

Rajasthan, India

Pharmaceuticals in Health Care Delivery

Mission Report 11-22 March 2013

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Programme Agenda

Monday, March 11th

Morning: Rajasthan Medical Services Corporation (RMSC)
Managing Director;
Afternoon: Drug Regulatory Authority, Drug Controller.

Tuesday, March 12th

Morning: Departments of drug procurement, quality assurance, and
Logistics and Supply Management in RMSC;
Afternoon: Private drug testing laboratory used by RMSC.

Wednesday, March 13th

Morning: Gangori Hospital (attached to SMS Medical College);
Afternoon: Jaipur 1 District Warehouse.

Thursday, March 14th

Morning: Jaipuria District Hospital and surrounding private pharmacies;
Afternoon: BDM Kotputali District Hospital and private pharmacies.

Friday, March 15th

Morning: Govindgarh CHC and private pharmacies in Jaipur 2 district;
Afternoon: Samod PHC in Jaipur 2 district.

Saturday, March 16th

Morning: Bichoon PHC and Dudu CHC and nearby private pharmacies
in Jaipur 1 district;
Afternoon: Drug and Chemist's Association, Manufacturer's Association,
PRAYAS - Non Governmental Organisation.

Sunday, March 17th

Morning: Report reading;
Afternoon: Preparation for workshop

Monday, March 18th

Morning: Mahila Chikitsalya (Maternity) Hospital in Ajmer
Afternoon: JLN Medical College Hospital in Ajmer and nearby private
pharmacies.

Tuesday, March 19th

Morning: Ajmer District Warehouse and Pisagan CHC in Ajmer;
Afternoon: Saradhana PHC and private pharmacies in Ajmer district.

Wednesday, March 20th

Morning: Pharmacology department and pharmacovigilance team in
SMS Medical College, Jaipur;
Afternoon: Rajasthan Medical, Pharmacy and Nursing Councils

Thursday, March 21st: Workshop for National stakeholders

Morning: Presentation of findings by Dr. K.A.Holloway;
Plenary discussion of findings and recommendations
Afternoon: Visit to an unregistered medical practitioner
Debriefing with Rajasthan Society for Promoting Rational use
of Drugs

Friday, March 22nd:

Morning: Rajasthan Medical Services Corporation, IT department
Afternoon: Departure to Delhi

Acronyms

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AHW	Auxiliary Health Worker
ANM	Auxiliary Nurse Midwife
CHC	Community Health Centre
CPD	Continuing professional development
CME	Continuing medical education
CMHO	Chief Medical and Health Officer
CMO	Chief Medical Officer
DMHS	Department of Medical and Health Services
DIC	Drug Information Centre
DHO	District Health Officer (doctor)
DPHO	District Public Health Office
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
E-Aushadhi	Electronic drug management system
EDL	Essential Drug List
EML	Essential Medicines List
HA	Health Assistant
HQ	Headquarters
HP	Health Post
IPD	Inpatient department
IRs	Indian Rupees
MNDY	Mukhyamantri Nishulk Dava Yojana (Chief Minister free drug scheme)
MO	Medical Officer (doctor)
MOF	Ministry of Finance
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
M&H	Medical and Health Department
MRA	Medicines Regulatory Authority
MTC	Medicines and Therapeutic Committee
NGO	Non-governmental organization
NDP	National Drug Policy
NRHM	National Rural Health Mission
OPD	Outpatient department
OTC	Over-the-counter
PHC	Primary Health Care Centre
RCDA	Rajasthan Chemists and Druggists Association
RMC	Rajasthan Medical Council
RPC	Rajasthan Pharmacy Council
RNC	Rajasthan Nursing Council
RUM	Rational use of medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
VDC	Village Development Committee
VEN	Vital Essential Non-Essential – method for classifying drug importance
WHO	World Health Organization

Executive summary

A visit was made by WHO to Rajasthan during March 11-22, 2013. The programme was arranged in agreement with the Ministry of Health & Family Welfare, the Rajasthan Medical and Health Department (M&H) and the Rajasthan Medical Services Corporation (RMSC) and in collaboration with the WHO Country and Regional Offices. The TORs were to undertake a situational analysis of the pharmaceutical situation, focusing on health care delivery, and to conduct a half-day workshop with stakeholders to discuss the findings and develop a roadmap for state action. Visits were made to public health facilities and private pharmacies in three districts, the RMSC, the major M&H departments (including the Drug Regulatory Authority), the clinical pharmacology department at SMS Medical College, two university teaching hospitals, the Rajasthan Medical Council, Pharmacy Council and Nursing Council. It was found that Rajasthan has an extensive health care system with trained health care personnel. The Rajasthan government started Mukhyamantri Nishulk Dava Yojana (MNDY) free drug scheme in October 2011. This scheme is operated by the Rajasthan Medical Services Corporation (RMSC) which has established an efficient drug procurement and distribution system and achieved availability of essential medicines in all public health facilities. As a consequence there has been a huge increase in patient attendance. There remain, however, a number of challenges in the pharmaceutical sector concerning drug supply, selection, use, regulation, policy, information and coordination, as highlighted below, but there are sufficient resources and capacity to address the problems.

Drug Supply and selection

Currently, about 400 essential medicines (which can treat about 90% of all illness) are supplied by the RMSC for use in inpatients and outpatients to all (about 15,000) public health facilities, including 22 medical college hospitals, 56 district/sub-district/satellite hospitals, 428 community health centres (CHCs), 1844 primary health care centres (PHCs), 12,701 sub-centres and dispensaries, through approximately 16,053 free drug distribution centers (DDC). Procurement is done by e-bidding and relies on technical evaluation prior to financial evaluation. Quality control is in-built into the procurement process. An electronic inventory management system, E-Aushadhi is established in all warehouses and drug stores and DDCs of all health facilities down to the level of CHCs and some PHCs and allows for very efficient stock management. A 'pull' system is used from health facilities to the district warehouses which receive medicines directly from the suppliers who have the contract to supply drug products. Essential drugs were available in all facilities. Quantification of drugs is based upon last year's consumption and senior staff estimates but is inaccurate due to a lack of past consumption data (since the MNDY is new). Stock management was good in all public facility pharmacy outlets, but could be improved for emergency drugs on the wards for inpatients. There is an Essential Medicines List (EML) 2012, updated in 2013, which the RMSC follows. Not all stakeholders outside the RMSC were aware of amount of work that RMSC undertakes to run an efficient drug supply system.

It was recommended that the RMSC publish an annual report on procurement, distribution and consumption; extend the E-Aushadhi to all PHCs¹; review the method of quantification for annual need; review how emergency drugs are managed on the wards; and continue to update the EML and monitor adherence to it.

Drug use

A number of prescribing surveys conducted in India have been published but few in Rajasthan. The consultant observed prescribing that showed greater use of EML drugs and prescribing by generic name but more polypharmacy and higher use of antibiotics than is described elsewhere in India. Nearly all upper respiratory tract infection was treated with antibiotics. While most prescribers knew of the State standard treatment guidelines (STGs) that cover both primary and secondary care, few prescribers seemed to be using them and some hospital specialists felt the STGs were not applicable to them. Since the start of the RMSC, patient numbers have doubled but not the doctor numbers, so many were complaining of the increased workload. Indeed many doctors were seeing over 100 patients per day which is not conducive to good prescribing. While, prescribing principles are taught at undergraduate pre-clinical level, this knowledge is later undermined by clinical studies and later work. Continuing professional development (CPD) is adhoc and does not include much on rational use of medicines. Although most hospitals have DTCs, they mostly focus on stock availability and whether prescriptions are for EML drugs and drugs are prescribed by generic name. Little other monitoring of prescribing is done, although some monitoring could be done centrally using the E-Aushadhi system which has individual patient treatment data entered in it. Public education on safe effective medicines use through the network of Ashas has not been done.

It was recommended that the RMSC monitor prescribing patterns and staff workload using the E-Aushadhi system and liaise with the M&H for follow-up supervision. Such supervision should be targeted, in a non-confrontational way, to poorly performing prescribers/facilities and focused on targeted required behaviour changes, as identified from prescription audit. Workload data should be used to advocate redistribution of staff. Other interventions recommended include: strengthening Drug and Therapeutic Committees (DTCs) in all hospitals and requiring them to monitor prescribing and report annually to M&H; distributing updated guidelines and incorporating them into undergraduate and Continuing Professional Development (CPD) curricula; and developing public education programs on safe and prudent medicines use to be delivered through the Ashas.

Drug Regulation

The State Drug Regulatory Authority (DRA) manages a pharmaceutical sector of about 100,000 registered products, 289 manufacturers, more than 13,000 wholesalers and more than 20,000 registered drug retail shops. There is a severe manpower shortage in the DRA, with only 43 staff in post (out of 152 sanctioned posts) thus severely limiting its ability to inspect all the registered drug outlets. Dispensing in

¹ E-aushadhi was reported to be extended to all PHCs in December 2013.

many private pharmacy shops is done by unqualified persons contrary to regulations and prescription-only drugs are often sold without prescription. There are many brands for the same active pharmaceutical ingredient available on the market so making regulation of the market very difficult. Drug registration may only be done at State level for active pharmaceutical ingredients already on the market and since October 2012 no new trade names may be issued. A pharmacovigilance program is managed by SMS medical college. The DRA is unable to monitor pharmaceutical drug promotion due to resource constraints. The DRA has its own drug testing laboratory and tests more than 1000 samples per year but does not have the capacity to do all the testing that it feels is necessary.

It was recommended that the manpower shortage be rectified as a matter of urgency, that the Standard Operating Procedures (SOPs) be established for all various procedures and committees, that drug schedules be enforced more strictly, and that a unit be established to monitor drug promotion activities.

Coordination

Many important functions such as monitoring of medicines use, supporting DTCs, ensuring adherence to the EML, updating and distributing STGs, are currently done by RMSC but there is some feeling that this should be handed over to the M&H Department. Some activities such as coordinating CPD, ensuring incorporation of EML and STGs into CPD and undergraduate curricula and public education on safe and prudent medicines use are currently not done.

It was recommended that a multidisciplinary, mandated, independent, statutory committee, reporting directly to the Minister of Health, be established and that an executive unit, possibly the RMSC, be established to carry out the recommendations of the statutory committee. It was also recommended that the RMSC continue to monitor medicines use and coordinate the implementation of strategies to improve use.

Terms of Reference

The objectives were:

- (1) to meet senior officials of the Rajasthan Ministry of Health and Rajasthan Medical Services Corporation.
- (2) to undertake a rapid situational analysis of the pharmaceutical situation - with a focus on health care delivery and use of medicines.
- (3) to conduct a half-day workshop with Rajasthan State stakeholders to validate the findings of the situational analysis and to develop recommendations for future use by MOH/M&H, RMSC, WHO and stakeholders in planning.

Background

This mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector in order to aid MOH in planning future action and also to plan for future WHO technical support.

The regional strategy to promote rational use of medicines (RUM), updated at the regional meeting of July 2010, recommends undertaking a situational analysis in order to plan for a more coordinated integrated approach to improving the use of medicines. The regional resolution, SEA/RC64/R5 on *Essential Drug Policy including the rational use of medicines*, made the same recommendation in 2011. This mission was undertaken during 11-22 March, 2013, for this purpose. During the situational analysis, a checklist/tool developed in HQ/WHO and now being revised in the region was used. This tool allows the systematic collection of information. The persons met during the fact finding mission can be seen in annex 1. An integral part of this mission was a half-day workshop with 25 stakeholders that was held at the end of the mission to discuss and validate the findings and to form a road map for action. The list of participants of the workshop can be seen in annex 2.

Rajasthan has an extensive health care delivery system. In the last 18 months, a new free drug distribution system, Mukhyamantri Nishulk Dava Yojana (MNDY), operated by the Rajasthan Medical Services Corporation (RMSC), has been started. This scheme has resulted in greatly increased access of the population to essential medicines. While saving out of pocket costs for patients, these costs are now borne by the government. With increased availability of quality medicines, there is increased consumption and some concerns about irrational use of medicines. For these reasons, the situational analysis was undertaken. It is hoped that the recommendations made will be incorporated into future plans of action.

The words “medicine” and “drug” are used interchangeably in this report.

