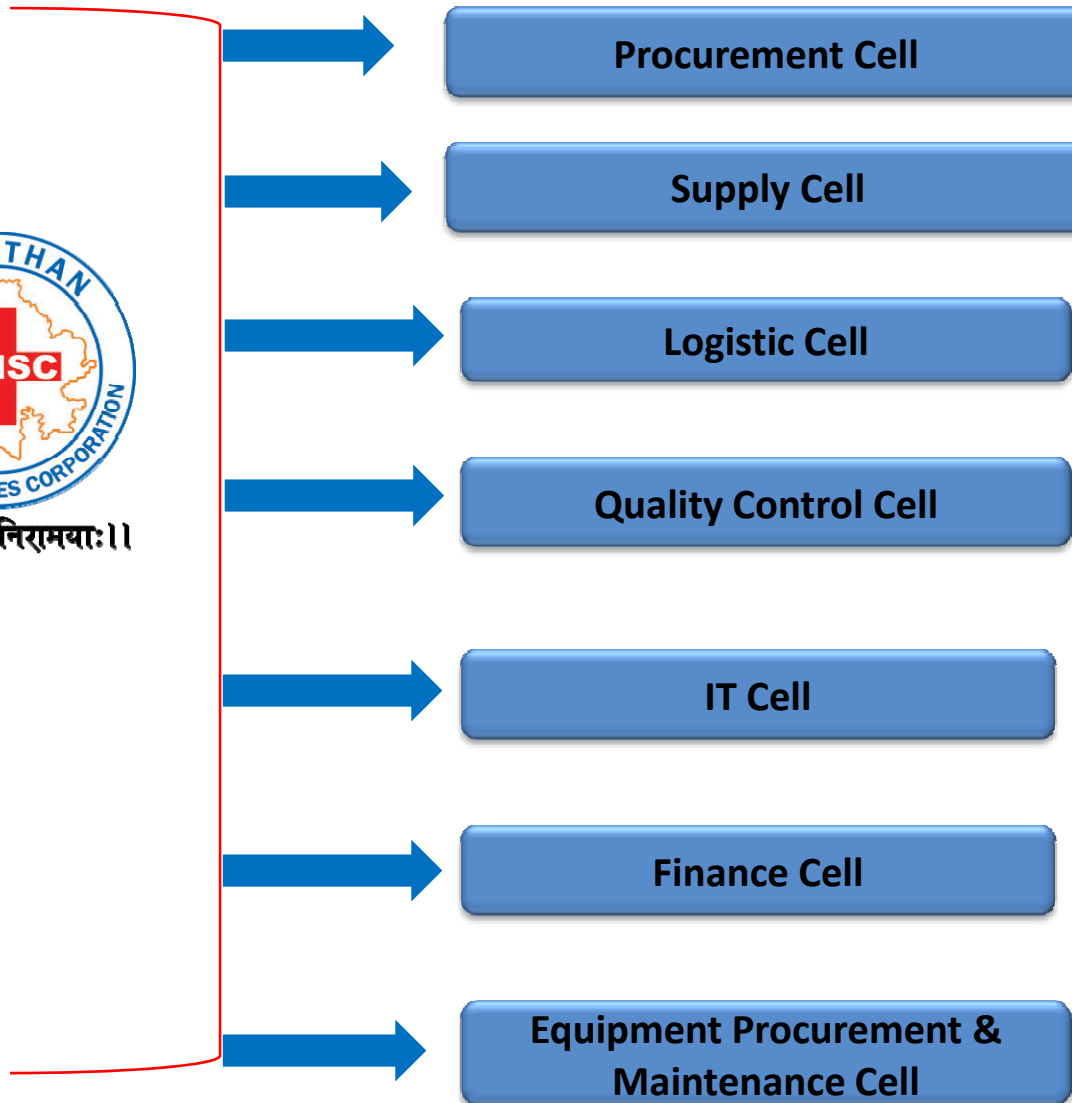


- ❖ Earlier the **Stores Purchase Organization under the Medical and Health Directorate was doing the Rate Contract** for Medicines, consumables, equipments and instruments. Out of these, the Rate Contracts of very few items use to get finalized.
- ❖ **Facility of procurement was decentralized** and the purchase orders were given by various Department Heads and purchase officers (PMO/CMHO/CHC in-charge etc)
- ❖ Due to lengthy processes in the Rate Contracts, **more time, efforts and money were spent as there was no standard procedure for procurement. Lack of transparency in procurement and payments .**
- ❖ The **facility of logistics and distribution was not inbuilt** in the system.
- ❖ There was a **need for computerized inventory management and setting up of Quality Control System.**
- ❖ There were **gaps in the system in assessing the medicine requirement .**
- ❖ Lack of **clearly defined criteria for selection of vendors .**
- ❖ **Lack of accountability at various levels of supply chain Management.**

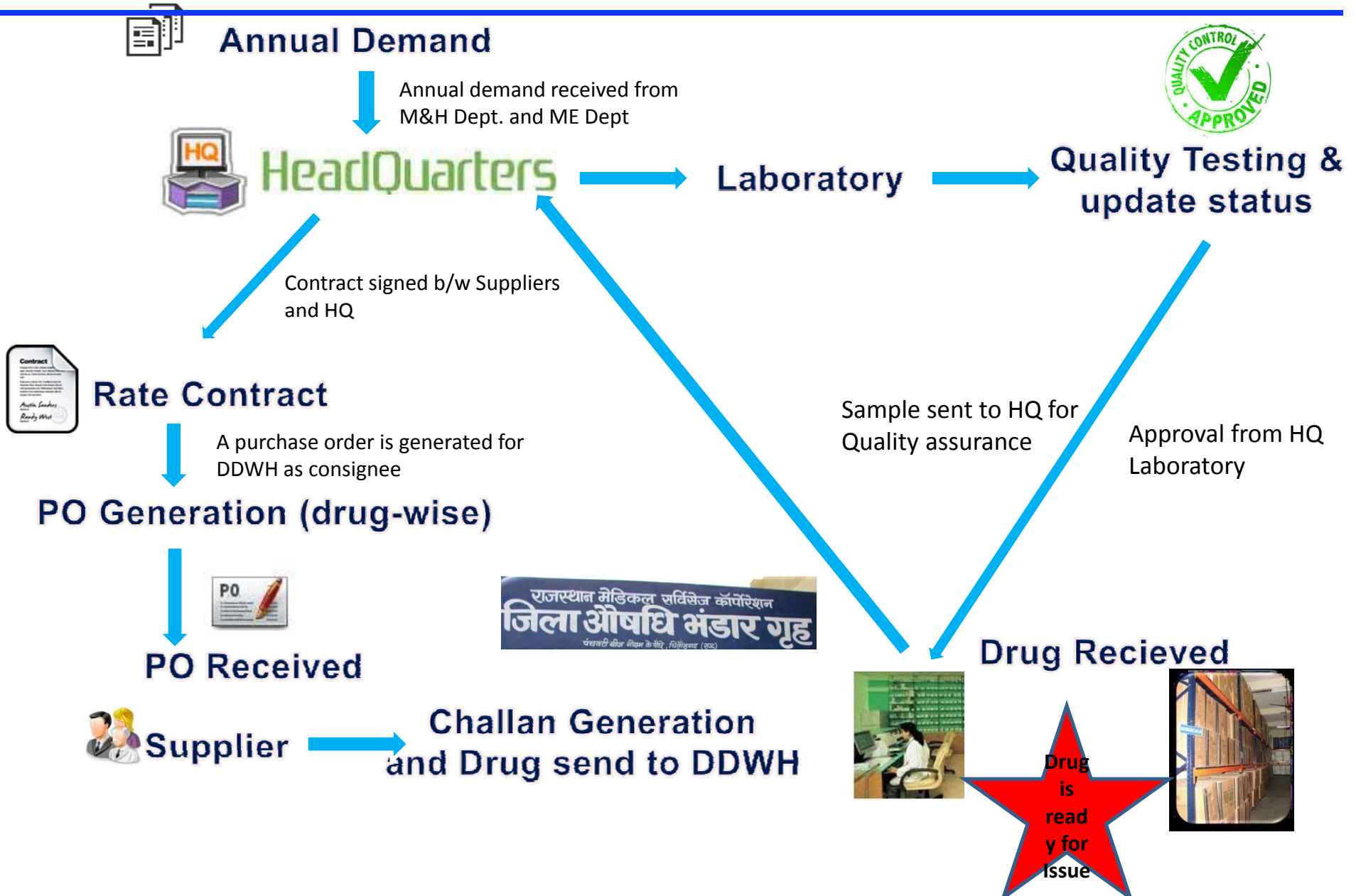
RMSC - Autonomous Centralized Procurement Agency



