

## **Chapter 4**

### **Drug Procurement and Purchase Process**

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In the overall management of a drug policy, the following objectives have to be borne in mind:

1. All essential drugs needed for health care should be available at all the times at all the health facilities.
2. Drugs so made available should be of good quality and should be safe.
3. Systems of procurement should be such that quality drugs are procured at the most competitive prices.

In spite of tremendous advance in the various fields of medicine, drugs have always remained and are likely to remain the core element in preventive as well as in curative health care. Medicinal drugs inclusive of vaccines, contraceptives, nutritional supplements etc. are indispensable for the prevention, control, treatment and amelioration of a number of maladies that affect human beings. Interestingly, after personnel wage, pharmaceuticals are usually the largest item of expenditure within the public health sector budgets of developing countries, ranging from 8 to 12% of recurrent health budget. Therefore, it becomes imperative that such resources are utilized optimally. The WHO has been assisting its member countries in the formulation and implementation of national drug policies in order to reduce morbidity and mortality from common illnesses by promoting the availability and accessibility to essential medicines.

For achieving this goal, a major thrust has been placed on four access links, namely - Rational use, Affordable price, Sustainable financing and reliable health and supply systems.

Furthermore, other aspects of the national drug policy relating to drug legislation and regulatory control, essential medicines production, training of human resources and technical cooperation among countries of the region, among other aspects, are supported in accordance with the priorities of the countries by WHO.

Most developing countries suffer from an increased disease burden on account of overall poor health and hygiene conditions, and have limited capability to manufacture pharmaceuticals. Therefore, in these countries majority of

pharmaceuticals are imported from external sources, thus, representing the health sector's major requirement for foreign exchange, which may seriously affect their balance of payment (BOP) situation.

In the area of pharmaceuticals, the theory of market competition under liberalized, globalised and privatized economies does not give any benefits to the consumer because, by and large, it is not the consumer who decides or chooses the drugs, but usually a doctor or a pharmacist makes this decision and it is often difficult to rationalize their motivation. In addition to this, the average doctor or pharmacist does not have expertise to independently assess the quality, safety or efficacy of each new drug in the market. A similar kind of price variation may occur within the country among various generic and proprietary-brand formulation produced by different manufacturers and the consumer remains completely unaware of such situations.

For most developing countries, especially for the smaller ones, it is neither possible nor desirable to have their own manufacturing units for drug requirements in their countries. There is only weak evidence that average wholesale drug prices are lower in developing countries than in developed countries (Scherer and Watal, 2001; Maskus and Ganslandt, 2002). Prices are often at least as high in poor countries while incomes are lower, suggesting a substantial limitation on patients' access to drugs, which may be unaffordable to most. For example, despite the large reductions in prices offered to South Africa by several manufacturers of anti-retroviral drugs in early 2001, the prices as a share of GDP per capita in that country were not lower than those in the United States.

There are several reasons why drug prices may be high in developing countries. First, tariffs, taxes, and monopoly distribution channels may keep the costs of medicines artificially high. Secondly, the governments may be unable to negotiate significant price discounts with pharmaceutical firms. Small countries especially may not have sufficient potential demand, even through the public sector, to win price discounts. Thirdly, private insurance markets may not exist for large volumes of patients, implying that insurance firms could not negotiate steep discounts. Indeed, the majority of patients likely are not covered by either public or private health insurance, forcing them to absorb drug purchases into their household budgets. Finally, the pharmaceutical firms and their distributors in poor countries may find it more profitable to sell drugs in low volumes and high prices to wealthier patients with

price-inelastic demand rather than in high volumes at low prices to poorer patients (Scherer and Watal, 2001). There are concerns that if medicines were offered to poorer patients at lower prices the drugs could be resold in the higher-priced segment of the market. In this context, an inability to achieve “internal price differentiation” seems to result in lower willingness by pharmaceutical firms to service low-income patients.

A related view is that the practice of health authorities in some richer countries to engage in “reference pricing” encourages pharmaceutical companies to set high prices in developing economies. In a reference pricing system, price controls in one country are based on an index of prices in comparison countries. To the extent that the comparison group includes developing economies, firms may prefer not to offer price discounts there.

In view of the ever developing sophistication, modernization, automation and upgradation of manufacturing technologies competing environment, an efficient procurement system is the only way to improve access to medicines for the majority of the population within the given budgetary ceilings. Since availability of financial resources is always a constraint for developing countries, it becomes all the more important to improve efficiency in all aspects of management in the countries.

