Best Practices in Pharmaceutical Procurement and Medicines Management

In the wake of government initiative to constitute J&K Medical Services Corporation, streamline procurement and ensure availability and supply of standard quality drugs Dr Geer Mohammad Ishaq enumerates best practices in supply chain management of medicines in tune with international norms and standards

Government of Jammu and Kashmir has in its cabinet meeting held on May 21st, 2013 approved the establishment of J&K Medical Supplies Corporation (JKMSC) with an objective to streamline the terribly derailed drug procurement and supply chain management system for government hospitals in the state. In view of the recently surfaced spurious drug debacle, credibility and faith of patients upon hospital drug supplies has received a serious jolt. Consequently it has turned out to be truly a Herculean task for the state govt. to restore its credibility and peoples’ trust upon the quality of drugs that are supplied at its healthcare centres. Constitution of JKMSC though late, can still be termed as a right step in this direction. As they say, “better late than never”. Civil Society Forum Kashmir had persistently been insisting upon the government to frame JKMSC and replicate TNMSC taking due care of local contexts, sensitivities and requirements.

Now that the govt. has made up its mind to establish JKMSC, it is time to set the drug procurement mechanism in order through “Standard Operating Procedures” and highlight best practices in tune with international norms and standards. The effectiveness of the medication management system depends on adherence to policies (broad, general statements of philosophy) and procedures (detailed guidelines for implementing policy). Four strategic objectives of Drug Procurement in the state should be to procure the most effective and safe drugs in right quantities; select reliable suppliers of high quality products; ensure timely delivery, reduce lead time and achieve the lowest possible total cost. Other best practices are as under:

Selection of Drugs:

The selection of pharmaceuticals is a basic and extremely important professional function of the JKMSC that may be charged with making decisions regarding products, quantities, product specifications, and sources of supply. It is the JKMSC’s obligation to establish and maintain standards assuring the quality, proper storage, control, and safe use of all pharmaceuticals and related supplies. ABC/VED analysis of past procurement has to be conducted regularly and drugs categorized into basic, supplementary and specialized lists. Drugs should preferably be selected for procurement from the specific Essential Drugs
List of the state. While selecting drugs local factors like local diseases, regional differences in sensitivity and resistance of micro-organisms, local climate, topography, environmental factors etc, should be duly considered. While selecting formulation types, stable forms should be chosen, giving preference to tablets over capsules, ointments over creams, powder for reconstitution over injectable solutions and avoiding syrups, to achieve a low-cost, high impact intervention in maximizing the therapeutic lifespan of medicines. Expensive combination drugs should be kept out of the supply list to reduce the actual cost of drugs to the state by as much as half. As far as possible generic drugsshould be purchased to reduce the cost.

**Quantification of Drugs:**

To avoid wastage through over-stocking or stock-outs of pharmaceuticals, a reliable system of forecasting or quantification of drug needs should be used that includes a combination of past consumption based and morbidity based methods. Accurate quantification of drug requirements, competitive drug procurement based on generic names, prompt payment and regular audits, and efficient distribution are some of the major aspects of effective pharmaceutical management. Budgetary allocations for drugs and pharmaceuticals should be kept anywhere between Rs. 100-200 per capita per annum.

**Procurement of Drugs:**

Competitive bid purchasing is an important method for achieving a proper balance between quality and cost when two or more acceptable suppliers market a particular product meeting the JKMSC’s specifications. Drugs should be purchased directly from the manufacturers and not from their agents, stockists or sub-stockists. Drug procurement through brokers and agents has to be avoided since brokers are prone to using corrupt practices such as paying kickbacks to secure their businesses. Economic considerations should be made subordinate to those of quality. A company which does not fulfill the technical criteria of a minimum annual turnover of Rs 50 crores, market standing of minimum five years and adherence to prescribed Good Manufacturing Practices (GMP), should be disqualified from making a price bid. ORG rankings of pharmaceutical companies may also be followed wherever required.

A double-envelope system should be used for bidding and the drugs should always be purchased using VFM (Value For Money) criteria instead of Low Bid criteria. Envelope B (price bid) of Companies not fulfilling technical criteria should be returned to them without opening. To eliminate sole dependence on one supplier, the next two lower suppliers willing to match the lowest price should also be approved. To the extent possible, all products should be made available by the supplier in single unit or unit dose
packages. Procurement should be effected in the largest possible quantities in order to achieve economies of scale.