RAJASTHAN MEDICAL SERVICES CORPORATION – MAY 2011



RMSC Work Flow





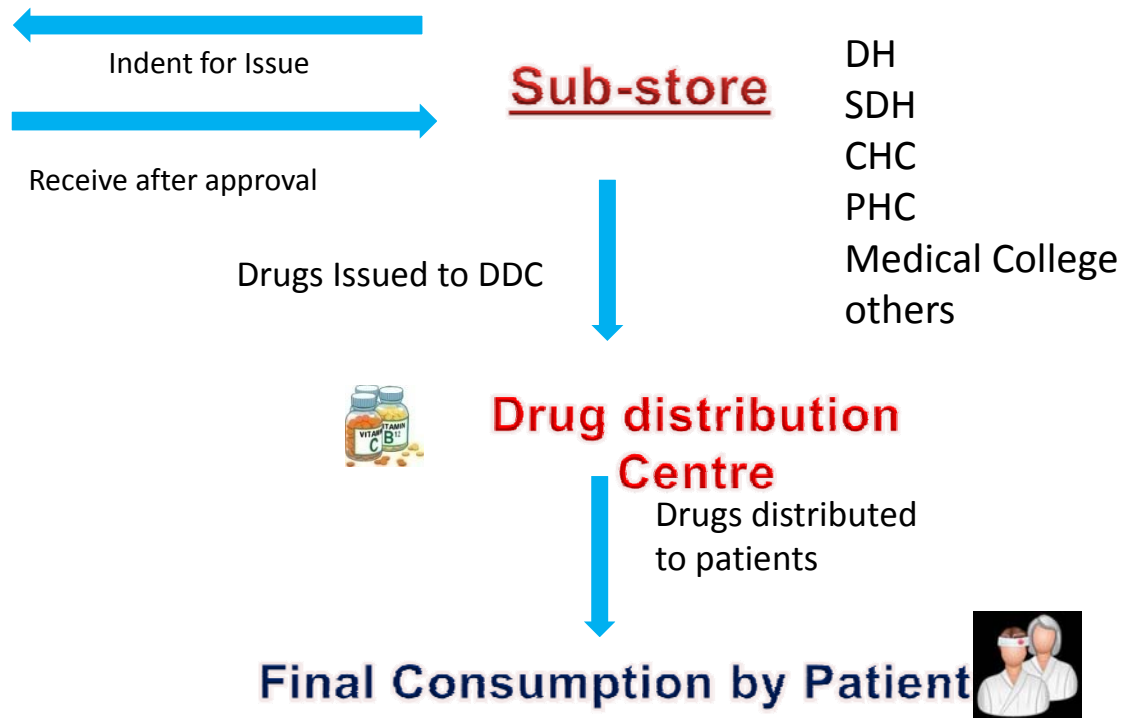
Work Flow(cont'd)



34 District Drug Warehouses
6 Medical College Drug Warehouses

Manpower at DDW/MCDW






- Officer in-charge-DDW
- 2 Pharmacists
- 2-3 Informatics Assistants
- Helpers – need based
- Security person – need based





Essential Medicines List

Provision of Drugs/Surgical and Sutures

Category of Healthcare Institutions	Numbers based on level of care			
	Medicines	Surgical Items	Sutures	Total
Medical College Hospitals 	605	146	77	828
District / Sub-dist / Satellite Hospitals 	525	141	37	703
CHCs 	446	110	11	567
PHCs/Dispensaries 	242	72	2	316
Sub Centers 	33	10	0	43

Institutions of M&H and ME Dept. covered under MNDY

S. No	Type of Institutions	No. of Institutions
1	Medical College Hospitals	28
2	District hospitals	60
3	Satellite Hospitals	
4	Sub-Divisional Hospitals	
5	CHCs	571
6	PHCs	2211
7	UPHCs +Dispensaries	245
8	Sub Centers	14408
9	MCWC	118
10	Mobile surgical units	7

NHM Procurement
Due to procurement through RMSC, the budget utilization from PIP on various drugs/sanitary napkins/ sutures /Asha kit and Equipments for different activities and projects has been encouraging.



Approximately 17648 institutions in total

Other Institutions/NGOs/Trusts Benefitted

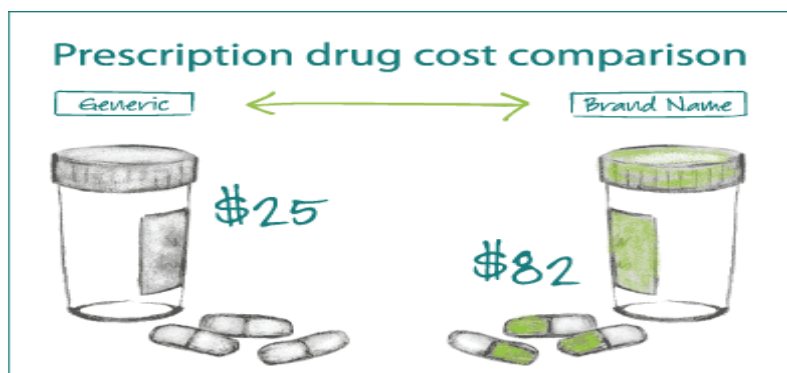


S.N	Type of Institutions	S. N	Type of Institutions
Law enforcement agencies		Private Hospital	
1	Jail Dispensary	1	Mahesh Hospital Jaipur
2	RAC battalion	NGOs/Trusts	
3	Police dispensaries	1	Acharya Shri Nanesh SVT, Chittorgarh
Others		2	Kuhad trust, Jaipur
1	ICDS – Anganwadi	3	Ma Madhuri Brij Waris Seva Sadan, Apna ghar, Bharatpur
2	School Education Department	4	Kota Super Thermal Power Station
3	NVBDCP	5	Indian Asthma Care Society, Jaipur
4	Rajasthan State Mines & Minerals Ltd.	6	WISH Foundation
5	Rajasthan University		
6	Sambhar Salts		
7	NREGA		
8	Election Department		

Price Comparison - Generic V/s Branded (As on 12.7.2017)



USE	NAME OF DRUG	PACK SIZE	EQUIVALENT POPULAR BRAND	MRP (RS.)	RMSC TENDER PRICE (IN RS.)
ANALGESIC	DICLOFENAC SODIUM TABLET IP 50 MG	10 TAB STRIP	VOVERAN	18.58	1.41
CHOLESTEROL LOWERING	ATORVASTATIN TABLET IP 10 MG	10 TAB STRIP	ATORVA (ZYDUS)	54.50	2.56
BLOOD THINNING DRUG	CLOPIDOGREL TABLET IP 75 MG	14 TAB STRIP	PLAVIX (SANOFI AVENTIS)	94.66	5.38 (10 Tab)
DIABETES	GLIMEPIRIDE TABLET IP 2 MG	10 TAB STRIP	AMARYL (AVENTIS)	56.60	1.17
ANTI-CANCER	PACLITAXEL 260 MG	VIAL	MITOTAX (Dr. Reddy's)	10119.00 (250 mg)	637.70



AND MANY MORE

??Acceptance of drugs with brand name



In case of :

- Imported drugs.
- Non- availability of Generic drug.
- Risk purchase through limited tender.