Medicines Supply

The Mukhiyamantri Nisulk Davai Yojana (MNDY) was started 18 months ago to ensure free access to essential medicines in all public health facilities. Prior to this scheme, very few drugs were available in the public sector and most patients had to purchase medicine. The Rajasthan Medical Services Corporation Limited (RMSC) is a new semi-independent company that was set up 18 months ago to undertake all drug procurement, quality check, storage and distribution. The RMSC took over drug supply from the previous central medical stores of Rajasthan state government, M&H Department. RMSC is a registered company with a Board, chaired by the Principal Secretary of Health, with 13 members including major Directors within the M&H, the State Drug Controller and the Financial Advisors to the M&H and the National Rural Health Mission. The RMSC also has a Technical Advisory Committee (TAC) that oversees technical issues, is chaired by the Managing Director of RMSC and has 17 members (mostly eminent medical practitioners) and other special invitees. The RMSC undertakes a great deal of work to ensure an efficient supply of good quality drugs but this may not be fully understood by some outside stakeholders.

The RMSC is accountable to the M&H but has more independence with regard to hiring staff. It currently enjoys strong political support, prompt funding by the Ministry of Finance (MOF) and a strong leadership. There are various 'cells' (sections) in RMSC – covering different functions:

- Procurement cell - for finalization of tenders of medicines, surgical and suture items and executing rate contracts;
- Supplies cell – for placement of purchase orders and maintenance of the supply chain in the state;
- Logistics Cell – for ensuring proper storage, temperature maintenance and dispensing;
- Quality Control cell – for quality testing of drugs at government approved empanelled laboratories;
- Finance Cell – for ensuring payments;
- I.T cell – for maintenance and smooth deployment of the “e-Aushadhi” software;
- Equipment Procurement Cell – for finalization of tenders for equipment and machines;
- Complaints cell – for following up complaints from patients about non-receipt of essential medicines from their local health facility.

Approximately 250 staff are employed in the RMSC (as compared to about 150 employed for drug supply and distribution pre-RMSC). Only medicines from the Essential Medicines List (EML) are supplied. Major changes in drug policy, particularly with regard to procurement, were instituted when the RMSC was formed. Competitive bidding (which has succeeded in purchase of all items) has replaced rate contracts (which only succeeded in purchase of 30% of items so necessarily resulting in decentralized procurement). Purchase preference to Pharmaceutical Public Sector Undertakings (PSUs) of 100% and Small Scale Industries (SSIs) of 80% were reduced to 10% and 15% respectively, provided they match the technical and financial bids of other bidders in the procurement process.

The medicines, surgical and suture items are procured centrally by RMSC according to annual estimates of need based on past consumption patterns of the items by government healthcare institutions. Supply orders are placed directly with suppliers to deliver directly to the institutions 3-monthly and to include 4 months buffer stock (which would cover 2 months pipeline stock likely to be in transit and under quarantine). About 400-450 essential medicines are supplied to medical college hospitals, 350-400 to district hospitals, 150-250 to CHCs, 150-250 to CHCs, 100-150 to PHCs/dispensaries and 20-30 to sub-centres.

The annual turnover of drugs was about 300 crore rupees in the last year all paid for by the state government. However, from next year, the federal government, National Rural Health Mission (NRHM), will pay 75% and the state government 25% of the budget. Drugs are dispensed free of charge in all the public health facilities, although the patients must pay a small registration fee of IRs.5-10 (outpatients) and IRs.10-20 (inpatients) per visit (covering 7 days treatment) in most facilities. A great increase in budget has been given by the state to cover many expenses which include:

- drug purchase and distribution (managed by RMSC)
- hiring of new staff (by M&H) which includes 1400 new pharmacists (soon another 1200 pharmacists), 1-2 data-entry clerks per facility (more in hospitals) to operate an electronic drug inventory system (E-Aushadhi) and more doctors to prescribe and nurses to dispense the medicines to more patients.

However, savings from reimbursement for the civil servant insurance scheme and payments for Below-Poverty-line patients has meant that the increased expenses are less than may be thought.

The State Government has allocated a drug budget for each facility according to the type of facility and number of beds, but not according to patient attendance or staffing. Ninety percent of all facility budgets are directly transferred to the RMSC to undertake procurement and distribution of essential medicines and ten percent is allocated to local purchase. In the case of CHCs and PHCs, the local budget is administered by the district health office. Hospitals may procure medicines themselves. Primary health centres (PHCs) have 5-6 beds and are allocated IRs 125,000/year. Community Health Centres (CHCs) have 30-100 beds and are allocated IRs 500,000 – 2,000,000 per year. District Hospitals have 50-400 beds and should cover all the major specialties and are allocated IRs 1,000,000 – 8,000,000 per year. There are seven Medical Colleges with 22 attached groups of hospitals in Rajasthan and they provide tertiary referral services as well as much primary care for the populations living nearby. They are allocated 100 to 800 million rupees per year. However, despite this system of allocation of approximately IRs 20,000 per bed per year, the outpatient attendance and inpatient bed occupancy are hugely different between facilities, even of the same type.

A Passbook System was created to maintain record of medicines issued to a particular facility against the allocated budget. Two copies of the passbook are maintained – one at the DDW and the second by the respective institution. The authorized person from the healthcare facility collects the medicines from the DDW in accordance with the

pre-decided calendar days and entries of the budget against the issued medicines are registered in the passbooks.

Some of the key challenges for the supply chain include: proper annual quantification and timely indent generation; cold chain maintenance (when summer temperatures rise to 51°C); a large population of 68 million spread over a large geographical area; and a heavy patient burden in many facilities with long waiting times.

Procurement

Drug procurement is done through a transparent e-tendering process according to a strict written protocol. Tendering is done once a year for most products, based on last year's consumption although this has been difficult due to the lack of consumption data in the relatively short time that RMSC has operated. The bidding process follows two processes – technical evaluation first, followed by financial evaluation for only those suppliers that pass the technical evaluation. Technical evaluation is done by a committee of 8-10 people that include staff from the procurement unit of RMSC and drug control department with staff deputed from the Drug Regulatory Authority. The Purchase Committee consists of 8 people, including Executive Directors from each unit in RMSC, the Drug Controller and the Chief Accounts Officer.

Criteria to pass technical evaluation cover both supplier and supply criteria and include:

- Supplier must be a manufacturer or importer,
- Supplier annual turnover of more than 20 crore,
- Production of the product by the supplier for more than 3 years,
- Supplier not blacklisted by any Medical Services Corporation or other State/central government procurement agency in India,
- GMP certificate for the product,
- Agreement to supply products with the specified shelf-life and labeling and packaging, which should include the RMSC logo and words “not for sale”,
- Agreement to supply general products within 45 days and imported or injectable products within 60 days.

All accepted bids must be accompanied by an Earnest Money Deposit of 2-5 lakhs. In addition, a bank guarantee against default at 5% of the value of the amount to be supplied must be made by the successful supplier at the time of contract. In the procurement documents it is also explained that 1.5% of the value of the medicine will be required to undertake QA testing and that this will be deducted by RMSC from their bills for products supplied, so the manufacturers may boost the prices quoted to take this into account. While the tendering process is underway the technical evaluation committee also undertakes a market survey to assess the prices of good quality products in the market.

Once the bids are submitted on-line by a specified date, the technical evaluation committee opens the technical part of all bids, undertakes a technical evaluation and presents the results to the Purchase Committee who decides which suppliers and products have passed the technical evaluation. Results of those suppliers and their products that pass and fail are then placed on the web and a few days given for failing

suppliers to appeal. The technical evaluation committee will reassess their bids, re-discuss with the Purchase Committee and respond on the web. Once the list of suppliers and products that have passed the technical evaluation is finalized, the Purchase Committee gives permission to open the financial bids of only those suppliers and products that pass the technical evaluation. Two out of three members of the technical evaluation committee (that have the concerned authority) can open the financial bid on-line.

The products that qualify with the lowest price (L1) are chosen, provided that their prices are equivalent to or lower than those found in the market survey. For a product where the quoted price is higher than that of the market survey, the supplier is invited to negotiate with the purchase committee. However, if he cannot equal the price, a retendering for that product is initiated. Other suppliers that match the lowest (L1) price or are the second (L2) and third (L3) lowest process are also identified as they may be approached for purchase should the first L1 supplier fail to supply all products on time.

Out of 477 products on the Essential Medicines List (EML), there are about 25-30 products for which they cannot get tenders, generally because the amounts are too small and the supplier cannot meet the 20 crore criteria. Examples of such products include ophthalmological products and antiseptics, where the manufacturers that produce them tend not to produce other products and so have a smaller turnover. In these cases a 2 crore turnover only is required. In addition, because of specialized manufacturing processes for these products, they are sometimes unable to comply with the normal deadlines of 45-60 days for delivery.

Since RMSC started, about 5-6 companies have been black listed for contravening technical criteria. Reasons have included inadequate documentation, failed quality testing and delayed supply. Suppliers who fail to meet their purchase orders may be asked to bear the cost of purchase by RMSC from another L1, L2 or L3 supplier, the costs being deducted from their bank guarantee against default. If a supplier fails to meet 50% of the purchase order on 3 consecutive occasions, then it is blacklisted from submitting tenders in the next year.

Quality assurance (QA)

There is a strict quality assurance system. Once drugs arrive at the district warehouses directly from the suppliers, in addition to requiring a certificate of analysis from the manufacturer, the consignment is placed under 'quarantine'. A sample of each newly arrived product is sent to the QA cell in RMSC for quality testing. Once the samples arrive, they are each given a code and all trace of the manufacturer or trade names are erased from the sample. A sample is then chosen for each product and sent for testing in a private laboratory. Upon receipt of a certificate of quality from the laboratory (and decoding the sample codes to match the laboratory results with the product names) new consignments are taken out of quarantine and may be used. In addition, the extra samples at RMSC are sent back to the local district warehouses for use. If any sample fails then RMSC will reject the products. RMSC may either ask the supplier to replace the complete batch of products or may decide to purchase elsewhere at the supplier's cost.

Testing is according to Indian Pharmacopoeia standards or in their absence according to British or US Pharmacopoeias. In order to get results within 2 weeks all samples are sent to private empanelled laboratories (since the government one does not have capacity). Over 10,000 samples were tested last year. This strict attention to quality has paid dividends. No doctors met complained of poor quality drugs. A few retailers (who had suffered reduced drug sales) stated that MNDY drugs were of poor quality but they were unable to substantiate their statements and were in a minority.

In summary, quality is ensured by:

- using only quality-compliant suppliers, who undertake regular audit;
- only accepting consignments of medicines at warehouses if a QC-passed test report for each batch accompanies the invoices;
- random blinded testing of samples from each delivered batch at government-approved empanelled laboratories.

Drug Quantification

The method of quantification is unclear. It appears to be based on the previous year's consumption plus an additional 20%. However, the government provides a drug budget based on a fixed allocation per facility according to its number of beds (which may not correspond to actual need). Since RMSC has only been operating for the last 18 months, prior to which few drugs were provided to patients in the public sector, there is only one year's consumption data on which to estimate need and this consumption may be rapidly changing. Currently, each district CMHO (after receipt of a demand from all the institutions under his/her supervision and validating and rationalizing the same) and each district hospital PMO makes an annual request and all such requests are sent to the Director (Public Health) where a total estimate is compiled, rationalized and validated before being sent to the RMSC. Similarly, demand from Superintendents of medical college hospitals are sent to Deputy Secretary (Medical Education) through respective Principals and Controllers and after due compilation, validation and rationalization, a total estimate is sent to the RMSC. The entire process has been computerized this year and demand is received online through e-Aushadhi software. The demand so received forms the basis for the quantities requested of manufacturers by RMSC during the tendering process. CMOs generally added 20% to last year's consumption in estimating need and RMSC adjusts these figures taking stock levels and the need for a 4-month buffer stock into account.

This method may not result in estimates according to need. Underuse or over use in past years will lead to under- and over-estimates respectively. Since the RMSC and MNDY free drug system is new with a rapid increase in drug consumption from a very low previous level, the amounts needed may have been under-estimated in the past year resulting in more frequent orders. In the future, one would expect demand for drugs to stabilize, although this may not happen. Easy availability of drugs may lead to over-demand and irrational over-use of medicines and/or frequent stock-outs, all of which may distort expected trends. If the actual amounts needed differ substantially from what is quantified this may result in future procurement difficulties. It may be wise to review the current system of quantification. One method to do this would be to estimate need according to morbidity patterns and treatment according to

standard treatment guidelines and compare the figures with actual consumption in some pilot districts.