Good procurement is a linchpin of access to quality and appropriate medicines. The WHO, in partnership with UNICEF, United Nations Population Fund (UNFPA) and the World Bank, has drawn on a common bank of extensive experience to produce “Operational Principles for Good Pharmaceutical Procurement”, to assist all involved in procurement to obtain lower prices, better quality and more reliable delivery of essential medicines, based on four strategic objectives:

1. Procure the most cost-effective drugs in the right quantities.
2. Select reliable suppliers of high quality products.
3. Ensure timely delivery.
4. Achieve the lowest possible total cost.

The 12 guiding principles of good pharmaceutical procurement, grouped in four categories, are outlined below:

## **A. Efficient and Transparent Management**

- A.1 Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.
- A.2 Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.
- A.3 Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

## **B. Drug Selection and Quantification**

- B.1 Public sector procurement should be limited to an essential drugs list of national/local formulary list.
- B.2 Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.
- B.3 Order quantities should be based on a reliable estimate of actual need.

## **C. Financing and Competition**

- C.1 Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.
- C.2 Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralised and decentralised systems.
- C.3 Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.
- C.4 Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

## **D. Suppliers Selection and Quality Assurance**

- D.1 Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process, which considers product quality, service reliability delivery time and financial viability.

D.2 Procurement procedures/systems should include all assurance that the drugs purchased are of high quality, according to international standards.

It is worthwhile to mention that some states in the country have adopted the system of pooled procurement, leading to enormous savings and better availability of drugs in the government hospitals. In particular, the “**Delhi Model**” of drug procurement has been applauded worldwide. The sections below detail the Delhi model, Drug procurement system in Tamil Nadu, Andhra Pradesh, Orissa. Finally, the procurement methodology followed by the Hospital Services Consultancy Corporation is also discussed.

#### **4.1 Drug Procurement Mechanism In India**

##### **4.1.1 Delhi Model**

The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is a non-profit organization which has introduced the centralized drug procurement system with the government hospitals of Delhi in 1996 with the technical support of the WHO. The objective of the Delhi model of procurement was to ensure availability of good quality medicines with these hospitals and to promote rational drug use.

Before the introduction of the system, it was nothing but a total chaos in the supply of medicines with the hospitals in Delhi as in any part of the country. This is despite that 30-35% of the health budget of the government was spent on medicines. Each hospital in Delhi used to procure the drugs independently. The system was ruined by mismanagement and corruption. Many of the drugs so procured by the hospitals were rarely needed while the required medicines were almost perennially in short supply.

The introduction of this system has transformed the situation dramatically; the new system procures drugs centrally for half a dozen main and many smaller hospitals run by the Delhi government. Under the initiative, it was found that only a limited number of basic drugs were actually needed for treatment in almost 90 per cent of the hospital cases. These were identified and procured centrally for supply to the hospitals.

Besides, in keeping with the WHO guidelines, the expensive combination drugs were kept out of the supply list. As a result of this, the actual cost of drugs to the hospitals was cut by as much as half. A sea change could be brought about the procurement

modalities, so that 75 to 90% of the medicines prescribed in the hospitals are now being provided to patients free of cost.

The pooled procurement system is now in place for all state-run hospitals and 150 primary health centers in Delhi. The system has resulted in a fall in drug prices to the hospitals by 30-40 per cent, better quality assurance and less duplication of effort. About 80 per cent of the patients in the hospitals run by Delhi Government are now supplied all prescription drugs.

The WHO has hence recommended extension of the Delhi Model to other states. Many states including Maharashtra, Rajasthan, Punjab, Tamil Nadu and Himachal Pradesh are now implementing the programme with minor modifications. Moreover, the components of the Delhi model are being implemented in countries like Thailand, Myanmar, Vietnam, Laos and Kampuchea, as recommended by WHO. A list of 250 essential drugs was prepared for larger hospitals and a list of 100 for smaller hospitals. The list is revised from time to time. The hospitals in Delhi now spend over 90 per cent of their drug purchase budget to buy these listed medicines and 10 per cent to buy drugs outside the list. Standard Treatment Guidelines covering 15 diseases affecting adults and five childhood diseases have been drawn up for the benefit of doctors working in primary health centers, who were also provided with an essential drug list and important patient information.

The pooled procurement system uses a two-stage tender system. This ensures that only those companies that are capable of supplying products of adequate quality receive orders. The tender process is limited to companies that fulfill the technical criteria. Through a **two-envelope system** (technical bid and price bid), the drug purchase committee of the society is able to ensure that the purchases are made from companies complying with the Good Manufacturing Practices. A company which does not fulfill the technical criteria of a minimum annual turnover of Rs 12 crore and adherence to prescribed Good Manufacturing Practices (GMP), is automatically disqualified for making a price bid. The companies are required to undergo GMP inspections and random testing of products. There are instances of companies being blacklisted for want of proper compliance with GMP and poor quality of products. Doctors are asked to prescribe only products on the procurement list, although hospitals are allowed to use up to 10% of their drug budget on unlisted products.