FUNDS – RECEIVED AND UTILIZED (As on 22.8.2017)



F.Y	Budget Received (Rs. in Crores)	Budget Utilized
2014-15	<ul style="list-style-type: none"> •Budget Provision: 295.00 Revised Provision:185.00 • State Plan:185.00 • NRHM-MNDY Drugs:186.83 • Others (Police, RAC, Jail, Sambhar salts, KTPS, RSMML,ICDS etc.):2.36 Total Received: 374.19 	<p>155.91</p> <p>157.58</p> <p>313.49</p>
2015-16	<ul style="list-style-type: none"> •Budget Provision: 280.00 Revised Provision:274.00 •State Plan:274.00 • NRHM-MNDY Drugs:173.29 • Others (Police, RAC, Jail, Sambhar salts, KTPS, RSMML,ICDS etc.):1.84 Total Received: 449.13 	<p>251.70</p> <p>135.03</p> <p>386.73</p>
2016-17	<ul style="list-style-type: none"> •Budget Provision: 280.00 Revised Provision:210.00 •State Plan: 210.00 • NRHM-MNDY Drugs:164.43 •Others: (Police, RAC, Jail, Sambhar salts, KTPS, RSMML,ICDS etc.) 3.31 Total Received: 377.74 	<p>278.54</p> <p>168.43</p> <p>446.97</p>
2017-18 (Upto 30th June 2017)	<ul style="list-style-type: none"> •Budget Provision: 310.00 •State Plan: 70.00 • NRHM-MNDY Drugs:57.11 •Others: (Police, RAC, Jail, Sambhar salts, KTPS, RSMML,ICDS etc.) 0.55 Total Received: 127.66 	<p>175.70</p> <p>27.69*</p> <p>203.39</p>

*UC is under process



UNIQUE FEATURES OF MNDY

SAVING LIVES

FREE MEDICINES FOR ALL

(A dream transformed into reality)



Policy entitlement - Universal in nature



Policy entitlement

Essential medicines
free of cost to all patients
visiting public healthcare institutions

Universal in nature

Entitles the entire **7 Crore** population of the state
No BPL card, Ration card, ID **proof required**

So that there is
NO BARRIER TO ACCESS TO TREATMENT

Prescription by Generic name



मुख्यमंत्री निःशुल्क दवा योजना

राजस्थान सरकार
चिकित्सा एवं स्वास्थ्य विभाग,
स्वास्थ्य भवन, तिलक मार्ग, सी स्कीम, जयपुर

No. RMSC/प्रपत्र/2011/213 Date : 26.08.2011


आदेश

माननीय मुख्यमंत्री महोदय द्वारा वर्ष 2011-12 की बजट घोषणा के अनुसार राज्य के सभी राजकीय चिकित्सालयों में आने वाले सभी मरीजों को सर्वाधिक उपयोग में आने वाली आवश्यक दवाइयों 2 अक्टूबर, 2011 से निशुल्क उपलब्ध कराई जायेगी। इस योजना के प्रारम्भ होने पर राज्य के सभी चिकित्सकों को दवा पर्ची लिखने सम्बन्धी निम्न निर्देश प्रदान किये जाते हैं।

- I जैनेरिक नाम से दवा लिखना (Prescription by Generic Name) :-**
राज्य सरकार के निर्देशानुसार चिकित्सकों द्वारा यथासम्भव प्रेस्क्रिप्शन (Salt/Pharmacopoeial/Generic) नाम से लिखा जाना है एवं आवश्यक दवाओं Essential drug का उपयोग मानक उपचार निर्देशों (Standard treatment guideline) के अनुसार किया जाना है। प्रत्येक पर्ची पर निदान (Provision/Final Diagnosis) व चिकित्सक के हस्ताक्षर आवश्यक रूप से होने चाहिये।
- II दो प्रति में दवा पर्ची (Double prescription slip) :-**
चिकित्सक को द्वारा दवा दो पर्चीयों (कार्बन कापी) पर लिखी जायेगी जिसकी एक प्रति मरीज के पास रहेगी तथा इसकी दूसरी प्रति निशुल्क दवा वितरण केन्द्र पर दी जाकर दवा प्राप्त की जा सकेगी।
- III उचित परामर्श (Counseling) :-**
प्रभावी चिकित्सक, चिकित्सकों, नर्सिंग स्टाफ व दवा वितरण केन्द्र के स्टाफ व सहकारिता विभाग के फार्मासिस्ट का यह दायित्व होगा कि वह राज्य सरकार की मंशा के अनुरूप रोगियों को उपचार में आवश्यक सहयोग करें व मरीजों को उचित सलाह (Counseling) प्रदान करें। संशय की स्थिति में वह जैनेरिक दवा के बारे में सम्बन्धित जानकारी दें व इस बारे में मरीजों की शंकाओं का निराकरण करने का प्रयास करें।
- IV प्रेस्क्रिप्शन ऑडिट (Prescription audit) :-**
राज्य सरकार के निर्देशानुसार चिकित्सा अधिकारी प्रभावी/पुनित हेड सम्य सम्य पर 10 प्रतिशत आउटडोर व इन्डोर पर्चीयों की जांच कर राज्यव्यापी की पालना सुनिश्चित करावें
- V उपचार की अवधि (Duration) :-**
सामान्यतया रोगी को तीन दिन की निशुल्क दवा उपलब्ध कराई जाये। अतिआवश्यक होने पर या विशेष परिस्थितियों में कारण इंगित करते हुए 7 दिन तक की दवा दी जा सकती है। लम्बी बीमारी (Chronic illnesses) यथा ब्लड प्रेशर/डायबिटीज/हृदयरोग/निर्मा/एनिमिया/ओस्टियोअर्थराइटिस आदि के रोगियों व पेयानर्स को एक माह तक की अवधि की दवाइयां उपलब्ध कराई जा सकेगी।
- VI लाईफ लाईन ड्रग स्टोर का सुदृढीकरण :-**
आर.एम.एस.टी. द्वारा उपलब्ध कराई गई निःशुल्क दवाइयों के अतिरिक्त अन्य दवाइयों को लाईफ लाईन ड्रग स्टोर के माध्यम से उपलब्ध कराया जाना है। आर.एम.आर.एस. नियमों के अनुसार प्रतिस्पर्धात्मक दसों

पर गुणवत्तापूर्ण औषधियों का क्रय तीन चिकित्सकों की समिति द्वारा किया जाकर विक्रय हेतु उपलब्ध कराया जाना है जिससे रोगियों को उचित मूल्य पर दवा मिल सके।

उक्त आदेशों की पालना सुनिश्चित करवें अन्ध्या विभाग द्वारा अनुशासनात्मक कार्यवाही की जाएगी।


मुख्य सचिव
राजस्थान सरकार

राजस्थान सरकार
राजकीय चिकित्सालय

रोगी उपचार पत्र

रोगी का नाम: आयु: रोगी का पता:
दिनांक:
R_x योग

हस्ताक्षर चिकित्सक प्रति हस्ताक्षर रोगी

• भूत सिंह परीक्षण करवाना जपजप अपराध है तथा इसकी दण्डनीयता 104 टोल प्री सेवा पर की जा सकती है।
• इस पर्ची पर लिखी हुई जैनेरिक दवायें "ब्रैंडेड दवायें" की तरह ही समान रूप से प्रयोग होती हैं।
• जैनेरिक दवाओं के विस्तृत उपचार से बचें।
• "शेप बन्दी दवायों" को मेडिसिन बांस में डालें।

राजस्थान सरकार
राजकीय चिकित्सालय

रोगी उपचार पत्र

रोगी का नाम: आयु: रोगी का पता:
दिनांक:
R_x योग

हस्ताक्षर चिकित्सक प्रति हस्ताक्षर रोगी

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Self Carbonated Prescription Slips by RMSC under CSR

- Medicines routinely prescribed for 3 days and in acute cases permitted up-to 7 days
- For chronic patients of HT/DM/Anemia/ long standing disorders can be prescribed for up-to 1 month

As an initiative by the Dept , the prescription slip now also carries message regarding **Bhamashah Health Insurance Scheme.**



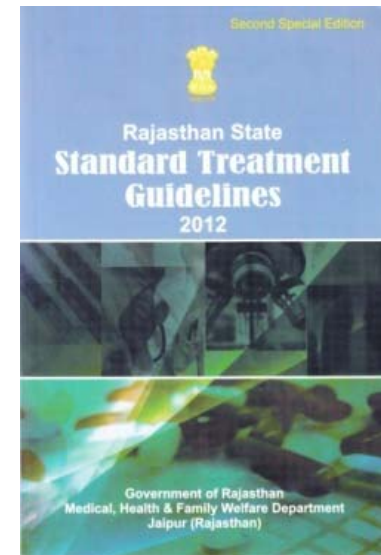
Essential Drug List & Standard Treatment Guidelines

Essential Drug List

- Developed by Technical Advisory Committee after detailed discussions and deliberations with subject experts.
- Based upon WHO and National List of Essential Medicines using explicit, previously agreed criteria, based on efficacy, safety, quality, and cost-effectiveness
- Incorporates generic name of medicine, levels of care and further differentiates drugs to be used in OPD, IPD, Operation Theatre, Injection room, Labour room.
- EDL 2013 comprised of 607 medicines, 73 surgical and 77 suture items.
- Upgraded to 612 medicines in 2014 by addition of 4 Swine Flu medicines & Vit K1 injection in October 2014
- After deletion of some obsolete medicines and addition of some new medicines **EDL 2015 comprises of 603 medicines, 137 surgical and 77 suture items.**
- Category changed recently for-
 - Tab Mifepristone from DH to PHC (MMA)
 - Inj. Iron Sucrose from CHC to PHC (Anemia management)
 - Inj. Mag. Sulphate from CHC to Sub-Centre (Management of Pre-eclampsia & Eclampsia cases)

Standard Treatment Guidelines

- Standard Treatment Guidelines (STG's) is an important tool for providing the most appropriate treatment through a list of essential medicines, complimented by a list of additional drugs when needed.
- Developed by the Delhi Society for promotion of Rational use of Drugs (DSPRUD) under RHSDP in 2006.
- Revised in 2012 by the Expert committee constituted by the Government comprising of clinical experts from various specialization and DSPRUD.
- Provided to all doctors across the state.