Distribution

Distribution takes place from the supplier who has the procurement contract for that product directly to 33 district warehouses every 3 months. Each warehouse sends in a request which is processed by the RMSC supply cell which then informs the manufacturers to which warehouse or hospital they must deliver the products. RMSC has an electronic e-Aushadhi inventory management system, which is extended to the level of CHCs and is in the process of being extended to PHC level. This allows requests for drugs to RMSC to be modified according to known consumption and balance. A buffer stock of 4 months is required. While supply to district warehouses is 3 monthly, supplies from district warehouses to hospitals, CHCs and PHCs is weekly and monthly, respectively. All facilities have a schedule for ordering and receiving drugs. Mostly they must pick up drugs from the warehouse but in some cases the warehouse delivers drugs. The distribution system is a 'pull' system, drugs being supplied to facilities according to their demands, although RMSC does adjust amounts requested according to E-Aushadhi information on the facility stock levels. In addition, there is regular monitoring of all stock in facilities and warehouses and redistribution of medicines in order to ensure that there is no expiry and no stock-outs.

It was observed that very few facilities complained of any stock-out. If there was any stock-out it was only for 1-2 products and was being corrected within 1-2 days. This excellent availability was reflected in over 90% of all prescribed drugs being dispensed from the facilities (see section on drug use). Sometimes OPD pharmacies (Drug Distribution Centers) ran out of a few items by the end of the day, but generally stocks could be easily replenished from the facility drug store (sub-store). The records and storage of medicines were excellent. In contrast, drug stores in hospital wards were less systematically organized and, sometimes, drugs were stored in loose boxes in the nurses' room. In addition there is a severe shortage of nurses. In one hospital, two nurses had to look after 67 patients. Severe staff shortages and poorly organized ward drug storage may lead to adverse drug events.

Free Drug Distribution Centers (DDCs) have been established based on the OPD and IPD load of each institution and a total of 16,053 DDCs have been created across the state. All DDCs operate during OPD hours and for IPD/Emergency/Casualty patients, 24-hour availability of medicines is ensured by the medical officer in-charge through identified DDCs. Each DDC is managed by a pharmacist who is responsible for the safe, accurate and timely dispensing of medicines, ensuring medicines availability by replenishment from the sub-store and proper storage of medicines as per issued guidelines. The data entry operator at the DDC captures all medicines transactions (dispensing) in e-Aushadhi and issues vouchers to all patients. At the DDC records of all prescriptions (duplicate prescription slips) are maintained as requested by the MOHFW and as provided for by the RMSC. Thus the pharmacist at the DDC takes the signature of the recipient, issues the medicines and returns the original prescription slip to the recipient, while retaining the duplicate slip (for a period of six months). These duplicate slips are provided to the medical officer in-charge and 1% of these are subjected to "Prescription Audit" by the Drug & Therapeutic Committees

(DTC) constituted at the institutional level. The DTCs generally examine whether essential drugs are prescribed by generic name.

Local purchase

Ten percent of the centrally allocated drug budget is available for local purchase. In addition, there are extra funds from fees for registration and diagnostic tests that can be used for local purchase. Local purchase may be done if RMSC does not have stock of required EML drugs or for non-EML drugs if justified by the prescribing doctor. For district facilities, only EML drugs are generally purchased and central approval is needed. For tertiary hospitals non-EML products are purchased as decided by the Medical Superintendent after discussion with his/her medical staff. While district local purchase is generally for EML drugs, the drugs purchased may be for drugs approved for a higher level of facility. For example, PHCs may purchase CHC drugs and CHCs may purchase district hospital drugs, although all such purchases must be approved by the Chief Medical and Health Officer. By contrast, tertiary hospitals may and do procure non-EML drugs locally using not only the 10% budget allocation but also other funds including donations. Large hospitals also have Life-line shops operated by Medical Relief Societies (where the Medical Superintendent and heads of department decide what drugs to stock) and Cooperative Shops that stock drugs for pensioners, government civil servants and other private patients. Any purchase using government funds must follow the financial rules and amounts of more than IRs 5000/- require 3 tenders.

Possible Recommendations

1. RMSC to produce annual report on procurement and distribution:
 - ABC analysis, per-capita allocation, comparison across districts.
2. Extend E-Aushadhi system to all PHCs:
 - Better estimation / forecasting of drug need and stock control.
3. Review system of quantification:
 - Collect morbidity data and estimate drug quantities needed according to STG treatments and compare estimated quantities needed to actual quantities demanded in pilot districts.
4. Review storage systems for drugs on inpatient wards.

Medicines Selection and Consumption

Rajasthan published its Essential Medicines List (EML) in 2012 and has again just revised the list although the 2013 EML will only be followed from April 2013.

There were 477 drug products in the 2012 EML but this increased to over 600 drug products in the 2013 EML although most of the extra drug items are for tertiary referral hospital use only. The 2013 Rajasthan EML now has a total 607 medicines, 73 surgical and 77 suture items i.e. in total 757 items. Despite this increase in the number of drug products, the number of Active Pharmaceutical Ingredients (APIs) is less than 400. The drugs in the EML are classified according to whether they may be used in all facilities, secondary and tertiary care facilities only, or only in tertiary care facilities (as previously mentioned under medicines supply).

The specialist doctors are agitating for more drugs to be included in the EML arguing that their patients have more complicated refractory conditions. The RMSC and some members of the Technical Advisory Committee that decides upon the EML were aware of the need to avoid a large increase in the number of items. Interestingly, the private sector also preferred that the items on the EML be limited (so that their sales would not decrease further). Unit prices for each drug product are provided – as purchased by RMSC and also for 1-2 equivalent brands in the market. This information may sensitize prescribers to the benefit of the scheme and may also be helpful in calculating the budget at health facilities.

RMSC together with the DRA are responsible for coordinating development of the EML. There is a core group in RMSC (one seconded DRA staff and one RMSC staff) which drafts the EML and presents it to the Technical Advisory Committee (TAC) of 17 people who ultimately decide on the list. The TAC is chaired by the Managing Director of the RMSC and includes the Principals of the Medical Colleges, invited subject experts covering pharmacology, pharmacy and each specialty, nominated members including various hospital superintendents and a representative from Rajasthan University of Health Science, and RMSC officers from the Procurement, Logistic and Quality sections, and the Finance Department. Many sub-committees for different specialties are formed to advise on drugs within different therapeutic categories. The final Essential Medicines List (RMSC Procurement List 2012) was arrived at after detailed discussions and deliberations. The EML was developed based upon the WHO and Indian National List of Essential Medicines using explicit, previously agreed criteria, based on efficacy, safety, quality, cost and cost-effectiveness. Each Medical College Principal discusses the EML with his Heads of Department prior to meetings of the Technical Advisory Group. In addition the EML was reviewed by the pharmacology department in SMS medical college.

Despite all best efforts, some specialists may not be aware of the process of drug selection for the EML and the reasons for inclusion or exclusion of new drugs. One senior specialist stated to the WHO consultant that the drugs he needed were not in the EML and that he had not been properly consulted. Increased transparency of the process and sensitization of senior specialist doctors could be achieved by making the process more participative, ideally web-based, and including all reasons for inclusion or exclusion of drugs on the web. Furthermore, application for adding new drugs could be made open to specialists with a requirement to include the evidence and justification for why a new product is better than an existing one.

The EML has been implemented well. Not only does the RMSC follow the EML exclusively in drug supply, but there has been education and supervision to ensure that all doctors prescribe EML drugs by generic name. Various orders have been issued by the Secretary of Health to all facilities requesting that:

- Essential drugs be prescribed,
- Any use of non-essential drugs be justified by the concerned doctor,
- Drugs be prescribed by generic name,
- Carbon copy prescriptions be used, one copy for the patient and one for the facility,
- Prescription audit be done by the CMOs or principals to ensure appropriate use of medicines,
- STGs to be followed by doctors,
- Diagnosis be written on all prescriptions which should be signed by the doctor,
- Patients be counseled,
- Drug and Therapeutic Committees be established in large hospitals,
- Dispensing be monitored.

In addition, there has been extensive education of the public such that patients now know that they are entitled to receive free medicines from the health facilities. The RMSC has a monitoring and evaluation unit, which operates a help-line. Patients are free to call this number if they do not get medicines from the facilities but are requested to buy them from outside. This unit receives about 25 calls a day and always follows up with regard to complaints of patients not receiving medicines from public facilities.

It was observed that more than 90% of all drug prescribed belonged to the EML and that more than 90% of all drugs were prescribed by generic name (see section on medicines use). Some PHCs were observed to use CHC level drugs and some CHCs were observed to use district hospital drugs. This may be done with permission of the CMHO and is likely to occur since the doctors in these facilities may have similar qualifications and experience. For example, some specialist doctors who had worked in district hospitals were found placed in CHCs. The majority of prescriptions also had diagnosis written and were signed.

Most health facilities reported a doubling in patient attendance since MNDY started. On discussion with public sector health workers, the Drug and Chemists Association, and private drug retailers near to public facilities, it appears that private drug sales have fallen dramatically since the MNDY started. This fall has been greatest (up to 70%) in rural areas where there is limited private practice and least in cities (15-20%) where private practice is greatest. A 30-50% reduction in sales was reported by retailers in district centres. For PHCs and CHCs, life-line shops and many surrounding private retail shops have actually closed down.

Thus, the RMSC has succeeded in a remarkable way in improving access to essential medicines and ensuring that all the drugs it is supplying are actually being prescribed by doctors.

Table 1 shows an ABC analysis of drugs issued from warehouses to facilities. It covers the first 16 months of the MNDY. This analysis only covers medicines and excludes medical devices and disinfectants. It can be seen that a large proportion of these top 28 drugs by value are antibiotics and some products such as cough syrup and paracetamol which are frequently used in outpatient care for simple diseases. It can further be seen that only EML drugs have been supplied.

Table 1: ABC Analysis of Drug Supply issued from warehouses during October 2011-February 2013

Drug Name		Value	Drug Name		Value
1	Human Antirabies IMG	132,704,000	15	Cefotaxime inj 1g	41,166,207
2	Azithromycin 500mg	107,933,856	16	Tetanus IMG	39,093,086
3	Cefixime 200mg	96,899,441	17	Ciprofloxacin500mg	37,213,573
4	Meropenem inj 500mg	93,646,692	18	Cephalexin 250mg	37,156,419
5	Ceftriaxome inj 1g	92,117,754	19	Cough syrup	35,631,414
6	Amoxycillin 500mg	71,733,743	20	Snakevenom serum	34,287,516
7	Rabies I/D vaccine	64,871,279	21	Defarasirox 500mg	33,290,632
8	Human AntiD IMG	64,497,200	22	Ofloxacin 200mg	32,352,553
9	Azithromycin 250mg	59,929,945	23	Ciprofloxacin250mg	31,165,276
10	Amoxy-clav 500+125mg	54,794,283	24	Methylprednisol inj	29,687,580
11	Beclomethasone Inhaler	48,444,241	25	Ceftazidime inj 1g	28,972,245
12	Paracetamol 500mg	42,794,950	26	Omeprazole 20mg	28,534,910
13	Hum Albumen 20% sol	41,890,250	27	Piperacillin+Taz inj	28,397,590
14	Enoxaparin inj 60mg	41,601,968	28	Cefixime 100mg	27,267,642
Total value of top 28 drugs (6% items) is IRs1,640,511,712/- (41% budget)					

More extensive ABC analysis showed that the top 94 (20%) items consumed 70% of the budget. Further analyses should be done to see what proportion of the budget is consumed by various therapeutic groups e.g. antibiotics and also to see what actual products within therapeutic categories are the highest by value. In this way one may target different drugs for investigation of whether use is appropriate or not.

Possible Recommendations

1. RMSC to produce annual report on consumption:
 - ABC analysis, per-capita consumption, comparison across districts.
2. Continue to update the EML and contain the number of items on the EML:
 - Have a more participative and ideally web-based process and strict criteria for inclusion of new medicines in the EML,
 - Include the EML and how it is formed in pre-service and in-service training curricula in order to sensitize doctors as to its utility.
3. Continue to monitor adherence to the EML:
 - Will require review of prescriptions as non-dispensed medicines are not entered into e-Aushadhi.

Medicines Use

Prescribing in India

There have been a number of studies of drug use in public health facilities done since 2000 in India. Table 2 summarizes the baseline data from these studies. In addition, it had been found that drugs are not labeled when dispensed (Chaudhury et al 2005, Karande et al 2005, Rishi et al 2003) and that up to 20-70% of patients may not know how to take their medicines (Chaudhury et al 2005, Karande et al 2005, Rishi et al 2003, DSPRUD 2002). Although the majority of patients seek health care in the private sector relatively few studies of drug use have been done in the private sector. Some studies have shown greater use of medicines in the private sector as compared to the public sector (Kumar et al 2008, Bhatia & Cleland 2004) although this has not been shown in other studies (Indira K 2004). Different types of private sector provider are likely to have widely varying prescribing and dispensing patterns.