#### **4.1.2 STATE OF TAMIL NADU(TN)**

A major initiative taken by the TN State Government was to set up a Government Company, Tamil Nadu Medical Service Corporation (TNMSC), with the primary objective of ensuring ready availability of all essential drugs and medicines in all the Government health facilities by adopting a streamlined procedure for their procurement, storage and distribution. It commenced its functions from January 1995.

The first step taken by TNMSC was to finalise the list of essential drugs to be procured. Keeping in view the WHO's Model List of essential drugs, the then existing list of nearly 900 drugs was pruned to a list of 240 drugs. Now, TNMSC has 271 items of drugs and medicines on its list, accounting for around 90% of the budget outlay for the purpose, leaving other drugs of small quantities to be purchased locally by the institutions from out of the remaining 10% budget. The TNMSC follows WHO's recommendation for the use of the international non-proprietary name (INN, commonly known as generics) for each drug. In order to ensure the procurement of only quality drugs at competitive prices, an open tender system is followed and purchases are made only from manufacturers and not through agents or distributors. It has been further stated that such manufacturers should have a GMP certificate and also have a market standing for at least three years. A minimum turnover is also fixed in order to eliminate the very small firms since such firms may fail to keep delivery commitments. To eliminate sole dependence on one supplier, the next two lower suppliers willing to match the lowest price were also approved.

With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practice of bulk packing which required manual handling at the time of distribution. Both inner and outer packages of all items are required to bear the logo of TNMSC with a marking to show that the drugs are manufactured only for the state government supply and are Not for Sale. On account of this, the credibility and acceptability of the drugs by the public also improved immensely. Samples drawn from different batches are coded and sent to private approved laboratories to ensure effective quality control.

In order to ensure a **regular supply** and for preventing stock-outs, TNMSC has established a chain of godowns to stock all items of drugs. Each district has a drug

warehouse as a point of distribution for all medical institutions in the district. The suppliers are required to supply the drugs to the district warehouses, which would keep a working stock of three months requirement at any point of time. Each institution is given a passbook indicating its annual entitlement (i.e. budgetary allocation) within which it can draw drugs from the district warehouse. There is no need for an advance indent because any drug in the approved list could be obtained within the entitled financial limit.

One of the **outstanding features** of TNMSC is the total computerisation in all aspects. Each district warehouse has a computer linked to the Head Office computer via the Internet. As the receipt and issue of drugs at all the district warehouses level is done using computers, the information on the inventory level for any drug at any warehouse at any point of time is readily available with the central computer at the Head Office, on the basis of which the stock position is effectively monitored and re-order is effected to prevent any stock out situation.

Further, on the basis of the inventory levels of all the warehouses, transfer of items from one warehouse to another are effected so as to optimise the utilization of drugs and to maintain minimum required stock levels. Other activities such as accounting, quality control, warehouse monitoring and administration are also conducted through computers for total error free strong logistic management. The solution starts from the identification of drugs to the Management Information System (MIS). Computerisation of the entire operation has improved inventory management, and cost control, and enhanced availability of drugs in government health facilities.

This **innovation** of the Government of Tamil Nadu in drug procurement and management has improved availability of drugs in nearly 2000 government medical institutions throughout the State. The competitive procurement system has resulted in savings in the outlay on drugs to the extent of 36% of the allocation. Apart from better budgetary control on drug consumption, medical institutions have become more cost conscious.

This system of **pooled procurement** aimed at quality drugs and a transparent tender system with well-defined pre-qualification criteria has resulted not only in substantial (36%) savings on drugs, but also in a better perception in people in addition to **enhanced availability** of drugs at all facilities. Though, there was considerable initial resistance to this new pre-qualification procedure, it was

accepted in due course, because the selection process was fair and an objective criteria was adopted. Although, the corporation has been permitted by the government to spend 5% of the annual turnover on its overheads, it is only around 1.5% at present, with a better inventory management, MIS and **improved access** to medicines.

#### **4.1.3 STATE OF ANDHRA PRADESH**

The state of Andhra Pradesh (AP) in India is the fifth most populous state with a population of over 66 million. The public health care system of AP comprises of three levels of service delivery and finance, viz. primary, secondary and tertiary care. The nodal agency for purchase of drugs in AP is the Drug Procurement Wing of the Andhra Pradesh Infrastructure State Development Corporation (APISDC).