Set up of requisite /unique infrastructure at HC Institutions

DDCs established based on OPD and IPD load of each institution:

Each DDC@ Rs 2.25 lacs

Infrastructure:

- Shelves/Racks
- Refrigerator
- Computer with printer.
- Stationary.

Total Number of DDCs : 15169

All DDCs operate during OPD hours and for IPD/Emergency/Casualty patients 24X7 availability of medicines is ensured by the medical officer in-charges through identified DDCs.



Role of Pharmacist and DEO at the DDC



Each Drug Distribution Centre is managed by a pharmacist who is responsible for -

1. Smooth transaction of medicines at respective DDCs of institutions.
2. Ensuring continuity of medicines by replenishment from Sub-store on a daily basis.
3. Proper storage of medicines as per issued guidelines.
4. Counselling of patients.
5. Informing doctors of drug availability at DDCs on a daily basis.

The Data Entry Operator at the DDC:

- captures the medicine transactions in e-Aushadhi software and
- issues voucher to all patients.



Prescription Record at DDC



- Records for all prescriptions are being maintained at the DDC as RMSC has provisioned for duplicate prescription slips.

- The pharmacist at the DDC takes the signatures of the recipient, issues the medicines and returns the original prescription slip, while retaining the duplicate slip (for a period of 6 months).

- These **duplicate slips** are provided to the medical officer in-charge, 1% of these are subjected to **“Prescription Audit”** by the **Drug & Therapeutic Committees** constituted at the institutional level.

राजस्थान सरकार
राजकीय चिकित्सालय
रोगी उपचार पत्र

पंजीयन क्रमांक..... दिनांक..... पंजीयन शुल्क ₹.....
रोगी का नाम..... आयु..... स्त्री/पुरुष.....
निवा.....

Rx	योग
हस्ताक्षर चिकित्सक	प्राप्ति हस्ताक्षर रोगी

- भ्रूण श्लिष परीक्षण करवाना जघन्य अपराध है तथा इसकी शिकायत 104 टोल फ्री सेवा पर की जा सकती है।
- इस पर्ची पर लिखी हुई जेनेरिक दवायें 'ब्रांडेड दवाओं' की तरह ही समान रूप से प्रभावी होती हैं। जेनेरिक दवाओं के विरुद्ध दुष्प्रचार से बचें।
- "शेष बची दवाइयों को मेडिसिन बॉक्स में डालें"

Guideline for Injectable Issuance from DDC



Injectables (**except Insulins**) are **not to be issued from Outdoor DDCs** and should be kept exclusively for IPD patients.

Sensitization & Orientation of the Prescribers



FDA ENGAGED IN CREATING AWARENESS, THAT -

1. Generic has same quality /performance
2. Average cost of Generic Vs its Brand-name counterpart is 80-85% less
3. The lower price doesn't mean inferior
4. Monitors adverse events reports for generic drugs

FACTS ABOUT GENERIC DRUGS

Today, nearly **8 in 10** prescriptions filled in the U.S. are for generic drugs.

GENERIC

SAME QUALITY & PERFORMANCE

BRAND

- FDA requires generic drugs to have the same active ingredient, strength, dosage form, and route of administration as the brand-name drug.
- The generic manufacturer must prove its drug is the same (bioequivalent) as the brand-name drug.
- All manufacturing, packaging, and testing sites must pass the same quality standards as those of brand-name drugs.
- Many generic drugs are made in the same manufacturing plants as the brand-name drugs.

ALL FDA-APPROVED GENERIC DRUGS MUST BE EQUIVALENT TO THEIR BRAND-NAME DRUG.

Any generic drug modeled after a single, brand name drug must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability just as there is for one batch of brand name drug compared to the next batch of brand name product.

This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name drug.

80-85% LESS
Average cost of a generic drug vs. its brand-name counterpart

\$\$\$

\$

In 2010 alone, the use of FDA-approved generics saved \$153 billion.

\$3 BILLION SAVED EVERY WEEK!						
Sun	Mon	Tues	Wed	Thurs	Fri	Sat

THE LOWER PRICE DOESN'T MEAN INFERIOR.

Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion. In addition, multiple generic companies apply to FDA to approve a generic for the same brand name drugs. Multiple generic companies are often approved to market a single product. Competition in the market place, often results in lower prices.

FDA MONITORS ADVERSE EVENTS REPORTS FOR GENERIC DRUGS.

The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient.

Reports are monitored and investigated when anecdotal investigations may lead to changes in how a product is used or manufactured.

FDA IS ACTIVELY ENGAGED IN MAKING GENERIC DRUGS SAFER.

FDA is aware that there are reports that some people may experience an undesired effect when switching from a brand name drug to a generic formulation or from one generic drug to another generic drug. FDA wants to understand what may cause problems with certain formulations. In fact, they are linked to specific generic products.

FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

David et al. Comparing generic and innovator drugs: a meta-analysis of 2 years of observations. *Journal of Clinical Pharmacy and Therapeutics*. 2009;34(6):563-72
 AnyPharmacist.com 2009-2010. All rights reserved.

Constitution of Drug & Therapeutics Committee & Prescription Audit



Drug & Therapeutic Committee's –

- Facilitate tremendously in curtailing inappropriate drug use;
- Reduce drug expenditures and
- Increase availability and accessibility to essential medicines thus optimizing the value of government funds.
- Supervision in form of "**Prescription audit**"(1% of **total OPD+IPD**) and feedback which consists of -
 - (1) analyzing prescription appropriateness and
 - (2) giving feedback - prescribers are informed of their prescribing compared with accepted guidelines or with that of their peers.



The defaulters are dealt with as follows –

Step 1 - Counselling by Unit head & DTC members

Step 2 - Written advice by Supdt./ PMO/MO/c/CM&HO with copy to the dept.

Step 3 - Case may be referred to Principal Secretary M&H / M.E Dept. for disciplinary action.

Appointment & Training - Pharmacists and Informatics Assistants



About 1400 Pharmacists recruited

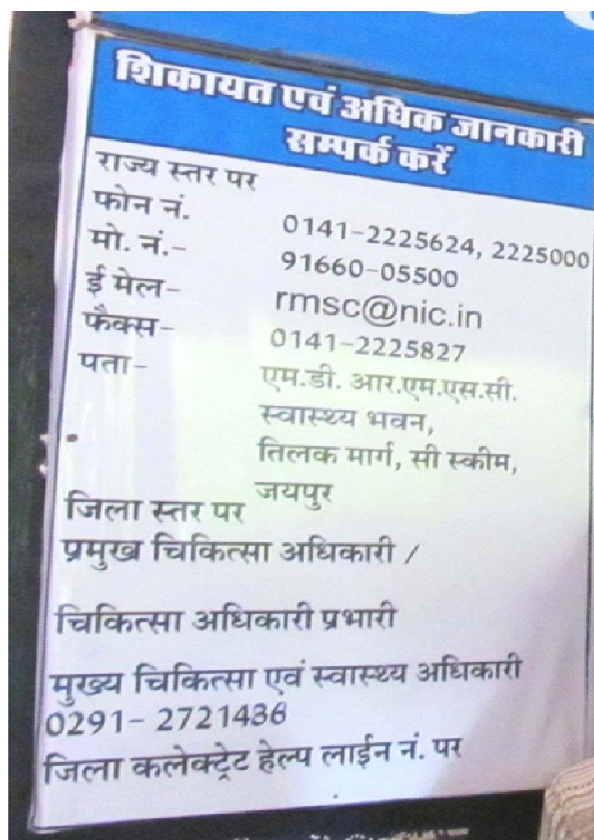


About 3200 Informatics assistant recruited



Orientation & training of Pharmacists

Effective Complaint & Feedback system



24x7 Complaint /Enquiry Number

- To resolve the complaint related to availability of drugs.
- To take necessary action according to feedback

91 66 00 55 00

“Not available (NA Hit)” drug reporting system

NA Hit Report:

- Every transaction of drug issued to patients is recorded in e-Aushadhi software.
- Information on prescription like name, age, sex, diagnosis, name & quantity of drugs, duration etc.
- During this not available “NA” drugs are also recorded.