With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules should be procured with only strip or blister packing, as against bulk packing which requires manual handling at the time of distribution. Both inner and outer packages of all items may bear the logo of JKMSC or labeling instructions to show that the drugs are manufactured only for JKMSC and are not meant for sale outside JKMSC. On account of this, the credibility and acceptability of the drugs by the public shall improve immensely. Doctors should be advised to prescribe only products on the procurement list, although anywhere upto 10% of drug budget can be used on unlisted products. The procurement office should have at least one senior qualified pharmacist as part of its senior staff, in addition to having qualified pharmacists’ all along the pharmaceutical procurement chain.

**Pre-Qualification of Suppliers:**

Pre-qualification should assess the quality of the manufacturer (respect for Good Manufacturing Practices-GMP); the quality of the product (registration status, Certificate of Pharmaceutical Product) and the quality of the batch (Certificate of analysis, labeling, appearance, packing and shelf life inspection, chemical analysis). It should be the responsibility of the drug supplier, if any, to sell only drugs from GMP-compliant manufacturers and drugs that are duly licensed. Technical specifications should include Analytical control data, Sterility testing data, Bioavailability data, Bioequivalence data, Descriptions of testing procedures for raw materials and finished products, Testing data developed by independent laboratories, and any other information that may be indicative of the quality of a given finished drug product. All information should be supplied at no charge. A Model Questionnaire consisting of four main sections: Business Information, Manufacturing Information, Quality and Product Information should be used for prequalification of suppliers. Pre-qualification should be done continuously as prospective suppliers express their interests and even before tenders are floated.

**Evaluation of Bids:**

Selection of suppliers should be done through a transparent, clear and explicit bidding process. After thoroughly evaluating the bids, a special committee or tender board usually awards the tenders. It is important that a pharmacist or a person with technical knowledge of pharmaceutical products and its manufacture be a member of the tender board. As often the case, the determining factor for awarding a tender is price. Quality must be a more important consideration due to the fact that purchase of cheaper pharmaceuticals without quality assurance invariably result in losses like expiration of stocks soon after delivery because of too short shelf-life; substandard drugs and health hazards. In
selecting a vendor, the Corporation must consider price, terms, shipping times, dependability, quality of service, returned goods policy, and packaging; however, prime importance always must be placed on drug quality and the manufacturer’s reputation. Transparency must be maintained throughout the procurement cycle by following formal written procedures. Decisions should be based on explicit criteria. A list of all contracts awarded, specifying the supplier and price for each product, should be made available to all bidders.

**Monitoring Supplier’s Performance:**

A continuous supplier performance monitoring system which tracks lead time, compliance with contract terms, partial shipments, quality of drugs, remaining shelf-life, compliance with packaging and labelling instructions of drugs should be evolved. Monitoring should include an annual external audit too. The supplier’s compliance with the terms and conditions of the contract should be recorded, with emphasis on timely delivery, quantities delivered as ordered, shelf life after delivery and quality. A system for reporting and recording quality problems noted by the healthcare professionals throughout the state should be part of the post qualification procedures.

**Quality Assurance System:**

A comprehensive Quality Assurance system involving both surveillance and testing of drug quality and including both technical and managerial activities, spanning the entire supply process from drug selection to patient use should be established. Quality should be checked through visual inspection of incoming consignments and randomly drawn samples from different batches should be coded and sent to private approved laboratories to ensure effective quality control. Drug quality should be assessed as compliance with pharmacopoeial specifications concerning a drug’s identity, purity, potency and other characteristics like uniformity of the dosage form, bioavailability and stability.

**Proper Storage of Drugs:**

Correct storage of drugs to avoid deterioration distribution and wastage should be developed through systematic stock inventory control system should be ensured using modern tool of computerization and management information system so that drugs are always available when needed in the state. IT enabled infrastructure is therefore an essential component of the supply chain management of medicines so that real-time monitoring of drug stocks at district and divisional levels could be monitoring round the clock.
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