A centralized pooled procurement system was initiated in September 1998. Accordingly, only those suppliers who had a stake in their long term reputation, and adopted good manufacturing and trade practices, were allowed to participate in the tender system, i.e. a technical bid was introduced before the actual financial bid.

This two-part system of bidding and procurement has considerably improved the supply and quality of drugs, and successfully discouraged the practice adopted earlier by certain firms of quoting unreasonably low rates in their bids to be included in the rate contract and then making up by short supplying and compromising on quality. A notified committee draws the selected list for procurement and rate contracts are finalized on the selected list of drugs centrally by another notified committee. Indents are collected from hospitals and consolidated by the nodal agency and orders are placed before the firm to make the delivery to the medical stores in each district with following **advantages**:

- (i) the drugs when purchased in bulk may be bought for a lower price directly from the manufacturers,
- (ii) transportation of these drugs is borne by the supplying firm and
- (iii) loss/theft during transport is the responsibility of the firm.

A pass book system has also been introduced and generally institutions draw their supply on a quarterly basis. A Primary Health Centre (PHC) can draw only 43 listed items. The superintendents of district hospitals have 10% of the allotted funds at their disposal for purchase of emergency medicines and the Superintendents of

tertiary hospitals have 20% of the allotted funds at their discretion for similar purpose. Drug samples are drawn from district drug stores and sent to a recognised laboratory for testing.

This experience reflects that an autonomous organisation with a supportive board can perform very well and approve the rates of procurement of drugs centrally, availing the advantage of bulk/pooled procurement, yet effect the deliveries of supplies in decentralised district drug stores, the cost of which is borne by the supplier. A single window system for all inputs, processes and outcomes can work effectively with a fairly close monitoring of flow of funds etc. The initial reluctance of the staff leading to slow improvement in financial and inventory management was overcome through a process of training and once the changes were set in motion, they proved to be very effective and finally computerisation was also put into place.

#### **4.1.4 STATE OF ORISSA**

Orissa is one of the eastern states of India having a population of about 36.7 million spread over an area of 1,56,000 sq. km. In 1997, it shifted from its earlier decentralised system of drug procurement to a more centralised, need based, procurement system with its Essential Drug List (EDL) based on the WHO model list comprising of 278 drugs in generic nomenclature.

In order to ensure quality procurement, a pre-qualification stipulation in the form of two envelopes, (A) containing quality parameters and (B) containing price quotation has been envisaged. Envelopes 'B' of only those who are technically qualified are opened. Only manufacturers having GMP certificate from the licensing authority are allowed to participate in the tender process and there is a provision for drawing samples from each batch of supply for testing. However, Small Scale Industries (SSI) units are entitled to 5% price preference along with partial exemption from earnest money deposit, concession in sales tax, exemption from quality testing charges and a provision for midcourse correction of prices during the year.

A recent evaluation of the Orissa Drugs System has revealed that though the key drug availability in all the facilities except one ranged from 80 to 100%, yet the perception of most doctors about EDL and use of generics is not positive enough and they often advocate patients to buy branded drugs from private pharmacies, claiming poor quality of government drugs as the excuse. The study team observed that the packaging of drugs supplied by SSI units was unsatisfactory. The perception

of doctors could be real or under the motivation of high powered salesmanship of pharmaceutical organisations. However, as per the prevailing procurement system 40% of the drugs have to be purchased from the State's SSI units and there have been instances where quality has been compromised on items from these sources.

One of the major limitations of this system is that in order to satisfy local SSI units, the orders for individual items of drugs (reserved for SSI units) are split over several units leading to multiple batches being delivered at the central warehouse leading to inventory management problems. This shows that although pooled procurement could prove to be very cost-effective, any element of local protection, in the form of preferential treatment, could sabotage the well intentioned policy by creating an element of suspicion about the quality of drugs. This may defeat the basic principle of cost- effective pooled procurement with the level playing of suppliers on the one hand and may lead to a poor perception of quality in the minds of the health providers, at the same time. Preferential or protectionism clause in favour of certain categories of industries may discourage many prospective quality manufacturers to stay away from the competitive bidding process.

