

Initiative for Free Supply of Essential Medicines and Diagnostics in Public Health Facilities in the country.

“Aushadi Adhikar Karyakram”

I. Rationale:

1.1 Access to essential drugs and diagnostics is one of the basic entitlements that a government should ensure. Availability of drugs in the market is a necessary, but not sufficient condition for ensuring such universal and free access. In a context where poverty is over 40%, and the legal private sector does not reach large sections of the population and where there are immense financial barriers to accessing private sector care, far greater responsibility for ensuring universal access to drugs depends on the robustness and soundness of the outreach of public health systems and their ability to ensure uninterrupted provisioning of the public health facilities.

India has one of the highest figures for out of pocket expenditure as a proportion of total health expenditure. Only eight nations in the world have a worse ratio, and many of these eight could be characterised as failed states. Of the 78 % of total health expenditure that represents out of pocket expenditure as much as 75% could be just the costs of drugs and diagnostics. It is estimated that 2% of the population are pushed into poverty every year due to the costs of health care. Health care now is amongst the top three reasons for households slipping below the poverty line.

Given the economic and political climate, drug prices rise steeply at a rate higher than inflation. Further because of introduction of new drugs and vaccines under strict patent control regimes, the cost of care per illness episode rises even more steeply than the general rise of drug prices. Further since drug prescription and consumption occurs in a context of considerable information asymmetry, a large part of the expenditures on drugs and diagnostics is inessential, wasteful and not infrequently hazardous as well.

Health care provision by the public sector though provides relief from such unprotected exposure of the poor to the rising costs of health care. However, currently there are serious limitations in the public health sector being able to provide social protection. Firstly the out of pocket expenditure on drug costs even in the public sector is very high. Though only about half of what it costs in the private sector, the average cost per hospitalisation episode is as high as Rs 1468 and of this costs drugs and diagnostics accounts for 78% of the costs- drugs alone accounting for 66% of this expenditure. The poorer the state, the worse its

performance in health outcomes the higher these costs are. Thus in UP, Bihar, and Rajasthan the costs per hospitalisation episode in the public hospital are Rs 3204, Rs 3078, Rs 4382 respectively. Some states like Jharkhand and Chhattisgarh and Madhya Pradesh, have lower costs- but here hospitalisation in the public sector is much lower.

1.2 There are five reasons for this. These could be listed as follows: 1. Poor and incomplete stocking of essential drugs and diagnostics due to inadequate budgetary support 2. Poor supply chain management leading to frequent stock outs 3. Prevailing prescription practice of providers leading to inessential and costlier prescriptions for drugs and diagnostics from outside the public health system. 4. Economic philosophy that tried for cost recovery from the public hospital and for exposing the public hospital to market forces and 5. Lack of confidence in the quality of drugs supplied and tests done through the public health system.

There are states like Tamil nadu and Delhi which have shown that all five of these problems could be overcome by good management and governance practices. The cost per hospitalisation episode in Tamilnadu is about 17% of the national average- a mere Rs 255, of which medicines account for Rs 102 and diagnostics for Rs 20- a proportion that is more typical of more developed health care(NSSO 60th round). **The budget on drugs per capita works out to only Rs 60 per capita- about Rs 400 crores per year.** Tamilnadu also sets the benchmark for supply chain management- a system that ensures that there is at least a three month buffer stock available in every district warehouse and health facility- with re-stocking happening automatically if stocks fall below the threshold. This makes drug demand forecasting unnecessary and budgeting can be based on the previous years patterns. The Tamilnadu system has also a transparent and efficient system of drug procurement which is able to bring tremendous savings and at the same time ensure the highest possible quality and safety of drugs purchased. This makes it possible for both provider and patient to have confidence in the quality of drugs supplied. Protecting all these institutional frameworks is an administrative and legal framework that ensures that these standards are maintained. Promotion of rational prescription practices is still a challenge, even in Tamilnadu, but as the out of pocket figures show- it's a relatively limited problem.