The Supply Cell monitors these NA reports daily and coordinates between DDW, Sub-store and DDCs to make drug available from DDW to sub-store and DDC .

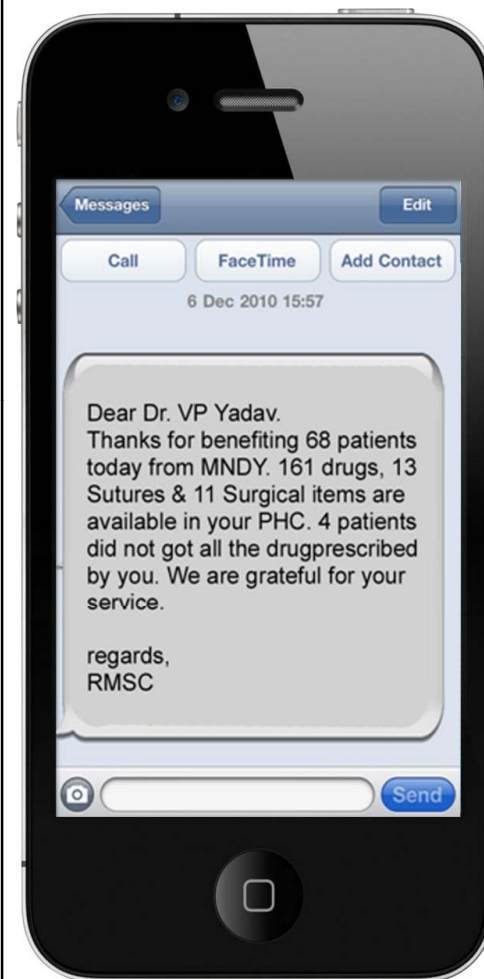
It also co-ordinates with supplier to expedite the supplies if in pipeline or issues a fresh purchase order if required.

SMS based daily monitoring and feedback system

About 7500 govt. doctors of the state receive SMS everyday after OPD hours –

- contains the number of patient he/she has attended and
- number of available /not available drugs.

Likewise each Officer in-charge – DDW /MCDW CMHO, PMO, MS, Principal Medical College receives message regularly about number of patients served, NA Hits, Near Expiry drugs etc.



Monitoring of “Near expiry” & “Danger zone” drugs

- Tracking of near expiry medicines is one of the best outcomes of online inventory management system.
- Near expiry drugs are arbitrarily classified into two major categories:
 - **Near expiry drugs:** The drugs which are about to expire within next 180 days (6 months).
 - **Danger zone drugs:** The drugs which are about to expire within next 60 days (2 months).
- Monitored closely by supply cell of RMSC which then informs Medical Superintendents, PMOs, CMHOs and OIC DDWs about the above so that the drugs may be consumed within their shelf life period.



Slow moving & Short drug management



- **Slow moving (Excess drugs) :** The stock of the drug at DDW exceeds the requirement for the next one year i.e more than the annual consumption.

Shift to another DDW

OR

“Sensitize doctors for consumption of the excess/slow moving drugs

- **Short drugs:** The stock which is not sufficient for 4 months at DDW keeping in view the estimated demand of that drug for 4 months.
 - Shift from another DDW
 - Sensitize doctors for the alternative prescription
 - “**Not available certificate**” issued by DDW to the respective hospitals so that short drugs are made available through **Local Purchase** (10% additional budget allotted to each institute for local purchase)



e-Aushadhi Software for Inventory management

- **Complete Supply Chain Management Solution** for drugs, surgical items and sutures, developed by CDAC.
- Provides inventory management at all DDWs and at sub stores / DDCs of Medical college hospitals, District Hospitals, CHCs and PHCs.
- Implemented across 4397 locations (including DDCs) across the state.
- Provides detailed information from the stage of procurement of the drug to its consumption by the end users.

Key Features of e-Aushadhi

- Facilitates online annual demand submission
- Online purchase order generation to suppliers
- Provision to maintain expiry date/shelf life
- Provides details of Quality control
- Ability to track drug inventory online
- Ability to generate customized reports
- Facilitates inter ware house transfer of drugs
- Alert generation in different colours for expired drugs, re-order level
- Maintains daily stock ledger of drugs



RMSC was awarded the **e-Governance award** for e-Aushadhi application on 12th Feb 2013 in **16th National e-Governance Conference**

The e-Aushadhi application has been replicated at the CMSS and various states across the country with requisite customization

General Features of MNDY

1. *Procurement*
2. *Quality control*
3. *Logistic & Storage*
4. *Supply chain management*

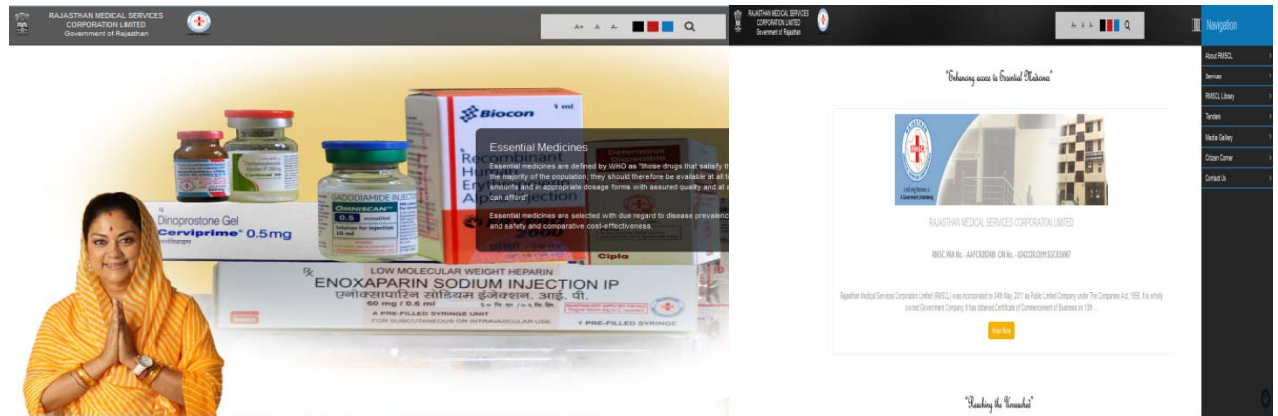
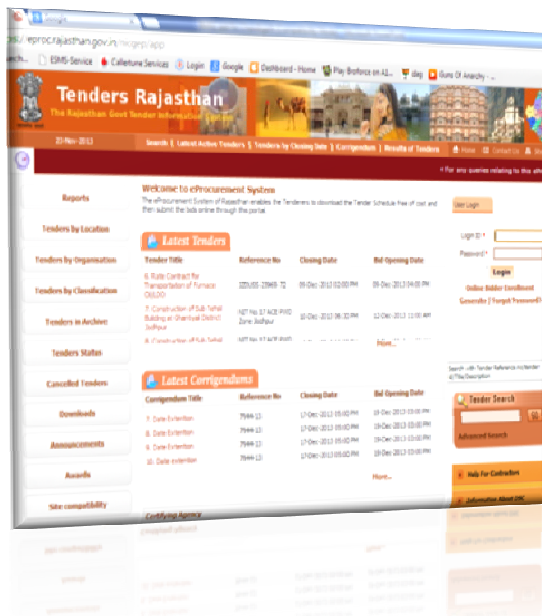


Procurement Criteria



A two-bid open transparent tendering process at RMSC

- Only manufacturer / Importer can participate.
- Annual turnover more than Rs 20 Cr in last 03 financial years
- WHO GMP Certificate mandatory
- 3 years market standing for the product. Bidder should also have manufactured at least three commercial batches of the quoted drug every year in the last 3 years
- Firm or product should not be blacklisted/debarred/convicted.
- Participation in e-procurement is mandatory.