Table 2: Summary of baseline drug use in public sector primary care in India as reported in studies conducted from 2000 onwards

Reference	Year of survey	Av. no. drug/Px	% Px with ABs	% Px with INJs	% generic drugs	% EML drugs	% Px with VITs	% viral URTI given AB
Malhotra et al 2001, N.India	2000	1.9			30	90		
DSPRUD 2002, Orissa	2001	2.4-2.7	63-78	8-13		77-92		
Chaudhury et al 2005, Delhi	2001	2.4	49-55		49-96	94-100		
Bhatia & Cleland 2004, S.India	2001			34				
Rishi et al 2003, Uttaranchal	2001	3.7	77	7	51		60	
Karande et al 2005	2001	2.9	40	0.2	73	90		53
Indira K 2004	2003	3.5	71	25				76
Kumar et al 2008, Uttar Pradesh	2003		79	3				
WHO 2009, Thatta/Mumbai	2002-3		43-49					
WHO 2009, Chandy/Vellore	2003, 2005		46					
Biswas et al 2007, Bangalore	2004		56					
Bhunja et al 2009, S.India	2007			22				
Singh et al 2010	2007	2.5	44	21	28	84		

Px=prescription; AB=antibiotic; INJ=injection; EML=Essential Medicines List;

VIT=vitamin; URTI=upper respiratory infection;

Data extracted from the WHO database on medicines use, updated to 2009.

Very few of these studies have been done in association with interventions to improve the use of medicines and even fewer have been evaluated for their impact (using adequate study design). Training to improve dispensing resulted in an increased dispensing time from 24 to 114 seconds, increased drug labeling from 0% to 100% and improved patient knowledge on how to take their medicines from 58% to 97% (Chaudhury et al 2005). Interactional group discussion between prescribers and patients resulted in 11% decreased injection use (Bhunja et al 2009).

Prescribing in Rajasthan

The consultant undertook a rapid prescribing survey in the outpatient departments in 10 public facilities (serving mostly acute patients) and 8 private pharmacies (serving acute and chronic patients). In each public facility 30 prescriptions in the OPD pharmacy (Drug Distribution Centre) were examined. In 2 life-line, 2 Co-operative and 2 private pharmacies, computer records of patient bills were examined and in 2 private pharmacies without computers patient bills were examined (only 15 in each shop). In public facilities, where prescriptions were examined, treatment could be matched against diagnosis. The results are shown in table 3.

It can be clearly seen, by comparing tables 2 (literature review) and 3 (WHO consultant's survey), that prescribing of EML drugs and by generic name is over 90% - much higher than has been found elsewhere. Over 90% of all drugs were dispensed and the average drug cost per patient was much lower in public facilities as compared to private pharmacies, thus demonstrating the efficiency of the RMSC's supply system.

Table 3: Prescribing survey undertaken by the WHO consultant

Drug use indicator	Referral hospital N=2	District hospital N=2	CHC N=3	PHC N=3	Private Drug Retailer N=8
Average no.drugs / Px	4.1	3.3	3.2	3.6	3.0
% Px with antibiotics	53	67	62	64	35
% URTI cases given antibiotics	81	100	97	96	-
% Px with injections	3	9	18	15	20
% Px with vitamins	24	12	11	6	35
% drugs prescribed by generic name	99	99	100	98	22
% prescribed drugs belonging to the EML	92	97	100	97	43
% drugs dispensed	90	92	100	96	100
Average cost/Px (IRs)	Approximately 15-30*				283.22

Px = prescription

* Information provided in a presentation by the RMSC Managing Director and from a study done by the Bikaner district In Charge.

The rapid survey would also seem to indicate that a greater number of drugs are prescribed per patient in Rajasthan public facilities than has been seen elsewhere. While one might expect a greater number of medicines to be prescribed on average to hospital patients who have more complex conditions, care was taken to select primary care type patients as far as possible. Even at PHCs, each patient was given on average 3-4 drugs. Higher rates of vitamin use (B Complex and multivitamins) were seen in the higher level facilities and retail shops. The proportion of patients prescribed antibiotics is very high. Lower rates of antibiotic use seen in the tertiary referral hospitals reflect the higher proportion of chronic cases and lower proportion of acute cases as compared to what is seen in primary health care. However, a particular concern is that nearly all patients with upper respiratory tract infections were prescribed antibiotics. This figure would be high even if these “upper respiratory tract infection” cases actually included cases of lower respiratory tract infection. However, effort was made to exclude lower respiratory tract infection cases from the analysis.

One third of OPD cases were diagnosed as having an upper respiratory tract infection. Virtually all such cases were prescribed an antibiotic (often a 3rd generation one such as cefixime or azithromycin), an antihistamine, an analgesic, a cough syrup and sometimes also a bronchodilator and nasal drops. Most of these drugs were in the top 28 drugs by value (see table 1) and were estimated to cost IRs 875,954,661 in 2012 i.e. 22% of the budget. Now it may well be that some of these medicines were used for patients with other conditions including inpatients. Nevertheless, it is very likely that excessive OPD prescribing is wasting resources as well as exposing patients to risks of side-effects, drug interactions, etc.

Other very common examples of inappropriate prescribing included the following:

- Omeprazole or Ranitidine to counter Diclofenac or Ibuprofen or even Paracetamol!
- Alprazolam in hypertension
- Methylprednisolone for back pain or bodyache
- Metronidazole and a fluoroquinolone for acute diarrhoea
- Paracetamol + Ibuprofen or Paracetamol + Diclofenac combination products instead of paracetamol alone for simple analgesia

Omeprazole and combination analgesic products were also in the top 20% of drug items (A category drugs) that consume 70% of the budget. There were also 1-2 examples of serious inappropriate prescribing. One child with pneumonia was prescribed ceftriaxone, amikacin, cefixime, cotrimoxazole, cetirizine and paracetamol as an outpatient and not referred. An adult with vertigo was prescribed ciprofloxacin, domperidone+cinnarizine, betamethasone, paracetamol and chlorpheniramine.

The polypharmacy seen is a likely consequence to the free availability of drugs. Patients are now becoming accustomed to free drugs and may demand more drug items. Doctors stated that if they did not give several drugs, patients would be unsatisfied and visit another doctor. This is a serious concern for private doctors but it should not be a concern for public sector doctors who are not paid according to the patients they see – unless they are worried about losing private patients in the evening time. Nevertheless, many doctors do not have the time to persuade patients to take fewer medicines.

In most of the public facilities visited, doctors were seeing about 50-100 patients per day. Some generalist doctors stated that they saw up to 200 patients per day and all complained of hugely increased patient numbers but not increased doctors since the MNDY started. Even, so most doctors see private patients in the evening time. Thus some prescribers will be constrained by overly short consultations from making proper diagnoses and this may contribute to irrational overuse of medicines. It will also constrain communication with patients. In one facility visited, doctors saw about 30 patients per day and it was mentioned by several senior public health staff that there was unequal workload between facilities and even within facilities (since patients sometimes prefer one doctor to another). Even though the problem of unequally distributed staff is recognized, the districts do not have power to redistribute staff, this being controlled centrally.

Dispensing

Dispensing was generally done by pharmacists or pharmacy assistants in hospitals and CHCs and nurses in PHCs. In most hospitals and busy CHCs one staff member may have to dispense medicines to over 250 patients per day. It was observed that the patient-dispenser contact time was often less than one minute, sometimes only a few seconds, so allowing little time to give patients proper instruction on how to take their medicines. There was no labeling whatsoever of medicines in any facility visited. Although patients keep their prescriptions, instructions on how to take medicines are not written in a manner that may be read by patients. It is likely therefore that a substantial number of patients do not know how to take their medicines on leaving the facility and do not take them properly at home. It would be worth conducting a study on this in different facilities in order to assess the size of the problem and then take action to correct the problem.

Private prescribing

The 8 private pharmacies observed served very different customers. Table 4 shows the rapid prescribing survey broken down by type of private pharmacy.

Drug use Indicator	Private retail shops n=4	Cooperative shops n=2	Life-line shops n=2
Average no. drugs / patient	3.9	2.6	1.6
% patients given antibiotics	40.0	5.4	56.6
% patients given injections	8.2	10.9	62.4
% patients given vitamins	52.2	22.6	27.9
% drugs prescribed by generic name	1.3	*	75.0
% prescribed drugs belonging to EML	30.1	50.5	60.6
Average drug cost per patient (IRs)	349.52	319.61	114.21

* The figure is not given here because of possibly inaccurate results since the data was taken from the computer (using only brand names) and not the prescriptions.

All prescriptions dispensed from private pharmacies showed low levels of EML drugs and prescribing by generic name as compared to public facility prescriptions. Life-line shops (inside hospital compounds) tended to dispense injections and other non-EML medicines to inpatients in public hospital. Since all other drugs are dispensed by the hospital, the average number of drugs per patient is low and hence the drug cost is lower than in other private pharmacies. Cooperative shops (inside hospital compounds) tended to dispense medicines to pensioners with chronic diseases and other private patients with government insurance; hence the average number of drugs is higher. Private shops outside hospital compounds tended to serve customers with prescriptions from private practitioners as well as selling medicines directly to customers. Such private pharmacies had the highest number of drugs per patient, the highest average drug cost per patient and the highest use of vitamins.

Many of the private retailers stated that their sales had dramatically decreased since the start of the MNDY scheme. In the rural areas around PHCs and CHCs it was mentioned by private retailers that many retail shops had closed down and that sales were down by 70%. Public sector workers agreed that many shops had closed. Around district hospitals, shops had generally not closed but all retailers reported at least 50% reduction in their sales. Private retail shops near to large hospitals reported 15-20% reduction in sales. They stated that they still received many private prescriptions from the hospital specialists when they worked in their private clinics.

A visit was made to a non-registered practitioner (quack). It was not clear what if any qualification the person had. He stated that the number of patients coming to him had reduced since the start of MNDY but he was still seeing 20-30 patients per day. He stated that people that came to him could not afford to wait in the queues of public facilities. A short prescription analysis was done from the prescriptions he generally kept for seeing patients daily. It was found that the average number of drugs per patient was 5.6, all patients were given antibiotics (often higher generation ones such as ceftriaxone, cefixime, levofloxacin), 70% were given injection (often 2 drugs mixed in the same syringe), 53% were given steroids and 10% vitamins. The average drug cost per patient was Rs 184.17 and 79% of the drugs were on the EML. Many doctors in the public sector stated that they had to provide new generation antibiotics because patients had already received the older antibiotics from quacks. However, this quack was prescribing all the latest antibiotics – mostly for coughs and colds, allergies, diarrhoea and abdominal pain.

Standard Treatment Guidelines (STG)

There is a Rajasthan State Standard Treatment Guidelines published in 2012. The STG covers conditions seen in primary and hospital care. Most doctors at district level knew of the STGs but none were found in consultation rooms and few doctors seemed to be using the STGs or other sources of independent drug information. Doctors in tertiary hospitals were generally not familiar with the STGs and, if they were, said that it was not for them. The STGs were prepared by an editorial board of 3 experts (from Delhi), with contributions from 19 specialists (from Delhi), review by the RMSC Technical Advisory Committee and also review by a committee of 19 specialists from Rajasthan State. It seems that most preparation was done by Delhi experts. If Rajasthan specialists had been more involved in development, perhaps they

might use it more often. The STGs cover most conditions and the book is large, which may be why none were seen in actual use during consultation. Furthermore, there is no section on how to manage patients with simple illness of uncertain diagnosis which are often self-limiting (e.g. coughs and colds, aches and pains, weakness, etc.) and so common in primary care OPD. Perhaps a section on not prescribing medicines may be appropriate in a future edition.

Drug and Therapeutic Committees (DTC)

All large hospitals have DTCs, chaired by the Medical Superintendent. The main function of the DTCs appears to discuss drug stocks and to decide on local purchase of medicines. In addition, they must monitor prescriptions to ensure that they contain EML drugs and that drugs are prescribed by generic name. Any non-EML drugs prescribed should be justified to the DTC by the prescriber. Although specialist departments have prescription committees they do not appear to be undertaking any more detailed drug utilization review or other form of prescription audit. There were no DTCs in any of the district hospitals or District Public Health Offices visited. All respondents mentioned that the list of drugs for local purchase was decided by the facility in-charge and approved by Chief Medical and Health Officer.

