

WHO/EDM/PAR/99.5

Original: English

Distribution: General

OPERATIONAL PRINCIPLES FOR GOOD PHARMACEUTICAL PROCUREMENT

**WORLD HEALTH ORGANIZATION
UNITED NATIONS CHILDREN'S FUND
UNITED NATIONS POPULATION FUND
WORLD BANK**

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The contents of this document were adapted from: Chapter 13: Managing procurement. Management Sciences for Health (MSH) in collaboration with the World Health Organization, Action Programme on Essential Drugs.* *Managing drug supply*, second edition. Edited by J.D. Quick, J. Rankin, R. Laing, R. O'Connor, H.V. Hogerzeil, M.N.G. Dukes and A. Garnett. Hartford, CT: Kumarian Press; 1997.

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Acknowledgements

The following persons have contributed to the development and review of this document and their advice and support are gratefully acknowledged:

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* Since July 1998 incorporated in the Department of Essential Drugs and Medicines Policy (EDM).

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Acronyms and abbreviations

BCT	Blood Safety and Clinical Technology
CDS	Communicable Diseases
CHS	Health Systems and Community Health
DAP	Action Programme on Essential Drugs
ECHO	Equipment for Charity Hospitals Overseas
EDL	Essential drugs list
EDM	Department of Essential Drugs and Medicines Policy
EURO	Regional Office for Europe
FIP	Fédération Internationale Pharmaceutique
ICRC	International Committee of the Red Cross
IDA	International Dispensary Association
INN	International Nonproprietary Name
IPC	Interagency Pharmaceutical Coordination Group
MIS	Management Information System
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
SEARO	Regional Office for South-East Asia
SUP	Supply Services
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
VAB	Vaccines and Biologicals
WHO	World Health Organization
WPRO	Regional Office for the Western Pacific

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Introduction

This document introduces four strategic objectives and twelve operational principles for good pharmaceutical procurement. These objectives and principles have been developed and endorsed by the Interagency Pharmaceutical Coordination Group (IPC), involving the pharmaceutical advisers of the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA), the World Health Organization (WHO) and the World Bank.

The aim of this document is to improve pharmaceutical procurement practices in countries served by the IPC members. These operational principles for good pharmaceutical procurement are not meant to regulate activities of international agencies, sovereign governments or private companies. They are presented strictly as a set of principles which can be reviewed and adapted by individual governments and public or private organizations in the process of developing their own internal procurement procedures.

These objectives and principles are published by WHO's Department of Essential Drugs and Medicines Policy (EDM) on behalf of the IPC, after an extensive review by experts from international agencies, governments, the pharmaceutical industry, essential drugs supply agencies and universities.

Pharmaceutical procurement occurs in many contexts. Although the operational principles presented here are in many respects applicable to all procurement settings and for most types of procurement situations, their primary target is pharmaceutical procurement for public sector health systems. It is recognized that public sector procurement may be managed in a variety of ways, ranging from total in-house systems, through various autonomous or semi-autonomous procurement agencies, to total privatization. These principles are applicable to each of those variations.

The document is composed of four chapters. Chapter 1 consists of a brief problem statement which illustrates the need for improvements in procurement practices. Chapter 2 presents the four strategic objectives of pharmaceutical procurement which apply to any health system, whether it is public or private. Chapter 3 presents twelve operational principles for good pharmaceutical procurement, grouped into four categories (management; selection and quantification; financing and competition; supplier selection and quality assurance). Chapter 4 gives more information on the practical implementation of the twelve principles and some useful information on mechanisms to further improve the performance of the procurement system. A section of references and further reading is also included.

Coordination and collaboration among technical development agencies continues to be a major issue. It is the hope of the IPC that these operational principles will foster cooperation and standard approaches among national governments and

donors actively attempting to improve public health and drug management around the world.

Comments on this document are actively solicited and can be submitted to:
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1. Problem statement

Pharmaceutical procurement is a complex process which involves many steps, agencies, ministries and manufacturers. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market.