#### **4.1.5 DRUG PROCUREMENT MECHANISM by HSCC**

The Ministry of Health and Family Welfare, government of India usually assigns the procurement of drugs and pharmaceuticals to an agency called Hospital Services Consultancy Corporation (HSCC). HSCC is a multi-disciplinary consultancy organization which was established to provide quality consultancy services in healthcare and other social sectors. HSCC has been dedicatedly involved in providing a complete range of services in the fields of:

- a. Construction of Hospitals, Laboratories, Research Centres etc.
- b. Procurement of drugs and medicines
- c. Procurement & commissioning of medical equipments
- d. Solid & medical waste management systems
- e. IT-based management systems in health care

HSCC adheres to quality standards and innovative approach to work in each case provide unique solutions to design and development of Hospitals/ Laboratories/ Health centres both in India and abroad. The corporation's competitive advantage lies in its intimate understanding of the requirements and its capacity to evolve a

matching project profile. HSCC undertakes procurement of drugs and pharmaceuticals including formulation of specifications, tendering, order placement, expediting and follow-up, inspection and dispatch. A number of World Bank supported programmes for procurement of drugs and pharmaceuticals have been undertaken by the HSCC viz. Malaria, TB, Reproductive Child Health etc. The procurement services are in accordance with the guidelines and norms of the World Bank.

The process flow chart of business unit procurement is detailed below and the activities are numbered as per their sequence in the procurement chain.

**1. Opportunity Search**

- Source of information MoHFW, other ministries & depts. Of Govt. of India. The World Bank, newspapers, magazines, journals, meetings with prospective clients etc.
- If required, discussion of business opportunities with director (E).
- Introductory letter or an offer is sent in consultation with director (E).

**2. Preparation of offer**

- With an offer is to be submitted, the same is prepared in consultation with director (E).
- Offer is reviewed by competent authority before submission. A copy of offer is kept as record.
- Record of offer preparation, its review and approval is maintained by noting in the respective file.

**3. Follow-up action**

- Follow ups are done by personal visits, letters or over phone. Record of reminder/follow-ups is maintained.
- The status of project is discussed with director (E) for further action as per the response.
- If the response is positive, a suitable course of action is planned and executed like submission of further information if asked or proceed with agreement/ contract.
- If the response is negative, then the project is dropped.

**4. Award of work**

- When a project is awarded it is reviewed by CCGM (BU-P)/DIR (Engg.) to resolve differences, if any, between offer and contract requirements
- If required, the approval of CMD is obtained
- The contract is signed by CGM(BU-P)
- On award of project, IT division is informed to allocate a project code

- 5. Amendment to contract**
  - Necessity to change/amendment to agreement/contract is reviewed by CGM (BU-P)/DIR(Engg.). Record of review is maintained.
- 6. Procurement plan**
  - Prepare procurement schedule in consultation with client.
  - Obtain World Bank's no objection
- 7. Technical specifications and bid documents**
  - If client does not provide specification, they are framed in detail in consultation with client
  - Obtain World Bank's no objection
  - Bidding documents are prepared based on standard bidding documents (SBD) of World Bank.
  - In case estimated value of contract exceeds prior review threshold of the World Bank. The bidding documents are sent for no objection
- 8. Invitation for bids**
  - In case of ICB, the general procurement notice is sent to world bank for arranging publication in UNDB magazine
  - In case of ICB, the invitation for bids (IFB) is sent to embassies & trade representatives of member countries of the world bank
  - IFB is published in leading newspapers with wider circulation and also posted on HSCC website
- 9. Bidding document sale & bid opening**
  - In case of ICB, bidding documents are made available for sale for a minimum period of 45 days
  - In case of NCB, bidding documents are made available for sale for a minimum period of 30 days
  - In case of national shopping, report for quotations are issued to approved short listed firms
  - Send clarifications/amendments wherever necessary to prospective bidders
  - Receipt of bids on due date & time
  - Open bids (Both techno-commercial and price bids).
  - Prepare minutes of bid opening
- 10. Bid evaluation**
  - Technical scrutiny committee (TSC), as approved by competent authority, examines & evaluates bids.
  - Wherever necessary, clarification are sought from bidders on historical data

- Prepare bid evaluation report (BER)
- 11. Client's (& World Bank's) approval for bid evaluation report**
  - Obtain client's approval for BER
  - In case, contract value exceeds prior review threshold of the World Bank, the same shall be submitted to World Bank for review & no objection
- 12. Notification of award & contract signing**
  - Release notification of awards on recommended bidders
  - Signing of contracts within 21 days
- 13. Contract administration**
  - All necessary inputs & directions are given to supplier
  - Supplier offer goods pre-dispatch inspection
  - Qualitative & quantitative inspection and/or testing are carried out to check compliance with specifications
  - Issue dispatch clearance
  - Monitor delivery of goods
  - Wherever necessary, supervise installation of equipment/arrange training to users
  - Make payments to suppliers
  - Submit statement of expenditure (SoE) to client
  - Accounts settlement with client

The HSCC is managed by professionals with background in projects, healthcare, engineering and other relevant areas.