This shows that it is possible to make major reductions in out-of-pocket expenditure in the public hospital by ensuring adequate, good quality, uninterrupted supply of all essential medicines and diagnostic tests. This would in turn lead to a much better utilization of public health services, which would also contribute to the social protection of the poor against the rising costs of health care. The estimate is that the utilisation of public health services would rise from the current 30% or less to about 50% or more, as many who are excluded from public health services due to financial barriers and now able to access such care.

To those who seek health care services in the private sector the availability of generic essential drugs at affordable costs through Jan Aushadis can help reduce the costs of care in the private sector.

It is in this background that this initiative is proposed as a major component of NRHM.

Objectives of “Free Supply of Essential Medicines and Diagnostics Initiative”:

1. To ensure free access to essential medicines and other medical supplies in public health facilities.
2. To ensure free access to medical diagnostics in public health facilities.
3. To protect the poor from the high and increasing cost of essential drugs and medical supplies and essential diagnostics.
4. To reduce out of pocket expenditures in for health care in the public health system.
5. To promote the rational use of drugs and diagnostics and reduce the consumption of inessential, unscientific and hazardous medicines.
6. To promote drug safety and drug quality.
7. To increase public health shares in health care provision to at least 50% of all curative care.

Main Strategies

1. Governance and Institutional Reforms.
2. Procurement Systems: Transparency, Efficiency, Safety and Quality.
3. Responsive supply of drugs to facilities
4. Factoring in Diagnostics
5. Essential Drug List, Drug Formulary and Standard Treatment Guidelines.
6. Public Awareness, IEC/BCC
7. Capacity building
8. Accountability and Oversight including Monitoring and Evaluation.
9. Budget Estimates and Financing

1. Governance and Institutional Reforms

1.1. Institutional mechanisms with sufficient autonomy to ensure centralised bulk procurement linked to a responsive supply chain management in line with the best practices in states in this regard.

1.2 The processes and process standards for such institutional mechanisms are defined further in the subsequent sections of this document. The governance and management practices and processes of TNMSC are the benchmark for setting standards for most processes.

1.3 Until such time as states manage to set in place such mechanisms they would have to tie up with other states where such institutional mechanisms are in place. Small states too could be allowed to place their orders through other larger states which have benchmarked and quality certified procurement and logistic systems.

1.4 The institutional mechanism will in the least include procurement of drugs, medical supplies, minor equipment especially those requiring frequent replacement, and also undertake all annual maintenance contracts for equipment.

1.5 A legal transparency act which would help make these changes difficult to reverse is desirable. (to discuss further)

1.6 The money that was spent in the pre-ceeding year from the state plan budget on drugs and diagnostics must be re-allocated in other areas of public health care provision.

2. Procurement Systems: Transparency, Efficiency, Safety and Quality.

2.1 Institutional mechanisms established should be responsible for all aspects of procurement and logistics/supply chain management. Existing corporations can also play the role if it develops the capacity and is not limited to procurement and also has the capacity to manage the logistics.

2.2 All procurement shall be limited to drugs and supplies on the essential medicines list, and shall be by generic names.

2.3 All procurement shall be centralised for economies of scale, and shall follow a two stage process, of a technical pre-qualification and a price bid. All procurement shall be bought directly from the manufacturers.

2.4 All manufacturers shortlisted for supply of medical supplies need to have GMP certificate, and preferably other national/international quality certification/accreditation.

2.5 After short-listing, inspection of the manufacturing unit's premises by qualified personnel/experts may be done to ascertain the capacity and quality of the manufacturers.

2.6 To make the procurement more transparent and quicker, e-procurement can be adopted by states. This may involve not only e-tendering (including call for tenders and submission of tender documents by bidders), but also posting the technical evaluation and financial comparison on the web site. The website may also contain provision for queries by email and also grievance redressal.