Carbon copy duplicate prescription slips were made available by RMSC at all government health care institutions and a circular to prescribe on these slips issued with the objective that the duplicate yellow slips be retained by the DDC pharmacists after issuing medicines to the patients and obtaining their signature/thumb impressions. In addition, the pharmacy must write on the prescription slip the quantity of medicines issued against each item or mark the item "Not available" if particular a medicine is not available at the DDC. The retained prescription slips (1% of total OPD and IPD slips) are then audited by the DTC constituted of the medical college hospital and district hospital of the state. The audits focus on whether essential medicines are prescribed and whether generic names are used but not on other aspects of prescribing. The amount of prescription audit done by DTCs appears to have decreased recently since doctors are now complying with orders to follow the EML and prescribe by generic name.

Education and Information

Undergraduate education

The pharmacology faculty teaches prescribing principles to undergraduate pre-clinical medical students. However, prescribing skills during the clinical years are taught by the specialists with very little input from the faculty of pharmacology. Thus, what they learn in the pre-clinical years is likely to be undermined by their clinical studies and later work with senior consultants.

Continuing Professional Development

Continuing Professional Development (CPD) is organized with the teaching hospitals for in-service staff. The M&H vertical disease control programs run refresher training for district level staff from time to time. However, for general prescribing outside of teaching hospitals, CPD is adhoc and not mandatory, neither is it followed by many

prescribers, nor does it include much on prescribing or rational use of medicines. It was mentioned that for many doctors CPD consists only of lectures accompanied by dinners sponsored by the pharmaceutical industry. Some lectures are organized by the specialist societies. While CPD is adhoc or minimal for many prescribers, daily visits by pharmaceutical representatives are common in the private sector. However, since the MNDY started, visits by pharmaceutical representatives in public facilities have virtually stopped. Indeed, it was mentioned that many representatives had lost their jobs.

Training of providers and consumers on rational use of medicines by RMSC

All 33 districts have been covered by a core team of RMSC for dissemination workshops on rational use of medicines. Workshops were attended by all government and also many private doctors in the districts, as well as by NGOs working on health issues. Particular focus was given to prescribing only essential drugs by generic name. There was also public education on patients' right to receive essential medicines at government facilities and various orders issued by the Principal Secretary of Medical & Health via the RMSC to all facilities (see section on selection of essential medicines). Furthermore, doctors and paramedics were sensitized during the workshops and review meetings to report on adverse drug reactions and counsel the patients on use of drugs. The newly recruited 1345 pharmacists were trained by RMSC staff in September 2012 on all issues related to medication errors, good dispensing practices, counselling of patients, and reporting on adverse reactions. The impact of all this effort is now observed in the public sector since nearly all patients receive all the medicines prescribed and nearly all these medicines belong to the essential medicines list and are written by generic name.

Rajasthan Branch of the Indian Medical Council (IMC)

The Rajasthan branch of the IMC administers the rules set out at the central level. They register all doctors practicing in the state, inspect all medical colleges and investigate complaints against doctors, mostly for asking too much money from patients or clinical negligence. Last year they investigated 45 complaints. The registration fee is IRs 1000/- for 10 years. Currently, there are about 33,000 members of whom 8,000 are in government practice, 5,000 are out of the state and 20,000 are in private practice. It was mentioned that a voluntary credit system has started for CME, whereby one day equals 4 credits and 30 credits are needed over 5 years. Central guidelines are followed with regard to whether CME sessions may be recognized for any credits. All CME sessions must have adequate content and must not be sponsored by the pharmaceutical industry. The Medical Council itself is not involved in delivering any CME sessions for doctors.

Rajasthan Branch of the Indian Pharmacy Council (IPC)

The Rajasthan branch of the IPC administers the rules set out at the central level. They register all pharmacists practicing in the state, inspect all pharmacy colleges and investigate complaints against pharmacists, mostly complaints brought by the DRA for not being present in the pharmacy while medicines are dispensed. Last year they cancelled 55 pharmacists' registration for 3-12 months following complaints. The registration fee is IRs 1000/- for the first year and then IRs 250/- per year for renewal. Currently there are 36,000 members of whom 1,600 are in the public sector and the rest are in the private sector. The Rajasthan branch of the IPC does organize 5-6 CME refresher training sessions for pharmacists in each district per year. These sessions

cover drug storage, patient counseling, regulatory affairs, drug pharmacology (side-effects, interactions, etc.) and dispensing. The officials of the IPC mentioned that the MNDY scheme had cause 15 – 20% reduction in drug sales from their members.

Rajasthan Branch of the Indian Nursing Council (INC)

The Rajasthan branch of the INC administers the rules set out at the central level. They register all nurses practicing in the state, inspect all nursing schools and investigate complaints against nurses. There are 40,000 members. Currently, they are extremely busy reviewing new applicants from different states for registration following the recent creation of 31,000 new nursing posts to address the severe nursing shortage.

Independent Drug Information

Sources of independent drug information are few. Some teaching hospitals were receiving journals and producing newsletters but this is not generally the cases elsewhere. There is no Drug Information Centre (DIC) in the state run by M&H.

Public Education

District-level PHCs have sub-centres attached to them. In each sub-centre is an Auxiliary Nurse Midwife (ANM) and under her are 6-19 ASHAs, one per 1000 population. ASHAs are local women selected by their communities to undertake health work. They are given training every year and they generally undertake work with regard to women and children's health. They are reimbursed according to how many activities they undertake including bringing pregnant women for delivery in hospital and bringing children for vaccination, etc. They also have a small quantity of drugs which they can use to treat simple illness in the community. Much public education with regard to maternal child health, treatment of childhood illness, vaccination, etc. has been undertaken by ASHAs. Messages concerning free drugs under the MNDY scheme were also spread through them. However, in general, the topics taught by ASHAs are decided by M&H and so far these workers have not generally been used to spread messages on the proper use of medicines to the community, although many people felt this would be good to do as patient demand for drugs is high. Relevant messages could include "don't take antibiotics without seeing a health worker first" or "medicines are not needed for simple coughs and colds" or "ask your doctor whether your child really needs more than 2 medicines".

Monitoring and Supervision

Supervision with regard to prescribing seems to be minimal. While hospital superintendents and facility in-charges do undertake prescription audit, it is only to check that EML drugs are prescribed and that they are prescribed by generic name. They also check that diagnosis is written and the prescription is signed. Other prescription audit is not generally done. Even in tertiary hospitals, specialist departments do not appear to be undertaking any drug utilization review, or if they are, it is not reported to the DTC or hospital superintendent.

The E-Aushadhi system was modified in October 2012 to allow patient prescriptions to be entered into the system. The information entered includes the patient name, facility name, prescriber name, the drugs prescribed and dispensed together with the quantities for each drug. In the long term it is hoped to match patient prescription data with overall consumption data although at present this cannot be done. Since stock management data is entered separately from prescription data it may be that drug consumption by both methods may not match. Indeed, in one facility it was observed that incorrect prescription data was entered into E-Aushadhi by a new staff member, although the error was later corrected. Nevertheless, errors of data-entry for prescription data are likely given the enormous number of prescriptions issued. It will be important to reconcile consumption data according to stock records and prescription data within E-Aushadhi and there are plans to do this.

Since prescriptions are now entered into E-Aushadhi, prescription analysis could be done centrally. Certain problems such as polypharmacy and high use of antibiotics, vitamins, injections, combination analgesic products in district facilities could be identified and supervision targeted to specific drug use behaviours and specific prescribers and facilities. Since the Drug Warehouse In-Charges are all doctors, they could work with the Chief Medical and Health Officer to undertake such targeted supervision.

Monitoring and supervision to promote rational use of medicines is likely to work best if:

- doctors are approached as friends and collaborating partners rather than in any confrontational way;
- clearly defined behaviours for change are focused on one at a time.
- similar messages are sent out to both prescribers and the community at the same time.

For example, one might say to doctors that their help is needed to reduce the number of drugs prescribed for simple primary care conditions in order to save drug costs and make the scheme more sustainable. Other messages might be not to prescribe omeprazole simply to counteract diclofenac or ibuprofen and not to prescribe combination analgesic products for mild pain. One could send out similar messages through the ASHAs to the community, stating that fewer medicines are better for simple illness, etc.

Prescription audit using E-Aushadhi could be made more targeted if diagnosis were entered into database. There are plans to do this. However, this would require considerable work both with regard to the IT system and training staff in order to ensure that diagnoses were entered into E-Aushadhi in a systematic way. The International Disease Classification (ICD) system could be adopted. In addition, workload of doctors and dispensers can be monitored in E-Aushadhi. This can be regularly analysed and the information used to lobby at the central level for redistribution of staff. Equal manageable workloads are likely to render prescribers and dispensers more willing and able to change their behaviours.

Possible Recommendations

1. Monitor drug use:
 - Prescription audit using diagnosis,
 - Consider adding diagnosis to the e-Aushadhi,
 - Identify specific inappropriate practices that one wants to change e.g. overuse of antibiotics in upper respiratory tract infection, use of omeprazole to 'counter diclofenac', overuse of vitamins.
2. Analyse prescriber workload:
 - Can be done through e-Aushadhi,
 - Lobby central level for redistribution of staff.
3. Make doctors your friends in improving use:
 - "Help us to make the free drug supply system sustainable by avoiding use of unnecessary drugs".
4. Standard Treatment Guidelines:
 - Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines,
 - Disseminate to every doctor and incorporate into CPD.
5. Drug and Therapeutic Committees (DTC):
 - Establish DTCs in every hospital and require them to monitor drug use, encourage CPD, and report annually on activities to M&H.
6. Continuing professional development (CPD):
 - IMA/IMC should establish a credit system,
 - Incorporate prescription audit and feedback and ethics into CPD.
7. Public Education:
 - Spread core pharmaceutical messages e.g. *does my child need more than one drug?* through ASHAs and the media.

Medicines Regulation

The Rajasthan State Drug Regulatory Authority implements the Drug and Cosmetics Act of 1940 and rules there under that apply throughout India in all States. They also implement the Drug Prices Control Order of 1995 and the Drug and Magic Remedies (Objectionable advertisements) Act of 1954.

Altogether the DRA has a staff of 152 sanctioned posts (2 drug controllers, 35 Assistant Drug Controllers, and 115 Drug Control Officers) but unfortunately, only 43 posts are filled. In addition there is one State Drug Testing Laboratory with 15 sanctioned posts of which only 4 are filled. Thus, testing of samples from the market often takes 3-6 months for processing and some tests cannot be done locally but must be sent to federal government laboratories in Delhi or elsewhere. Despite lack of staff in DRA, some DRA staff members are seconded to the RMSC. It was mentioned that 62 new staff are being appointed but this will still not fill all sanctioned posts. Furthermore, more sanctioned posts would be needed to fulfill all regulatory functions.

The pharmaceutical sector consists of 289 manufacturing units (of which 50 undertake formulation of drugs and 24 manufacture basic drugs), 20,024 retail pharmacies, 13,061 wholesale outlets, 4102 wholesale plus retail outlets, 719 shops licensed to sell OTC drugs only and 418 homeopathic outlets. In addition they regulate 48 government and 41 charitable blood banks and 131 blood storage centres.

Regulation of drug outlets

Licenses are granted to all outlets which should be inspected annually at least. Manufacturing plants are inspected for GMP compliance annually. However, due to lack of staff they cannot inspect all drug outlets, such as wholesale and retail shops, regularly. In 2012-13 to date, the DRA carried out 7338 inspections and tested 1452 drug samples from the market of which 72 failed quality standards and court action has/will be taken in 62 cases.

There are prescription-only drug schedules but, in practice, many prescription-only drugs are available over-the-counter (OTC). A new H1 schedule has been notified by the Drug Controller General of India at the federal level to ensure that various drugs such as new generation antibiotics and second-line TB drugs are not available OTC. However, in practice, this new H1 schedule is yet to be enforced.

Drug Registration

While the Federal Drug Controller is responsible for the registration of new molecules/drug products in the India, State Drug Regulatory Authorities may provide market authorization for molecules/drugs which are no longer 'new' drugs i.e. they have been approved by the federal level more than four years ago. Once such a product is registered in one state it may be marketed throughout India. Registration generally last for 5 years and then needs renewal. The number of drug products on the market is unknown but may be up to 100,000. There are hundreds of different branded

generics for commonly used medicines such as paracetamol, amoxicillin, etc. It is recognized that regulating a market with so many products is extremely difficult and the federal drug controller issued an order in Oct 2012 that no more trade names were to be allowed in the registration of new me-too drugs.

The issue of multiple brands is not only a problem for Drug Regulatory Authorities to regulate; it may also be dangerous for the patients. Large sections of the community still use the private sector, going from one doctor to another or from one pharmacy shop to another, seeking medicines. Many people do not understand that products with different brand names may contain the same drug. Furthermore, the generic name is often less legible than the brand name since the letters are more spindly than the letters used for brand names which are generally in bold font. Also the generic name may be spread across several tablets/capsules in strip packages whereas the brand name is not. Thus, when strip packages are cut to dispense individual tablets/capsules, the generic name often cannot be read. The use of different brands containing the same API may lead to instances of drug poisoning.