Information of rate contract (RC), tender conditions, supplier contact details etc. are available on website - www.rmhc.health.rajasthan.gov.in

Rate Contract Status – Medicines (As on 28.8.2017)



S. No	Particulars	Numbers
(A)	Total Number of Drugs in EDL	605
(B)	Status of Rate Contract availability , including Letter of Acceptance	562
(C)	Remaining items(RC not available)	43
(i)	Agenda in TAC	03
(ii)	Items in new tender	35
(iii)	Demand not received	02
(iv)	Tender to be floated	03

Rate Contract Status – Surgical & Sutures (As on 28.8.2017)



S. No	Particulars	Numbers
(A)	Total Number of Surgical and Sutures in EDL	223
(B)	Status of Rate Contract availability , including Letter of Acceptance	159
(C)	Remaining items(RC not available)	64
(i)	Tender under process	49
(ii)	Tender under process	01
(iii)	New Tender will be floated	14

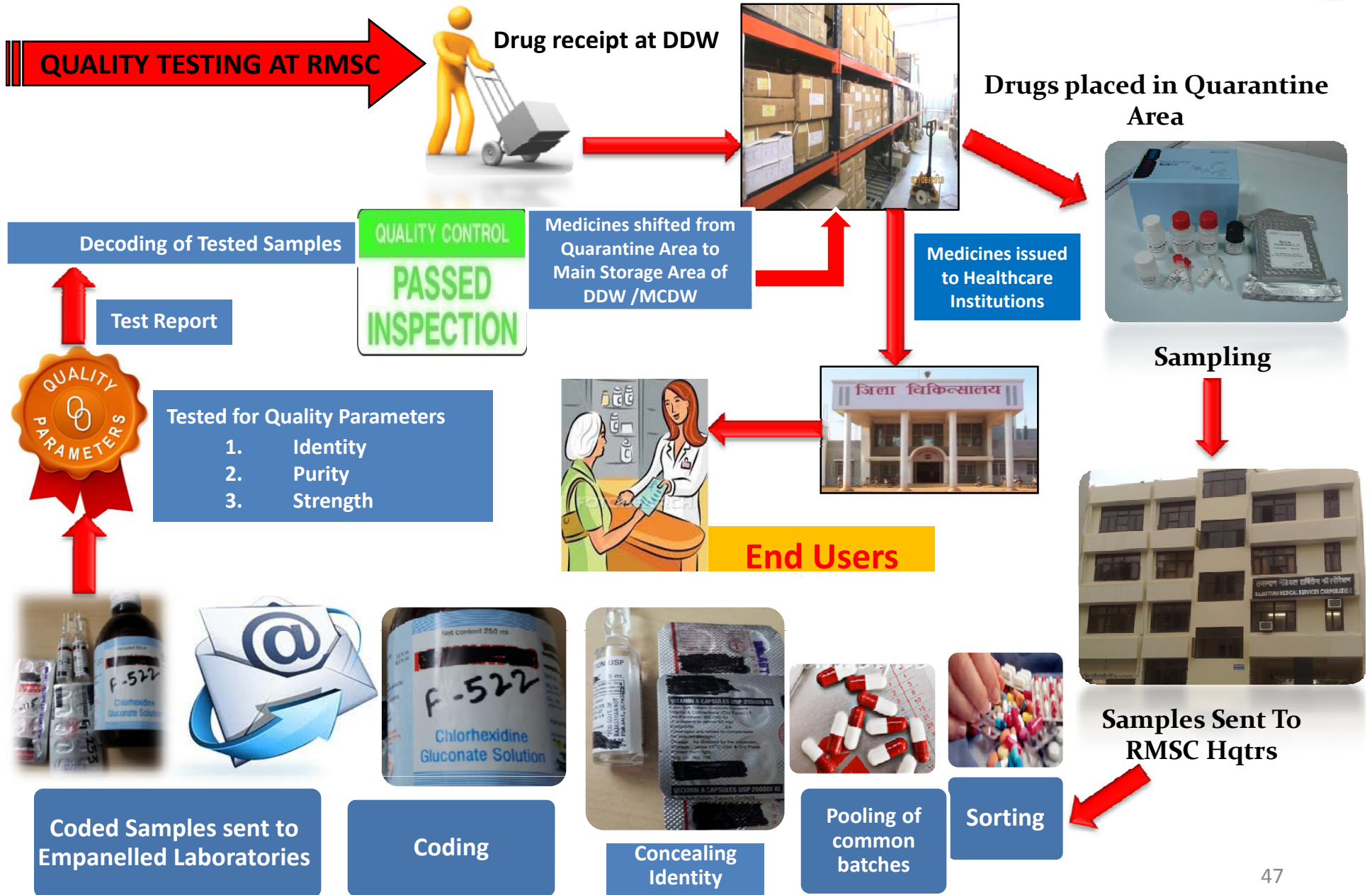
Quality control - Three Step quality checking system



- 1. Check at procurement level** – Strict parameters for selection of reputed supplier companies.
- 2. Check at supply level** – Acceptance of drugs only with QC passed batch release certificate (Certificate of Acceptance)
- 3. Check at issue level** – Pre-release quality assurance
 - Stock quarantined
 - Samples sent to QC cell
 - Retesting of all batches of drugs in Govt. approved empanelled labs.



Reassurance of Quality prior to Release of Medicines



QUALITY CONTROL TEST REPORTS:YEAR–WISE STATUS

(As on 28.8.2017)

S. No	Financial Year	Total Reports Received	No. of Failed Reports (1 st Testing & Retesting)	Failure %	No. of Passed Reports (1 st Testing & Retesting)
1.	2011-12	4429	55	1.24	4374
2.	2012-13	7036	313	4.44	6723
3.	2013-14	9394	351	3.73	9043
4.	2014-15	9835	249	2.53	9586
5.	2015 -16	11402	205	1.79	11197
6.	2016-17	9895	345	3.48	9550
7.	1.1.2017-23.8.2017	4665	130	2.79	4535

Number of Empanelled Laboratories – 2 Private + 2 Government

- 1.Oasis Test House Ltd. Jaipur
- 2. Amol Pharmaceuticals Pvt. Ltd.(Analytical Division)

- 1.National Institute of Biologicals, Noida
- 2. Central Drugs Laboratory, Kasauli

Since Inception:

Firms debarred /blacklisted /banned by Disciplinary Committee – 19
 Products debarred by Disciplinary Committee – 83

Storage & Logistics Management-Warehouse in Districts & Medical College



34 DDWs/6 MCDWs

Warehouse Storage & Issuance of Medicines



Maintaining Cold Chain at DDWs/MCDWs



ILRs for Back-up



Walk in Cooler (WIC) for storing Medicines / Inj / Vaccines requiring temperatures 2-8 degree Celsius



DEEP FREEZER for Ice-packs

System for transportation of drugs



- Own Vehicles.
- Hired Vehicles.

Cold chain maintained using:-

- Cold box
- Ice packs



IMPACT



INCREASE IN NUMBER OF PATIENTS IN GOVT. INSTITUTES

Before MNDY	After MNDY
44 lac patients per month	About 80 lac patients per month (>2.5 lakh per day)

Year	Beneficiaries (in Crores)
2011-12	3.78
2012-13	6.59
2013-14	5.81
2014-15	8.23
2015-16	9.31
2016-17	10.33



Note:

1. No. of beneficiaries from Jan-Jun 2014 includes Medical College Hospitals
2. From July 2014 onwards the figure is without data of Medical College Hospitals

Source:

- From Jan to June 2014 – RMSC&SMS Hospital, Jaipur .
- From July 2014 onwards on the basis of information received from CM&HOs and PMOs at MNDY Cell, DM&HS



IMPACT



संप्रदाय | निःशुल्क दवा योजना ने बचा ली जान
फिर चली बालिका की सांसें

गाई को बांधनी थी राखी

विशेषज्ञ

संप्रदाय से मृत प्रायः हुई बालिका को निःशुल्क दवा योजना को बदलत गुरुवार को नया जीवन मिल गया।

जानकारी के अनुसार विजयपुर क्षेत्र के पद्मशूल गांव में रहने वाली शंभुलाल मोगा की तैयार वर्षा पानी पुष्पा को गुरुवार को रोग्य उठाते समय कण्ड में बैठे कोबाय ने ड्रग लिया।

परिजन उसे सांघलियायी चिकित्साग्रहण सार, लेकिन जब तक बालिका को इलाज मृत प्रायः हो चुकी थी। मौके पर मौजूद भेल नर्स हेमन सां ने एंटी सेक वमन लगकर तुरंत चिकित्सक को बुलाया और बालिका को आईसीयू वार्ड में ले जाकर 2.5 बॉयल एंस्टेसी के इंजेक्शन लगाए। इसके बाद बालिका को नवम में स्थान