2.7 Tendering would need to follow the provisions of the respective state government's GFR norms (regarding limits for quotations, tenders, etc.).

2.8 But sometimes, exceptions might need to be made especially for rare goods (like new drug or medical devices). In such cases, adequate technical justification (which may also be vetted by competent authority) may constitute a sufficient case for exceptions (especially from the requirement of competitive bidding – requirement for minimum number of bidders).

2.9 Preferences may be given to drugs manufactured by central or state PSUs, provided the manufacturing units meets basic Indian GMP requirements, and all quality parameters as applied to all other drugs. States may consider earmarking a percentage of their requirements for purchase from such PSUs. (This is meant to keep public sector drug manufacturing units functional as a means of drug security for the nation and to exercise the option of compulsory licensing, where required for public health reasons).

2.10 After finalization of the bids, sample testing (by accredited laboratories) may be done at two stages – pre-supply and post –supply i.e. after receiving the stock at the intended unit (district/ facility).

2.11 A dedicated quality reporting system (manual or electronic) may be put in place across all levels, to keep track of the samples taken for testing, lab reports (for tracking delays in reports), action taken (on finding problems with the sample). A Quality control (QC) team comprising of specialists may be constituted at the state level to coordinate with the Food and Drug Inspectors and for other QC related tasks.

3 Responsive Supply of Drugs to Facilities: (Supply Chain Management-Logistics)

3.1 The supply chain management should ensure uninterrupted supply of medicines and diagnostic reagents to all district hospitals, sub-divisional hospitals, CHCs, primary health centres, health sub-centres and ASHAs as per the essential medicines list as applicable to

that level. At the second stage all medical college hospitals and tertiary care facilities would also be included.

3.2 District warehouse is central to this system. State must ensure that district warehouse has adequate infrastructure, and processes, with ISO certification.

3.3 Procurement system must ensure that if the stock position of any drug in any district warehouse falls below a three months level, an order is placed automatically and within a month the stock is topped up again.

3.4 Each facility has a pass-book which shows the stock position of drugs it has. This pass-book is visible at the district office- electronically, failing which at least manually once a month. At any time if the stock position of any drug in the facility falls below a three month position, the district warehouse sends the refill within one month. If it falls to less than one month, then refill within a week.

3.5 Each facility pass book must have annual cash value quota of drugs sanctioned. Every time drugs are issued to it, that much value is deducted from the value assigned and a new balance is computed. If the entire cash allocation for the whole year is exhausted, the facility would have to seek sanction for a further allocation from appropriate district authority.

3.6 One could start the cycle with a value allocation based on the previous year's figures plus the anticipated increase based on analysis of OPD and IPD trends. This could be derived from the HMIS data of the districts and facilities. All states have data at least to the district level, and many states have data disaggregated by facility.

3.7 Reagents for diagnostics and consumables used in diagnostics and therapeutics like catheters and bandages and minor equipment requiring frequent replacement like weighing machines, thermometers, etc. -- would also be part of the same supply side management principles.

4 Factoring in Diagnostics:

4.1 In diagnostics, the objective at this stage would be only a set of diagnostics as recommended by IPHS for that level of facility.

4.2 Since equipment and consumables flow along with the drug procurement and logistics systems, there is no additionality in bringing in diagnostics except manpower cost (laboratory technician) and of course the budget implications. Since laboratory technicians are part of the IPHS, there is no cost recovery through user fees or service charges for diagnostics needed to support them.

4.3 Rational use of diagnostics has its own set of problems, especially as related to defensive medicine. Popular understanding and use of standard treatment protocols would ameliorate

the problem, but it would not go away so easily and one would have to learn how to curb the moral hazards of over use.

5 Essential Drug List(EDL),Drug Formulary and Standard Treatment guidelines(STG) :

5.1 Every state should put in place an Essential Drug List. This list should be graded for sub centre, Primary health centre, Community health centre, district hospital and medical colleges.