Price control

In practice the prices of only 74 drugs belonging to the national EML at the time of the original drug price control order are regulated. Of these 74 drugs only 38 are currently used. The newly notified National Pharmaceutical Pricing Policy has fixed the prices allowed for all essential drugs (on the 2011 EML) at the simple average of all the brands in the market. RMSC buys these drugs at well below the upper limit of price control imposed by government.

Pharmacovigilance

The pharmacovigilance committee within the faculty of pharmacology in SMS Medical College is responsible for collecting and reporting ADRs from Rajasthan to the national coordinating centre. The latter then forwards reports to the WHO Uppsala Monitoring Centre, Sweden. Since 2010 when the national pharmacovigilance program started, 682 ADRs involving 41 medicines, mostly in HIV patients have been reported from Rajasthan to the central level. Although the pharmacovigilance committee investigates causality superficially, in practice all events are reported and no investigation has been conducted to see if drugs were administered properly or of adequate quality. Furthermore, the reporting system only operates in the six medical colleges.

ADRs are also reported to the DRA who then reports them to the pharmacovigilance unit in SMS Medical College. All drugs with apparent ADRs that are reported to the DRA are sent for drug testing. ADRs are also reported by health professionals to the pharmacovigilance center, which submits all ADRs via vigiflow to the Uppsala Monitoring Centre by the National Coordinating Centre. The relationship between the DRA and SMS Medical College for pharmacovigilance is not clear.

Drug promotion

In practice, drug promotional activities are not monitored. No pre-approval of advertisements is required.

Possible Recommendations

1. Strengthen the DRA:
 - Appoint more inspectors and pharmacists – an adequate number of pharmacists to inspect all outlets regularly,
 - Develop standard operating procedures and guidelines for all procedures.
2. Strengthen Drug Testing Laboratory:
 - Fill all posts so samples can be processed more quickly.
3. Start a unit to monitor drug promotional activities:
 - Develop monitoring of promotional activities and adverts.
4. Implement drug schedules more strictly:
 - Focus on implementation of the new H1 schedule to ensure that certain prescription-only drugs e.g. new antibiotics are not sold without prescription.

Medicine Policies and Health system issues

There is an extensive public health care system and the MNDY free drug scheme administered by the RMSC has seen remarkable success. Access to essential medicines has been hugely increased and patients now receive all the medicines they are prescribed at the public health facilities.

At the completion of one year of MNDY implementation, on 2nd October 2012, the WHO India Country Office with the RMSC organized a National Conference on “Access to Essential Medicines in India” at Jaipur. Key stakeholders and many high officials signed the Jaipur Declaration and committed to the cause of rational use of medicines in India. The Jaipur Declaration states that:

- Free access to essential medicines will be supported by all state governments so that no one is deprived of medicines and no one dies for want of medicines.
- Strategy of pooled/bulk purchase can bring down the procurement prices of medicines.
- Those medicines which are not included in the free drug distribution scheme may be made available through fair price retail medical shops.

- All health professionals will follow the principle of rational use of drugs and standard treatment guidelines. Further, no irrational and non-essential drugs shall be prescribed and ethical guidelines prescribed by the Medical Council of India will be followed in the true sense.
- We understand that every human life is precious hence every effort should be made to cure ailments of all fellow citizens in our country.
- The signatory states / associations will collaborate with one another in achieving the above objectives.

There is no state medicines policy (NMP) document that describes a full set of pharmaceutical policies. However, the RMSC document on the Mukhyamantri Nishulk Dava Yojana (MNDY) 2011 does set out objectives and a wide set of policies for the pharmaceutical sector in Rajasthan.

The main objectives of the RMSC are to:

- Execute procurement of good quality drugs, surgical items and sutures at reasonable prices in the State of Rajasthan to meet the requirements of the Government Medical and Health Institutions allowing healthy competition among pharmaceutical manufacturers.
- Streamline the distribution of drugs to institutions and ensure availability of drugs at all times.
- Strengthen the system of quality control over drug procurement and distribution to make quality an essential attribute of the RMSC and promoting rational use of medicines.

In order to achieve these objectives, policies have been enunciated concerning drug procurement, drug quality control, drug accounting and distribution including the E-Aushadhi system, and rational use of medicines including use of an EML and STGs and prescribing by generic name.

The various medicine policies that may impact on drug use and that are in place are shown in table 4. This information is adapted to Rajasthan state from the findings of this mission and from a report sent by the central MOH for all India to WHO Geneva in 2011.

Table 4: Medicine Policies in place in Rajasthan according to the WHO Pharmaceutical Surveys in 2007 and 2011 and the consultant visit in 2013

Drug Policy	State of implementation
State Medicines Policy	RMSC document 2011, which covers policies for the public sector but not the private sector. Many of the policies are being implemented.
Monitoring the use of medicines	Monitoring of drug consumption is done centrally by RMSC and some prescription audit is done by medical superintendents but it mainly focuses on use of EML drugs and prescribing by generic name, not other types of drugs use.
Essential Medicines List	State EML 2012, recently revised in 2013. RMSC strictly follows the EML.
Standard Treatment Guidelines	State STGs published in 2012 covering both primary and secondary care conditions.
Formulary booklet	No Rajasthan state formulary booklet.
Generic Policies	Generic prescribing policy in the public sector enforced.
Regulation of promotion of medicines	Government regulation only but DRA has very little capacity to monitor promotion and does not undertake any pre-approval for drug adverts.
Monitoring of ADRs	Done by the State centre for Pharmacovigilance at SMS medical college.
Payment for medicines	All medicines are dispensed free of cost to all OPD and IPD patients in public health care facilities.
Health Insurance	Public health insurance does not cover a significant proportion of the population but all medicines are dispensed free of charge in public facilities.
Revenue from medicines	Never used to pay salaries in the public sector.
Medicine Pricing policies	RMSC buys drugs at prices lower than the maximum prices set by the Centre for essential drugs. No pricing policies for non-essential drugs.
Undergraduate medical training	National EML and STGs are part of the curricula but training by the pharmacology faculty on prescribing only occurs in the pre-clinical years.
Continuing medical education	Little non-commercially funded CME, some CPD provided to district level staff by MOH vertical disease control programs And by RMSC.
Medicines Information Centre (MIC)	Central MIC but no Rajasthan MIC.
Public education on medicines use	No public education campaigns on safe medicines use done in the past 2 years although public education campaigns on MMNDY have been undertaken.
Drug and Therapeutic Committees (DTCs)	DTCs are mandated in various orders issued by the Secretary of Health via the RMSC but only secondary level hospitals have DTCs which review stock levels check that EML drugs are prescribed by generic name.
National Strategy for containing antimicrobial resistance	No national strategy on antimicrobial resistance. Antibiotics frequently available over-the-counter without prescription.

Coordination and Management

Many aspects of the state public sector drug policy have been implemented through the MNDY by the RMSC. Objectives concerning drug availability, procurement and distribution policies and prescription of EML drugs by generic name have been achieved. One of the reasons for such success has been the coordinating role of the RMSC with regard to many aspects of drug management. This has required liaison with the DRA and the M&H, which has been possible due to high political support. Thus, the RMSC has not only managed drug procurement and distribution, but has also coordinated the development of the EML and the STGs, has instituted prescription audit and the establishment of DTCs and has informed the community about the MNDY. In order to address the remaining serious challenge of irrational use of essential medicines such coordination of partners by RMSC must be continued.

It was expressed that the RMSC should only concern itself with drug procurement and distribution and that all other functions, such as prescription monitoring and promotion of rational use of medicines, will be handed over to the M&H. However, RMSC has much capacity to monitor medicines use and promote rational use of medicines. For example, RMSC has E-Aushadhi and thus the ability to monitor drug use and distribution of human resources. RMSC also has medically qualified district warehouse in-charges who could contribute to promoting rational use of medicines in their daily supervisory functions. Furthermore, it is in RMSC's interests to promote rational use of medicines in order to decrease costs, improve patient safety and ultimately improve the sustainability of the MNDY scheme. Therefore it may be wise for RMSC to recognize the need to work with M&H in the long term to promote rational use of medicines.

Promoting rational use of medicines requires effective management of the whole pharmaceutical sector. This, in turn, requires liaison with many departments and ministries. Other relevant Ministries include Education (health worker undergraduate training), Finance (drug budget), Public Services Commission (Human Resource Allocation), Trade and Industry (Pharmaceutical Manufacturers), Chemicals and Fertilizers (Drug Prices) and the Drug Regulatory Authority. Other relevant departments in the MOH/M&H include those responsible for the ASHA system for public education, hospital care and the health management information systems, amongst others. Which department in the MOH/M&H will coordinate amongst all these entities?

WHO recommends that countries or states have a high level multidisciplinary body accountable to the most senior health official possible to advise the Minister of Health or Chief Minister on pharmaceutical issues and to coordinate policy (WHO 2007). Such bodies need an executive in the MOH/M&H to carry out their directives. What is the situation in Rajasthan? Could the RMSC fulfill some of these functions to ensure the safe and rational use of medicines in the public sector? An impact analysis of the RMSC and the MNDY may shed light on this issue. It should cover all aspects of drugs in health care delivery in the public and private sectors, including drug availability, use, patient attendance, financing and out-of-pocket expenditures. Furthermore, such an analysis should use all sources of information (including internal monitoring data and external studies).

Possible Recommendations

- Establish a permanent, independent, state level statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOH/M&H), in Rajasthan, under the chairmanship of the Principal Health Secretary, to advise the Chief Minister of Rajasthan on Pharmaceuticals.
- Establish an Executive Division in the MOH/M&H to carry out the statutory committee recommendations – RMSC?
 - a. To coordinate action between various departments and ministries, including the Ministry of Education with regard to undergraduate training of health professionals;
 - b. To be responsible for promoting rational use of drugs including: EML, STGs, DTCs, monitoring drug use, CPD, Medicine Information Centres, public education on medicines.
- Evaluate the overall impact and sustainability of the RMSC, using all sources of information (monitoring data, external studies, etc.):
 - a. Access of all patients to essential medicines,
 - b. Drug financing in the public sector and on out-of-pocket expenditures in the private sector,
 - c. Use of medicines,
 - d. Coordinating role of RMSC between the various stakeholders.

[WHO is committed to provide all technical and operational support to undertake the impact analysis of the Rajasthan Free Medicine Scheme, in terms of both improving access to medicines in the state at various levels in the state, and reducing the out-of-pocket payments on medicines.]

Workshop

At the end of the mission, a half-day workshop was held on March 21st with 25 national stakeholders to discuss the consultant's findings and to develop recommendations. The participants in the workshop can be seen in annex 2. The consultant's presentation at the workshop can be seen in annex 3.

Objectives of workshop

- Review the WHO fact finding results,
- Identify the main priority problems to be addressed,
- Formulate recommendations to resolve / address the problems.

Agenda

- Presentation of the findings by the WHO consultant,
- Plenary discussion of the findings with identification of main problems and possible solutions.

Discussion

There was a lively discussion and the stakeholders agreed with many of the consultant's findings and most of the consultant's recommendations. During the workshop, recommendations were agreed by consensus in plenary discussion. Following the workshop, the recommendations were edited (for language and coherence) and circulated to all the stakeholders. The following conclusions and recommendations were agreed by all stakeholders and incorporate all comments from the workshop participants.

Conclusions and Recommendations

The MNDY scheme run by the RMSC started in October 2011 and has succeeded in ensuring that essential medicines are available in all public health facilities and freely available to patients. Procurement and distribution of medicines are efficiently managed and EML drugs are prescribed by generic name by all prescribers. There remains the challenge of irrational use of essential medicines for which a coordinated approach involving many different stakeholders is needed.

A. Drug Supply

- RMSC to produce annual report on procurement and distribution:
 - ABC analysis, per-capita allocation, comparison across districts.
- Extend E-Aushadhi system to all PHCs:
 - Better estimation / forecasting of drug need and stock control.
- Review system of quantification:
 - Collect morbidity data and estimate drug quantities needed according to STG treatments and compare estimated quantities needed to actual quantities demanded in pilot districts.
- Review storage systems for drugs on inpatient wards.