Market constraints differ from country to country. Public sector drug procurement must take place in the context of both the local pharmaceutical market and the international market. In many countries public health officials have limited experience in designing an optimal procurement system to fit their market context. An increasing number of countries have moved, or are moving, away from a pharmaceutical procurement and distribution system which is totally operated by the public sector, and are investigating various options for involving the private sector in order to enhance public health. A recent MSH/WHO publication¹ explores various models which exist. Each of the models discussed in that book has advantages and disadvantages, and each presents a different challenge to effective procurement management.

There are many steps in the procurement process. No matter what model is used to manage the procurement and distribution system, efficient procedures should be in place: to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to lack of access to appropriate drugs and to waste. In many public supply systems, breakdowns regularly occur at multiple points in this process.

If there is an appearance of special influence on the selection of products and suppliers or if the procurement process is not managed in an efficient and transparent manner, interest among suppliers in competing for procurement contracts decreases, leading to fewer choices and higher prices for drugs.

If the procurement system cannot guarantee access to funds at the time they are needed, drug shortages and procurement inefficiencies are inevitable. Government funds for procurement are, in some countries, released irregularly during the financial year. In some countries government regulations specify that funds must be spent in the year for which they are allocated or be returned to the treasury; this compounds the problem. Where this combination exists it

¹ Management Sciences for Health in collaboration with the World Health Organization, Action Programme on Essential Drugs. *Managing drug supply*, 2nd ed. Edited by J.D. Quick, J. Rankin, R. Laing, R. O'Connor, H.V. Hogerzeil, M.N.G. Dukes and A. Garnett. Hartford, CT: Kumarian Press; 1997.

compromises procurement planning and execution. Limited or irregular funding which leads to delays in payments worsens procurement problems as suppliers deny credit or insist on advance payments. A degree of financial autonomy for the health system, while providing flexibility, requires proper accountability and efficient management.

External financing of drug procurement for the public sector by international agencies, bilateral donors or development banks can also be a source of problems in some countries. In such cases the donors or banks may have conflicting policies and regulations regarding drug procurement, which in turn may conflict with existing local laws and regulations. In these situations it is extremely difficult to carry out procurement in a timely and efficient manner. Development assistance should be more consistent with the policies of the country. And it is essential that this assistance should reinforce good pharmaceutical procurement practices and aim at sustainability, rather than undermining or delaying the development of such procurement practices. Thus international, multilateral and bilateral agencies may need to review their own procedures, requirements and technical advice in the light of the operational principles presented here.

The recent trend towards decentralizing responsibility for procurement can be positive, in that local authorities should have the strongest interest in maintaining a consistently effective drug supply system. However, without procedures to maintain economically viable procurement quantities, drug prices may increase dramatically. Moreover, without mechanisms to monitor local performance and to ensure adherence to good procurement practice, public health objectives may not be met and scarce funds may be wasted on inappropriate purchases. Contracting out parts of the procurement/distribution function may improve efficiency and reduce costs. But this will only be true if public health systems can properly monitor and manage such contracts. In many countries the necessary experience and information systems for this are lacking. In some countries initial decentralization of drug procurement was followed by pooled procurement by hospitals or cooperatives.

Unbiased market information on product availability, comparative pricing, product quality and supplier performance is difficult to obtain in many countries. Poor access to information is most common in countries where it is most needed in the light of inadequate regulation of the local market. This information deficiency can result in gaps in essential drug availability and in procurement of poor-quality products at unnecessarily high prices. It may also facilitate undue influence on the procurement process by special interest groups.

Even if appropriate policies and procedures are in place, lack of properly trained staff in key positions can doom any procurement system to failure. While effective training programmes can remedy this problem, in many supply systems there is limited access to training in good procurement practices. Also unattractive public sector salaries and lack of career development tend to restrict capacity to attract and retain qualified staff.