5.2 The list will be made by an expert committee and upgraded once in two to three years, through a consultative process. The state may refer to the National List of Essential Medicines- 2011.

5.3 Based on EDL, a drug formulary would be prepared. The formulary will be limited to the drugs on the essential drug list, and will be updated annually and distributed to all facilities in the state.

5.4 The state would also introduce standard treatment guidelines for each level of care. Till such time as a standard treatment guideline is in place, the state can choose from some of the existing options like the AFMC guidelines or the STGs prepared by the states of Maharashtra, Chhattisgarh, or Delhi. These too like in the case of the EDL should be made and revised by expert committees through a consultative process.

5.5 Till the time state/states does not have an existing formulary and need a base line to start national formulary/WHO formulary may be referred to. The drug formulary can then be adapted as per state context.

6. Public Awareness, IEC/BCC:

6.1. 1% of the total budget allocated to a state has to be allocated for IEC/BCC activity for rational use of drugs, availability of drugs free of cost in public facilities.

6.2 Ensuring that IEC and other forms of public awareness shall focus on following key messages

a. Comparative price lists of common prescribed drugs by different brands to explain the need for a generic drug policy.

b. Problems due to irrational use of drugs - to the individual and to the community- increased costs, more errors and hazards. The list of inessential, irrational and hazardous drugs- available and the reasons why these are not included in the essential drug list- so that people understand that it is not because of weak

supply but because of patients interests that some drugs are not available. This also includes public and provider understanding of strategies of drug promotion and how information asymmetry affects both provider and user perceptions and practice. How this leads to certain clearly irrational drugs are market leaders.

e. Criteria and process on the basis of which essential drugs list and standard treatment guidelines are made and the need and uses of such guidelines.

f. The process of quality assurance in place - so that free supply of drugs is not perceived or portrayed as poor quality of medicines.

g. Irrational diagnostics- reasons behind and how standard treatment guidelines help reduces misuse.

6.3. Behaviour change communication is also needed to reduce public pressures for unnecessary injections and costly drugs.

6.4. At least 1% of the total budget allocated to a state has to be allocated for IEC/BCC activity for all the above messages that lead to public awareness on rational use of drugs, availability of drugs free of cost in public facilities and the other messages as outlined earlier.

7. Capacity building

7.1. State must allocate 2% of the total allocated budget towards establishment cost and for capacity building of the staff. At state level management expertise with specialisation in supply chain management and in pharmaceuticals quality assurance systems would be required.

7.2. Skill development would be needed in all district warehouses and hospital stores managers and pharmacists in the system. There should be adequate full time store managers in place in all district warehouses and in large hospitals.

7.3. Working software where facility level stock positions can be seen at district warehouses and district stock positions can be seen at the state level is essential.

7.4. Workshops and continuing medical education and nursing education programmes to for using the EDL, drug formulary and STGs and for sensitisation on the reasons for the same.

8. Accountability and Oversight including Monitoring and Evaluation:

8.1. A drug logistics information system would ensure information that could be used by the institutional mechanisms at state and district level for effective oversight. Through interoperability with HMIS systems, triangulation with data on patient attendance would also be enabled.

8.2. Rogi Kalyan Samitis would be assigned the task of monitoring at the facility level. They would be trained and supported to ensure availability of free drugs and diagnostics in public health facilities.

8.3. There would be administrative insistence on prescription and purchase in public health systems based only on generic names and promotion of a similar practice in the private sector as well. There would also be regulatory measures and enabling orders, put in place to ensure ethical promotion of drugs, especially in the public sector.

8.4. Prescription audits as form of measurement of good prescription practices and their promotion.

8.5. There would be independent sample surveys of facilities to ensure that any time the entire list of essential medicines, supplies and diagnostics as applicable to that facility- are not only available, but without interruption for the last year and that there is one month's stock at hand and that essential processes are being followed. There would be at least one such sample survey of facilities every year.