B. Drug Selection

- RMSC to produce annual report on consumption:
 - ABC analysis, per-capita consumption, comparison across districts.
- Continue to update the EML and contain the number of items on the EML:
 - Have a more participative and ideally web-based process and strict criteria for inclusion of new medicines in the EML,
 - Include the EML and how it is formed in pre-service and in-service training curricula in order to sensitize doctors as to its utility.
- Continue to monitor adherence to the EML:
 - Will require review of prescriptions as non-dispensed medicines are not entered into e-Aushadhi.

C. Promoting rational drug use

- Monitor drug use:
 - Prescription audit using diagnosis,
 - Consider adding diagnosis to the e-Aushadhi,

- Identify specific inappropriate practices that one wants to change e.g. overuse of antibiotics in upper respiratory tract infection, use of omeprazole to 'counter diclofenac', overuse of vitamins.
- Analyse prescriber workload:
 - Can be done through e-Aushadhi,
 - Lobby central level for redistribution of staff.
- Make doctors your friends in improving use:
 - "Help us to make the free drug supply system sustainable by avoiding use of unnecessary drugs".
- Standard Treatment Guidelines:
 - Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines,
 - Disseminate to every doctor and incorporate into CPD.
- Drug and Therapeutic Committees (DTC):
 - Establish DTCs in every hospital and require them to monitor drug use, encourage CPD, and report annually on activities to M&H.
- Continuing professional development (CPD):
 - IMA/IMC should establish a credit system,
 - Incorporate prescription audit and feedback and ethics into CPD.
- Public Education:
 - Spread core pharmaceutical messages e.g. *does my child need more than one drug?* through ASHAs and the media.

D. Drug regulation

- Strengthen the DRA:
 - Appoint more inspectors and pharmacists – an adequate number of pharmacists to inspect all outlets regularly,
 - Develop standard operating procedures and guidelines for all procedures.
- Strengthen Drug Testing Laboratory:
 - Fill all posts so samples can be processed more quickly.
- Start a unit to monitor drug promotional activities:
 - Develop monitoring of promotional activities and adverts.
- Implement drug schedules more strictly:
 - Focus on implementation of the new H1 schedule to ensure that certain prescription-only drugs e.g. new antibiotics are not sold without prescription.

E. National Structure & Drug Policy

- Establish a permanent, independent, state level statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOH/M&H), in Rajasthan, under the chairmanship of the Principal Health Secretary, to advise the Chief Minister of Rajasthan on Pharmaceuticals.
- Establish an Executive Division in the MOH/M&H to carry out the statutory committee recommendations – RMSC?
 - To coordinate action between various departments and ministries, including the Ministry of Education with regard to undergraduate training of health professionals;
 - To be responsible for promoting rational use of drugs including: EML, STGs, DTCs, monitoring drug use, CPD, Medicine Information Centres, public education on medicines.
- Evaluate the overall impact and sustainability of the RMSC, using all sources of information (monitoring data, external studies, etc.):
 - Access of all patients to essential medicines,
 - Drug financing in the public sector and on out-of-pocket expenditures in the private sector,
 - Use of medicines,
 - Coordinating role of RMSC between the various stakeholders.

[WHO is committed to provide all technical and operational support to undertake the impact analysis of the Rajasthan Free Medicine Scheme, in terms of both improving access to medicines in the state at various levels in the state, and reducing the out-of-pocket payments on medicines.]

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Annex 1: Persons met and places visited during the situational analysis:

	Name	Affiliation
1	Dr Samit Sharma	Managing Director RMSC
2	Mr R S Thakur	Advisor to RMSC
3	Dr P C Ranka	Logistics Director RMSC
4	Mr Prem Singh	Supply Manager RMSC
5	Dr Ajay Aswal	Supply management RMSC
6	Mr D K Shringi	State Drug Controller, M&H/MOH
7	Mr Vinod Kumar Dhal	Drug Controller, MOH
8	Dr Kalpana Vyas	Logistics, RMSC
9	Dr Sanjay Pareek	Procurement, RMSC
10	Dr Ajay Mathur	Medical Superintendant, Gangori Hospital
11	Dr Arvind Gupta	Deputy Superintendant, Gangori Hospital
12	Dr Arvind Mathur	Senior Physician, Gangori Hospital
13	Dr Sudha Mathur	Emergency physician, Gangori Hospital
14	Dr Usha Mathur	Emergency physician, Gangori Hospital
15	Dr Mohammed Rafique	RMSC Jaipur 2 District Warehouse in-Charge
16	Dr Narendra Gupta	Secretary, PRAYAS
17	Mudit Mathur	Program Coordinator, PRAYAS
18	Chhaya Pachauli	PRAYAS
19	Dr S.M. Mittal	Joint Director, Integrated Child Development Scheme, M&H
20	Dr Kalpana Sharma	PV Convener, Pharmacology Dept, SMS Medical College
21	Dr Mukul Mathur	PV Coordinator, Pharmacology Dept, SMS Medical College
22	Dr Rupa Kapadia	PV Secretary, Pharmacology Dept, SMS Medical College
23	Dr Monika Mishra	Pharmacology Dept, SMS Medical College
24	Dr Monica Jain	Pharmacology Dept, SMS Medical College
25	Dr Lokendra Sharma	Pharmacology Dept, SMS Medical College
26	Ms Shruti Upadhjay	Pharmacology Dept, SMS Medical College
27	Dr Pradeep Sharma	Head of Psychiatry SMS Medical College
28	Dr Subhash Nepalia	Principal & Controller SMS Medical College
29		Registrar Rajasthan Medical Council
30	Mr Dinesh Sachdeva	Registrar Rajasthan Pharmacy Council
31	Mr Parveen Chandra	Registrar Rajasthan Nursing Council
32	Vinod Vijay	PO to Medical Director RMSC
33	Dr M S Krishnia	Field Monitoring Officer RMSC
34	Sandeep Sapra	Managing Director AMOL Pharmaceuticals
35	Girish Maheshwari	Vice President, AMOL Pharmaceuticals
36	Dr Shailendra Lakhan	Medical Officer, Saradhana PHC, Ajmer District

37	Dr Ravindra Kaushi	In-Charge, Pisagam CHC, Ajmer District
38	Dr Archana Mittal	Gynaecologist, Pisagam CHC, Ajmer District
39	Dr G Soni	Pisagam CHC
40	Dr R K Gupta	Block CMO, Pisagam CHC
41	Dr Manjurani Gupta	Deputy Superintendent, Mahila Chikersalya Hospital, Ajmer
42	Ms Ivy Margaret Massey	Nursing sister, Mahila Chikersalya Hospital, Ajmer
43	Dr J Prakash Narayan	Senior Paediatrician, Mahila Chikitsalya Hospital, Ajmer
44	Dr Ashok Choudhary	Medical Superintendent, Jawaharlal Nehru Hospital, Ajmer
45	Dr Mohit Deval	RMSC Ajmer district warehouse in-Charge
46	Dr K.L. Meena	Acting Principal Medical Officer, BDM Kotpuli District Hospital, Jaipur 2 district
47	Retailer	Pandit Medical Store near to BDM Kothpuli District Hospital
48	Dr Priyanka Mann	Health Manager, Jaipuria District Hospital, Jaipur 2 district
49	Dr R.N. Jaiswal	Deputy Controller, Jaipuria District Hospital
50	Dr V.D.Sharma	Principal Medical Officer, Jaipuria District Hospital
51	Dr A.A. Pathan	Paediatrician, Jaipuria District Hospital
52	Dr Krishna	Internist, Jaipuria District Hospital
53	Dr Raguraj Singh	RMSC Jaipur 1 district warehouse in-Charge
54	Dr Kamal Yadav	Medical Officer in-charge, Bichoon PHC, Jaipur 1 district
55	Dr Rain Yadav	Medical Officer, Bichoon PHC
56	Dr Rajiv Gupta	Medical Officer, Bichoon PHC
57	Dr D.L. Jakhar	Medical Officer in-charge, Dudu CHC, Jaipur 1 district
58	Dr Gunmala Jain	Medical Officer, Dudu CHC
59	Dr Rajendra Mittal	Medical Officer, Dudu CHC
60	Retailer	Kashaya Medicals near to Dudu CHC
61	Dr R.S.Roondla	Surgeon and Medical Officer in-Charge, Govind Garh CHC, Jaipur 2 district
62	Retailer	Siri Ganesh Medicos near to Govind Garh CHC
63	Dr Santosh Kaushik	Medical Officer, Samod PHC, Jaipur 2 district
64	Retailer	Chaudhury Medical Store near to Samod PHC
65	Retailer	Medicos, Ajmer city
66	Retailer	Bhawani Medical Store, Ajmer city
67	Retailer	Cooperative shop in Jawaharlal Nehru (JLN) Hospital, Ajmer

68	Retailer	Life-line shop in JLN Hospital
69	Retailer	Cooperative shop in Jaipuria hosp
70	Retailer	Life-line shop in Jaipuria hospital
71	Mr Saxena	Unregistered medical practitioner
72	Vikram Sankhla	RMSC ACP Deputy Director
73	Dr Nirmal Gurbani	Institute Health Management Research, Jaipur
74	Dr Jawahar Bapna	Institute Health Management Research, Jaipur

**Annex 2: Participants of Workshop on Medicines Supply and Use,
Jaipur, Rajasthan, India, 21 March 2013**

SN	Name	Designation	Organization
1	Surendra Maheshwari	ED (R.C.)	RMSC
2	S. C. Sharma	ED (P)	RMSC
3	Dr D. P. Thakan	CM&HO JPR-1	M&H Dept.
4	Dr Raghuraj Singh	Officer In-charge-DDW JPR-11	M&H Dept.
5.	Vinod Kumar Dhal	Drugs Controller	M&H Dept.
6	D. K. Shingvi	Drug controller	Drug Control
7	Dr Rupa Kapadia	Associate Profession	Pharmacology Department, S.M.S Medical College
8.	Dr Monica Jain	Associate Professor	Pharmacology Department, S.M.S Medical College
9	Mr Ajay Aswal	O.S.D	RMSC
10	Mr Brijesh Sharma		RMSC
11	Dr M. S. Krishnia	CO. FM	RMSC
12	R. S. Thakur	Advisor	RMSC
13	Dr. P. C. Ranka	ED (L)	RMSC
14	Dr. Kalpana Vyas	AGM (L)	RMSC
15	Dr Hoshiyar Singh	ED (EMP)	RMSC
16	Mudit Mathur	Sr. Prog. Coordinator	PRAYAS
17	Dr N. K. Gurbani	Admin. RMSC	IIHMR
18	Rakesh Verma	ADC (QC)	RMSC
19	Vikram Singh	AHM IT	RMSC
20	Dr N. K. Gupta	DPC	RMSC
21	Dr Rakhea	PPL	RMSC
22	Dr M. M. Tripathi	Medical Officer	Warehouse SMS Hospital
23	Dr Lokendra Sharma	Asso. Prof. Pharma SMS Medical College	SMS Medical College Jaipur

24	Mr Prem Singh	Manager (Supply)	RMSCL
25	Sanjay Pareek	ADC	RMSCL

Annex 3: Slide presentation given by consultant to stakeholders in the half-day workshop

Medicines supply and use in Rajasthan, India

WHO mission: 11-22 March 2013

Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Agenda of the workshop

- Presentation by WHO with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
 - include practical steps and the human and financial resources needed
- Presentation of group work with plenary discussion and finalization of recommendations
 - for MOH, RMSC, WHO and partners to follow

Background

- **Lack of access to medicines in many SEAR countries**
 - Increasing demand for medicines but limited budget
 - Rajasthan Medical Services Corporation (RMSC) started in 2010
- **Irrational medicines use in all SEAR countries**
- **Regional SEARO meeting of 9 countries, July 2010**
 - Recognised the need for a comprehensive health system approach
 - Recommended undertaking a national situational analysis to identify the major problems and possible solutions
- **Resolution SEA/RC64/R5, September 2011**
 - National essential drug policy including rational use of medicines
 - Requested WHO to undertake national situational analyses
 - Regional consultation in 2013 in order to report progress to RC66
- **Situational analysis**
 - WHO fact finding mission, 11-22 March, 2013
 - Workshop to develop recommendations for future state action

Mission 11-22 March, 2013

- **11 Mar:** visits to RMSC Medical Director; State Drug Controller
- **12 Mar:** visits to RMSC depts; private drug quality assurance lab;
- **13 Mar:** visits to Gangori hospital; Jaipur 2 district warehouse
- **14 Mar:** visits to Jaipuria & BDM Kothupali district hospitals and nearby private pharmacy shops in Jaipur 2 district
- **15 Mar:** visits to Govind Garh CHC & Samod PHC and nearby private pharmacy shops in Jaipur 2 district
- **16 Mar:** visits to Bichoon PHC & Dudu CHC and nearby private pharmacy shops in Jaipur 1 district; Drug & Chemists Association and Drug Manufacturers Association; and PRAYAS NGO
- **18 Mar:** visits to JLN Medical College Hospitals and nearby private pharmacy shops in Ajmer
- **19 Mar:** visits to Pisagam CHC & Saradhana PHC and nearby private pharmacy shops in Ajmer district
- **20 Mar:** visits to SMS Medical College; Medical/Pharm/Nurs Councils
- **21 Mar:** workshop