नवाया कि पुष्पा अपने पाई प्रकाशचन्द्र को राखी बांधने के लिए तैयार हो रही थी, तभी स्मन करने के लिए रोग्य लेते समय सां ने ड्रग लिया। जब में अस्पताल में रोग्य आने

निशुल्क दवा से बढ़े 67 प्रतिशत मरीज

मास्कर नयन | झलावाड़

निशुल्क दवा वितरण योजना को 2 अक्टूबर को एक साल पूरा हो रहा है। इस दवा योजना ने एक साल में ही इतना प्रभाव जमाया कि जिले के सरकारी अस्पतालों में ही 67 प्रतिशत मरीज बचा दिए। यह संख्या तो केवल आउटडोर (ओपीडी) की है। आईपीडी में भी 61 प्रतिशत मरीज बढ़े हैं। इन मरीजों को अस्पताल में भर्ती कर निशुल्क इलाज उपलब्ध कराया गया है। इसी का नतीजा है कि जिले में निशुल्क दवा वितरण योजना के बेहतर प्रबंधन और उत्कृष्ट सर्विस के लिए पूरे राजस्थान झालावाड़ जिला तीसरे नंबर पर आया है। मंगलवार को एक साल पूरा होने पर झालावाड़ जिले को जयपुर में सम्मानित किया जाएगा। निशुल्क दवा वितरण योजना से सबसे अधिक फायदा ग्रामीण क्षेत्र की गरीब जनता को हुआ है। इन लोगों को बीमार होने पर अस्पताल जाने से पहले अपनी जेब टटोलनी पड़ती थी। अगर जेब में रुपए हों तो इलाज कराते थे नहीं तो



झालावाड़, जिला अस्पताल में इलाज के लिए जंजीव करवाते लोग।

384 प्रकार की दवाएं वितरित

जिले में एक साल में 384 प्रकार की दवाइयों व 104 प्रकार के सर्जिकल आइटम मरीजों को उपलब्ध कराए गए हैं। हालांकि सरकार ने एक साल में 400 प्रकार की दवाइयों उपलब्ध कराने का दावा किया था। अगर चिकित्सा प्रशासन का मकलना है कि 384 प्रकार दवाओं में वे सभी दवाइयों आ गई हैं, जिनकी मरीजों को आवश्यकता थी।

आज से दवा के साथ वितरण पत्र भी मिलेगा

2 अक्टूबर से मरीजों को निशुल्क दवा वितरण के साथ सुधमन्त्री चिकित्सा दवा वितरण पत्र भी दिया जाएगा। इसमें पत्र से मरीज को यह जानकारी मिल सकेगी कि उसे जो निशुल्क दवाइयां मिली हैं, वह कितने की हैं, कितने से

सरकार ही नहीं आम आदमी के खर्च में भी कमी

मुफ्त दवा ने सुधारी सेहत

अरुणाम हर्ष @ जयपुर

मुफ्त दवा योजना से न सिर्फ आम आदमी का स्वास्थ्य सुधरा है बल्कि गुल्लक का गला भी भरना जा रहा है। चिकित्सा विभाग और फार्मा मार्केट से जुड़े विशेषज्ञों की मानें तो योजना लागू होने के बाद से आम आदमी की जेब में करीब एक हजार करोड़ रुपए बचने लगे हैं। तस्वीर का दूसरा पहलू यह है कि इतनी ही राशि का फार्मा बाजार राजस्थान में सिमटता जा रहा है। निशुल्क दवा वितरण योजना से पहले राज्य में करीब बाईं हजार करोड़ रुपए की दवाओं की खरीद हो रही थी। अब यह खरीद घटकर 1500 करोड़

बंद हो रही हैं दुकानें

प्रदेशभर में चल रहे करीब 15 हजार निशुल्क दवा वितरण केंद्रों के कारण दुकानें बंद हो रही हैं। दो से दस गुना फायदा लेने के लिए क्लिन क्लोनी ने दवा वें दुकान खोली थी, वो अब ताला लगा चुके हैं। जयपुर, जोधपुर, बीकानेर, कोटा और अलवर सहित अनेक शहरों में सैकड़ों दुकानें बंद कर दीं या फिर लाइसेंस का नवीनीकरण ही नहीं कराया। विदेशी सरकारों अस्पतालों के सामने स्पष्टीकरण दुकानों का बाजार शिफार गवा है।

दवा के अभाव में नहीं

drao jaipur 12-04-2013

Poor man's pocket now immune to med expense

Free health schemes saving precious money of poor people

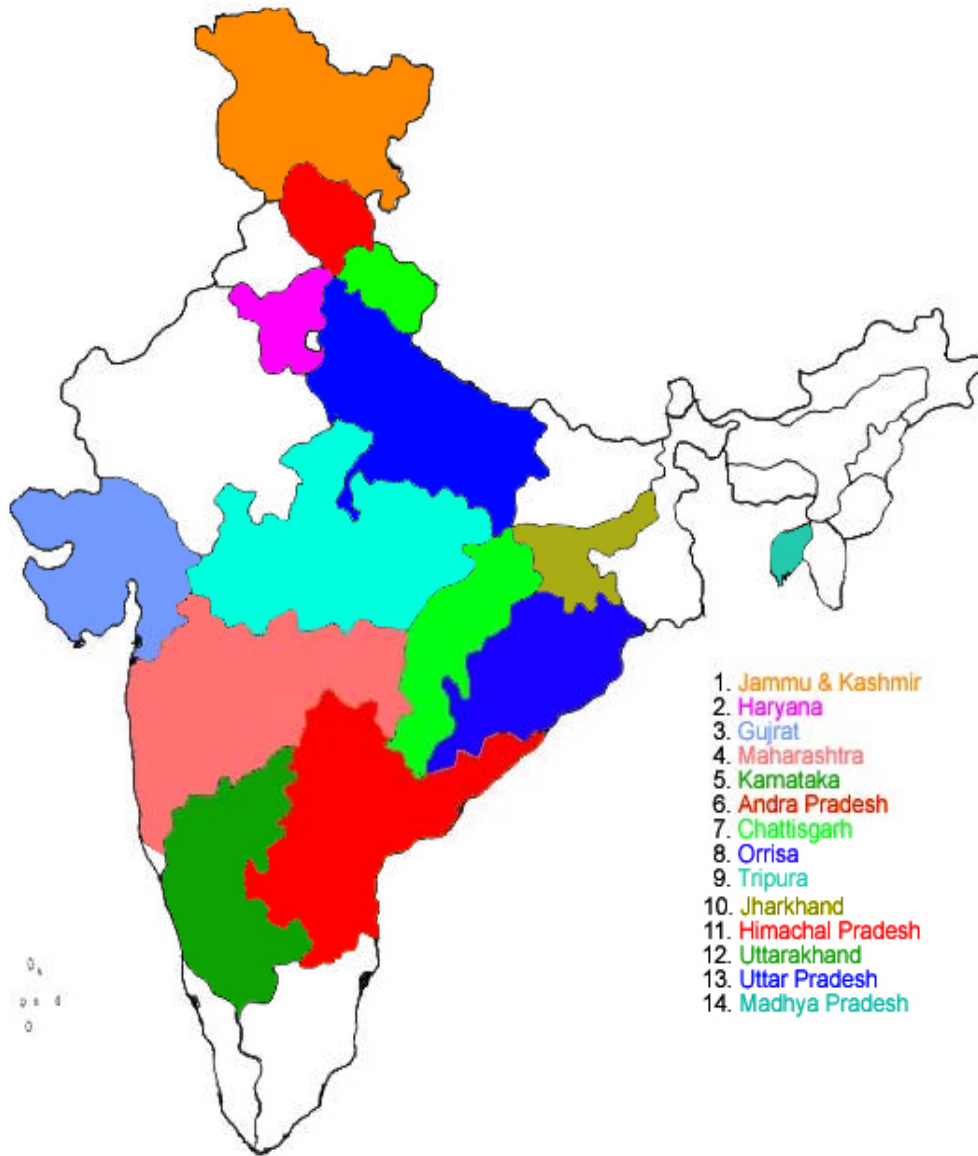
संजित ठापा, छापी, राजस्थान गैजटिंग सर्विस कॉन्सल्टेंट, जयपुर

निशुल्क दवा से बाजार फ्रावित हुआ है लेकिन सरकार को यह तय करना चाहिए कि जो व्यक्ति लक्षण है, उसे निशुल्क दवा लेनी चाहिए या नहीं। गरीब और जरूरतमंद तक योजना सीमित रहनी चाहिए थी।