8.6. Outcome reports, and utilization certificates have to be submitted. Audit rules of appointment of auditor can be the same as adopted for National Rural Health Mission. Audit cycle of maximum 18 months is to be permitted.

9. Budget Estimates and Financing:

There are many approaches to budget estimates:

- A. Thus we could start with a normative allocation for every facility as a device for estimating the budget. Of course we would give to facilities only based on the responsive logistics system. The calculation is only for estimating the budget requirement. Thus we could start with a normative of PHC - one lakh; CHC 5 lakhs and every DH 40 lakhs of drugs per year. This comes to Rs 720 crores for the whole nation. (23,000 PHCs, 5000 CHCs and rural hospitals, 600 DHs). Another 1800 crores for sub-centers and ASHAs. That is about Rs 2500

crores for all primary and secondary care. Medical colleges and tertiary hospitals would be over and above this. *This is for the first year. In subsequent years we just reimburse what has been spent the previous year. Reimbursements could be every six months.*

(Sub-centers would require about Rs 50,000 per year, but since there are 160,000 subcenters, it would come to 800 crores. ASHA drug kits could also be included in the system. At a mere Rs 12,000 per year per ASHA it would still be over 1000 crores. These include iron and folic acid, vitamin A etc, but not vaccines).

B. Using TN as a bench mark and Rs 100 per capita as public health expenditure then we arrive at Rs 10000 crores as the costs for one billion populations. Less than 2% of these costs would be adequate for all the infrastructure and management and communication costs.

Phasing:

Phase -1: Preparatory:

The state can be given one year to establish the district warehouses, establish the state procurement and logistics agency and the passbook system in facilities and to train the storekeepers and put an IT system in place. Once this is done a sum is paid to the state procurement agency for the first full cycle of operation. The first procurement should be completed within the year.

Phase -2: Starting up: Primary Health Care: The state shall ensure that every district facility and district warehouse is given 9 months supply of essential drugs based on an initial estimate of monthly turnover. When the stock position declines to the estimated three months stock position, shall refill and bring the stock back to 9 months (or 12 months) estimated position. In subsequent years this estimation of what is monthly requirement would be based on the consumption of drugs the previous year in those same months. At this stage all the process conditions should be achieved, documented and externally certified. An ISO system could also be put in place. There is no supply to medical college and tertiary care hospital in this phase. However it could undertake to fund some categories of tertiary care like cancer care, where inflationary pressures are less likely and the programme is more needed and more manageable.

Phase -3. The supply is extended to all medical colleges and tertiary hospitals in the public sector. All standards are met and external monitoring has verified achievement of objectives.

Annexure I

Jan Aushadhis:

- These would be set up as part of a public para-statal organisation or as a contracted in unit.
- These would be largely for responding to prescriptions in the private sector. Since public sector is dispensing free drugs, Jan Aushadhis have as a rule, no role in them.
- Only drugs on the essential drugs list would be made available and that too in generic names.
- Management of Jan Aushadhis could be involved in promoting the use of generics and rational prescription in the private sector. NGOs, with a tradition of working on public health, or for health rights or rational drug use could also be recruited to promote the concept in the public and in the professionals.

Annexure II

Thus for example every PHC would have one lakhs and every CHC 5 lakhs and every DH 20 lakhs of drugs per year- then we start with a cash allocation of about 600 crores for the whole nation. (23,000 PHCs, 5000 PHCs and rural hospitals, 600 DHs). Sub-centers would require about Rs 25,000 per year, but since there are 160,000 subcenters would come to 400 crores. ASHA drug kits could also be included in the system. At a mere 12,000 per year it would still be over 1000 crores. Reagents for diagnostics and consumables used in diagnostics and therapeutics and minor equipment- weighing machines, thermometers, etc. -- would also be part of the same supply side management principles.