Objectives of the workshop

- Review the WHO fact finding results
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems
 - for use by MOH, RMSC, WHO, partners

Mission findings

- Extensive health care system, with substantial infrastructure, trained health care personnel
- Huge improvement in access to medicines following the start of the RMSC 18 months ago
 - Supplies all essential drugs
- Some problems in the pharmaceutical sector concerning:
 - Drug supply, selection, use, regulation, policy, information and coordination, but...
- Sufficient resources & capacity to address the problems
 - Will require effort by MOH as well as RMSC

Drug supply: availability

- **Drug availability**
 - Most public facilities visited had no stock-out of any item but most reported using their 10% local budget for purchase of emergency items which were out of stock in RMSC about twice per year
- **RMSC**
 - Supplies 300 crore essential medicines per year
 - Staff of 250 in RMSC plus employment of extra 1200 pharmacists in public facilities by MOH (compared to about 150 staff in central medical stores pre-RMSC)
 - Patient attendance doubled (but not doctors)
 - Decreased private drug sales
 - 70% in rural areas, 30-50% in districts, 15-20% cities

Drug selection

- **State EML 2012, 2013**
 - RMSC coordinates the development of the EML and supplies all the medicines on the EML
 - categorisation by level of facility but PHC and CHCs may use their local 10% budget to purchase higher level EML drugs
 - 477 items in 2012 and 611 items in 2013
 - Technical Advisory Committee of 17 people (incl principles of Medical Colleges and chaired by the RMSC MD) and many sub-committees
- **Local purchase**
 - 10% local budget to purchase EML drugs
 - Other funds e.g. registration fees (Rs 5-10/outpatient visit, Rs 10-20/inpatient) may be used to purchase non-EML drugs
- **Hospital shops**
 - Medical Relief Society – Life-line shops supply drugs for emergencies and also non-EML drugs as decided by the hospital PMO and department chiefs
 - Cooperative Shops – supply pensioners and other private patients

Drug supply: procurement

- Annual e-tendering with technical & then financial evaluation
- Technical evaluation:
 - GMP certificate for the product
 - Supplier annual turnover of more than 20 crore
 - Production of the product by the supplier for more than 3 years
 - Supplier not blacklisted by any Medical Services Corporation
 - Agree to supply drugs in 45 days (60 days: injectables & imports)
- Results placed on web for transparency
- Earnest Money Deposit (2-5 lakh) and Bank guarantee (5%) against supply default
- Quality testing of every batch (1.5% drugs costs included in quote)
- For 20-30 products (of 477), tenders cannot be got due to small quantities or specialised manufacturing process (e.g. ophthalmology) so 20 crore & delivery time line criteria may need changing for these items
- 5-6 companies black listed for contravening technical criteria

Oct/11-Feb/13: Top 28 (6%) drug items cost 41% budget

Human Antirabies IMG	132,704,000	Cefotaxime inj 1g	41,166,207
Azithromycin 500mg	107,933,856	Tetanus IMG	39,093,086
Cefixime 200mg	96,899,441	Ciprofloxacin500mg	37,213,573
Meropenem inj 500mg	93,646,692	Cephalexin 250mg	37,156,419
Ceftriaxome inj 1g	92,117,754	Cough syrup	35,631,414
Amoxycillin 500mg	71,733,743	Snakevenom serum	34,287,516
Rabies I/D vaccine	64,871,279	Defarasirox 500mg	33,290,632
Human AntiD IMG	64,497,200	Ofloxacin 200mg	32,352,553
Azithromycin 250mg	59,929,945	Ciprofloxacin250mg	31,165,276
Amoxy-clav 500+125mg	54,794,283	Methylprednisol inj	29,687,580
Beclomethasone Inhaler	48,444,241	Ceftazidime inj 1g	28,972,245
Paracetamol 500mg	42,794,950	Omeprazole 20mg	28,534,910
Hum Albumen 20% sol	41,890,250	Piperacillin+Taz inj	28,397,590
Enoxaparin inj 60mg	41,601,968	Cefixime 100mg	27,267,642

Drug supply: distribution

- **Push/pull distribution system**
 - Drugs supplied from manufacturers to 34 warehouses 3-monthly
 - 4 months buffer stock
 - Warehouses supply weekly to hospitals & monthly to CHC/PHCs according to a schedule & facility requests but many extra orders
- **Quantification**
 - based on previous year's consumption and estimates by Chief Medical Officers, which may not reflect actual need
- **E-Aushadhi electronic management inventory system**
 - Covers hospitals and CHCs but some PHCs not covered
 - Allows review & adjustment of drug requests according to stock balance and consumption and redistribution of drugs between facilities and districts
 - Includes information on drugs prescribed to individual patients and by individual doctors (but this may not match the stock data which is entered separately)
 - Does not include diagnosis

Possible solutions for supply and selection

- **RMSC to produce annual report on consumption**
 - ABC analysis, per-capita consumption, comparison across districts
- **Extend E-aushadhi system to level of the PHC**
 - Better estimation / forecasting of drug need and stock control
 - ABC analysis for monitoring & feedback to prescribers
- **Review system of quantification**
 - Collect morbidity data & do pilot comparison of estimated need according to morbidity & standard treatment vs demand
- **Contain the number of items on the EML**
 - Have web-based process & strict criteria for inclusion of new medicines in the EML
- **Continue to monitor adherence to the EML**
 - Will require review of prescriptions as non-dispensed medicines are not entered into e-aushadhi

Drug use

- **Monitoring of prescribing is limited**
 - only whether EML drugs are prescribed, generic names used, diagnosis written and the prescription signed
- **Few prescribers use STGs**
 - No STG was found in the OPD consultation rooms
- **Most doctors do private practice in the evenings**
 - receive pharmaceutical representatives there
- **Prescribing taught at undergrad pre-clinical level but**
 - undermined by clinical studies and later work
 - little focus on primary care cases
- **No state-wide public education on medicines use**
- **CPD/CME adhoc & includes little on prescribing**
- **DTCs only in tertiary hospitals**
 - Only discuss drug availability and adherence to the EML

Treatment of upper respiratory tract infection

- One third of all OPD cases, mostly mild viral infections
- Typically 4 drugs prescribed (IRs 875,954,661 in 2012)
 - ABs e.g. cefixime, cephalixin, azithromycin, amoxycillin, ciprofloxacin, cotrimoxazole, ofloxacin, doxycycline
 - IRs 614,780,224
 - Antihistamines e.g. cetirizine or chlorpheniramine
 - IRs 13,464,741 + ?
 - Analgesic e.g. paracetamol \pm diclofenac \pm ibuprofen
 - IRs 130,187,362
 - Cough syrup or dextromethorphan syrup
 - IRs 48,956,963
 - Sometimes bronchodilators and/or nasal drops
 - IRs 68,565,371 + ?

Drug use indicator survey

Drug use indicator	Referral hospital n=2	District hospital n=2	CHC n=3	PHC n=3	Drug Retailer n=8
Av.no.drugs/patient	4.1	3.3	3.2	3.6	3.0
% patients given ABs	53	67	62	64	35
% URTIs given ABs	81	100	97	96	-
% patients given INJs	3	9	18	15	20
% patients given VITs	24	12	11	6	35
% generic drugs	99	99	100	98	22
% EDL drugs	92	97	100	97	43
% drugs dispensed	90	92	100	96	100
Av.cost/Px (IRs)	Approx 15.0 - 30.0				283.22

Inappropriate prescribing in primary care patients

- Omeprazole or ranitidine to counter diclofenac or ibuprofen or paracetamol!
- Alprazolam in hypertension
- Methylprednisolone for back pain or body ache
- Metronidazole and a fluoroquinolone for acute diarrhoea
- Ceftriaxone, amikacin, cefixime, cotrimoxazole, cetirizine and paracetamol in a child with pneumonia
- Domperidone+cinnarizine, betamethasone, paracetamol, chlorpheniramine, ciprofloxacin for an adult with vertigo

Private sector drug use survey

Drug use indicator	Private retail shops n=4	Cooperative shops n=2	Life-line shops n=2
Av.no.drugs/patient	3.9	2.6	1.6
% patients given ABs	40.0	5.4	56.6
% patients given INJs	8.2	10.9	62.4
% patients given VITs	52.2	22.6	27.9
% generic drugs	1.3	-	-
% EDL drugs	30.1	50.5	60.6
Av.cost/Px (IRs)	349.52	319.61	114.21

Health worker views

- **PHC medical officer**
 - We have to give antibiotics like azithromycin and cefixime because the patients have already been prescribed the simpler antibiotics by quacks.
- **District hospital doctor**
 - The RMSC is very good for patient but since it started the number of patients has doubled but the number of doctors has not – so it is very difficult to cope.
- **Public health medical officer**
 - The workload of doctors and facilities is very uneven but we cannot redistribute staff and resources according to need.

Possible solutions for improving use (1)

- **Monitor drug use**
 - Prescription audit using diagnosis
 - Consider adding diagnosis to the e-aushadhi
 - Identify specific inappropriate practices that you want to change e.g. overuse of antibiotics in upper respiratory tract infection, omeprazole to 'counter diclifenac', vitamins
- **Analyse prescriber workload**
 - Can be done through e-aushadhi
 - Lobby central level for redistribution of staff
- **Make doctors your friends in improving use**
 - Help us to make the free drug supply system sustainable by avoiding use of unnecessary drugs

Possible solutions for improving regulation

- **Strengthen the DRA**
 - More inspectors & pharmacists – adequate number of pharmacists to inspect all outlets regularly
 - Standard operating procedures and guidelines for all procedures
- **Strengthen Drug Testing Lab**
 - Fill all posts so samples can be processed quickly
- **Start unit to monitor drug promotional activities**
 - Develop monitoring of promotional activities
- **Implement drug schedules more strictly**
 - Focus on certain prescription-only drugs e.g. new antibiotics, second-line TB drugs

Possible solutions for improving use (2)

- **Standard Treatment Guidelines**
 - Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines
 - Disseminate to every doctor and incorporate into CPD
- **Drug and Therapeutic Committees (DTC)**
 - Establish DTCs in every hospital and require them to monitor drug use, encourage CPD, and report annually on activities to MOH
- **Continuing professional development (CPD)**
 - IMA/IMC should establish a credit system, incorporation of prescription audit and feedback and ethics into CPD
- **Public Education**
 - Core pharmaceutical messages e.g. *does my child need more than one drug?* through Ashas and the media

Coordination and management

- **RMSC**
 - Highest political support of Chief Minister
 - 5 technical departments under Managing Director
 - Procurement
 - Finance and IT
 - Logistics and Supply Management
 - Quality Assurance
 - Administration
 - Has achieved access to essential drugs in facilities
- **MOH**
 - is hiring more staff, but...
- **Which MOH unit coordinates pharmaceutical services?**
 - e.g. STGs for hospitals as well as districts, monitoring DTCs in hospitals, monitoring use, CPD/CME and public education?

Drug regulation

- **Rajasthan State Drug Regulatory Authority implements:**
 - Drug and Cosmetics Act 1940 & rules that apply throughout India
 - Drug Prices Control Order of 1995
 - Drug & Magic Remedies (Objectionable advertisements) Act 1954
- **DRA under-resourced**
 - Has 43 staff in post (out of 152 sanctioned posts)
 - Manages a sector consisting of about 100,000 products, 289 manufacturing units, >13,000 wholesalers, >20,000 retail shops
 - asked for vacant posts to be filled & more sanctioned posts
- **Drug testing lab**
 - 1452 samples tested last year: 72 failed, 62 cases face prosecution
 - Only 4 of 15 posts filled so tests may take 3-6 months
- **Outlet inspections**
 - Carried out 7338 inspections last year but not enough
- **Prescription-only drugs often available OTC**
- **No monitoring of drug promotional activities**
- **Many brands on the market so difficult to control**
 - DCGI ruled in Oct 2012 that no more brand names may be registered by State DRAs

Possible solutions for coordinating structure and national policy

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies ...**
- **Executive Division in MOH to carry out the statutory committee recommendations – RMSC?**
 - To coordinate action between MOH, RMSC, ??
 - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CPD, MIC, public education