राजीव जैन, सचिव, जयपुर रेगिस्ट्रार (सर्विस), जयपुर

SMILING PATIENTS & THOUSANDS OF LIVES SAVED

Role Model for States/Countries and Agencies



1. Jammu & Kashmir
2. Haryana
3. Gujarat
4. Maharashtra
5. Karnataka
6. Andhra Pradesh
7. Chattisgarh
8. Orissa
9. Tripura
10. Jharkhand
11. Himachal Pradesh
12. Uttarakhand
13. Uttar Pradesh
14. Madhya Pradesh

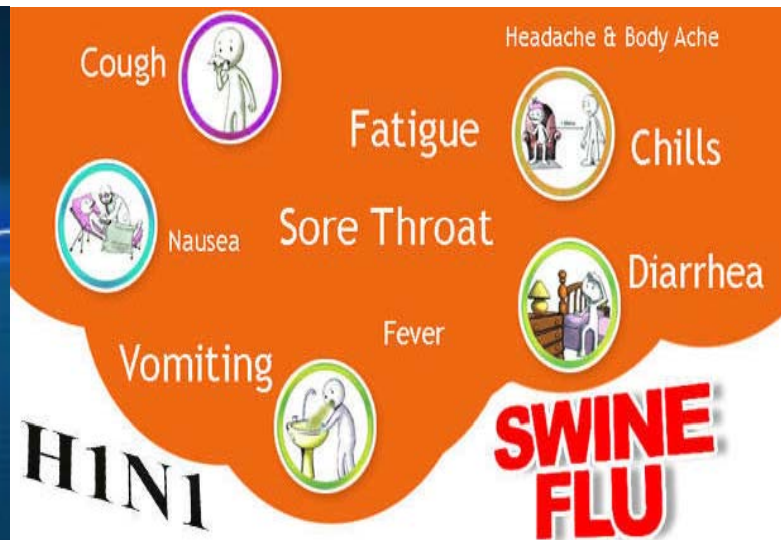
Other Team Visits

- BPPI, Gurgaon
- Deloitte, Delhi
- NGO (United Multipurpose Club), Assam, Guwahati
- North Korea Team of Govt. Officials
- Nepal –Centre for Labour and Social Studies
- UNFPA
- WHO & PHFI Team
- USAID
- Grp-B Officers of Central Secretariat Services from Institute of Secretariat Training and Management, Department of Personnel & Training, GoI
- Open Society Foundation
- Students from Indian Universities and Tuff's University, USA
- Medicines Procurement Department, Nepal Govt.

Timely Procurement of Capsule Oseltamivir in 2014 Handholding Support to States for managing Swine Flu



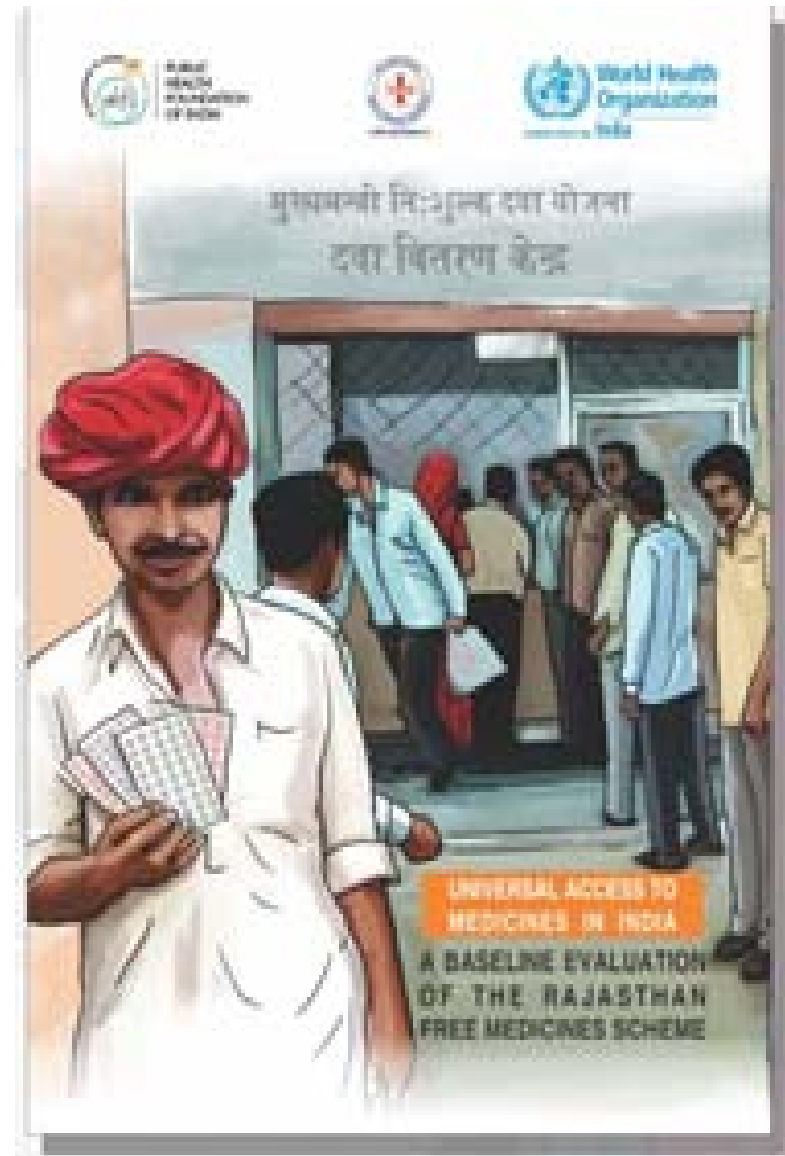
- 30,000 Cap. of Oseltamivir 30mg supplied to Govt. of *Kerala* for managing Swine flu outbreak in the State.
- 10,000 Cap. of Oseltamivir 30mg and 5000 Cap. of 75 mg supplied to Govt. of *Madhya Pradesh* to address shortage
- 25,000 Cap. of Oseltamavir 30 mg provided to *Uttar Pradesh*.
- 2000 Cap. Of Oseltamivir 75 mg and 30 mg each supplied to *Jammu & Kashmir*



Evaluation by Development Partners/NGOs



1. Baseline Evaluation of the Rajasthan Free Medicine Scheme - by PHFI & WHO (2013-14)
2. Showcasing Successful Models in Procurement and Logistics in the Health Sector – The World Bank Study of RMSC, TNMSC & KMSC (April-May 2016)
3. Photo documentation of RMSC HQ & MNDY by Prayas (students from India & Tufts University, USA) conducted in 05 districts: Bikaner, Banswara, Chittorgarh, Jaipur & Udaipur (report awaited)





Study description

- 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

Study findings



- **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-offs 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**



Vital role of Drug Prescription in health-care delivery

During the survey analysis two parameters were estimated ,
i. Average number of medicines prescribed per encounter
ii. Proportion of generics, antibiotics, injections, fixed drug combinations and syrups prescribed.

Indicator	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

MNDY.... towards Universal Health Coverage

- Step towards “Right to Treatment” and thereby *promoting Universal Health Coverage* in the state.
- Aims to **reduce Out of pocket expenditure** by decrease in expenditure being incurred on medicines.
- **Health seeking behavior is promoted** on account of increased access and affordability to treatment.
- **Optimal utilization of public health resources** – credibility of healthcare services and healthcare providers is enhanced.
- **Improvement in health indicators of the state** is expected- as scheme will aid in early treatment and contribute to reduction in morbidity and mortality trends. IMR, Under 5 mortality rates and MMR are expected to come down.

Challenges of the Journey so far



- Population- 70 million population - longer waiting times (Increase in both OPD IPD patients after MNDY/MNJY schemes)
- Cold chain maintenance (in summer temp rises upto 51⁰c)
- High patient load in tertiary care centers & shortage of Doctors / Pharmacists/Data Entry Operators.
- Timely Procurement
- Inventory Management
- Quality
- Issues related to pilferage, breakage, deterioration, drugs becoming obsolete etc, leading to adverse media reports at times
- Issue of Drug Expiry
- Incidents of Stock-outs
- Failure to generate realistic annual demand and non submission of timely indent.
- Unforeseen epidemics of swine flu, malaria, dengue, Chickenguinia, scrub typhus, etc



We have covered a long journey
towards free-drug scheme for the
common man, aiming at UHC



But

We have a long way to go.....



RMSC motto

All essential medicines

At all public health institutions

At all times

so that

No human being dies for want of treatment



*a candle loses
nothing
by lighting
other candles*

RMSC Ltd



Thankyou!