Summary of main problems

- inadequate rules, regulations and structures;
- public sector staff with little experience in responding to market situations;
- absence of a comprehensive procurement policy;
- government funding which is insufficient and/or released irregularly;
- donor agencies with conflicting procurement regulations;
- fragmented drug procurement at provincial or district level;
- lack of unbiased market information;
- lack of trained procurement staff.

2. Strategic objectives for good pharmaceutical procurement

The twelve operational principles for good pharmaceutical procurement, which form the bulk of this document, are based on four strategic objectives. Both the strategic objectives and the operational principles are relevant to any public sector drug supply system, no matter what combination of public and private services is used to manage the system.

Four strategic objectives of pharmaceutical procurement

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

1. Procure the most cost-effective drugs in the right quantities

The first strategic objective is that all organizations responsible for procurement, whether they are public, private non-profit or private for-profit, should develop an essential drugs list to make sure that only the most cost-effective drugs are purchased. Procedures must also be in place that accurately estimate procurement quantities in order to ensure continuous access to the products selected without accumulating excess stock.

2. Select reliable suppliers of high-quality products

The second objective is that reliable suppliers of high-quality products must be (pre-)selected, and that active quality assurance programmes involving both surveillance and testing must be implemented.

3. Ensure timely delivery

The third strategic objective is that the procurement and distribution systems must ensure timely delivery of appropriate quantities to central or provincial stores and adequate distribution to health facilities where the products are needed.

4. Achieve the lowest possible total cost

The fourth objective is that the procurement and distribution systems must achieve the lowest possible total cost, considering four main components:

- the actual purchase price of drugs;
- hidden costs due to poor product quality, poor supplier performance or short shelf-life;
- inventory holding costs at various levels of the supply system; and
- operating costs and capital loss by management and administration of the procurement and distribution system.

3. Operational principles for good pharmaceutical procurement

Efficient and Transparent Management

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.

Justification and explanation

Senior managers responsible for procurement must ensure that pharmaceutical procurement is carried out effectively, efficiently and in accordance with the country's policies, laws and regulations. The health system's procurement office, under various names, is normally responsible for actually managing the procurement function. The procurement office should be responsible for coordinating inputs to achieve the desired result. But in most public sector contexts the reality is that all functions of the drug procurement process are entirely in the hands of one office or official.

Without appropriate separation of function and authority the procurement process is much more susceptible to influence by special interests. In that case, procurement personnel may be able to bias drug selection, manipulate orders to increase the quantities of certain drugs, prejudice supplier qualification decisions, manipulate the final award of tender, and slant product specifications to limit competition. Separation of key functions contributes to professionalism, accountability and an efficient procurement system.

Practical aspects

A number of key procurement functions typically require different expertise and should be separated. Examples include:

- *Drug selection*, which should be done by a national formulary or essential drugs list (EDL) committee. Where such a committee does not exist an ad hoc committee should be set up for this purpose.
- *Quantification of drug requirements*, which should have inputs from the medical stores and/or from district or health facility managers in decentralized systems. However, the procurement office should draw up the final procurement list.
- *Product specifications*, which should be prepared by a standing committee or an ad hoc technical committee.

- *Pre-selection of suppliers*, which should be done by a broad-based procurement committee composed of managers and technical staff, including quality assurance experts.
- *Adjudication of tenders*, which should be reserved for the procurement committee or tenders board. Procurement office staff can make technical recommendations but should not have a vote in the contract decision.

Pharmaceutical procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists' expertise all along the pharmaceutical procurement chain.

2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.

Justification and explanation

Fairness and the perception of fairness are essential to attract the best suppliers and achieve the best prices. When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair. There may be accusations of unfair influences. Whether true or not, such charges are damaging and suppliers, health care providers and the public lose confidence in the system. Unsuccessful suppliers may feel that they have no chance of winning and consequently withdraw from future tenders. As the pool of potential suppliers decreases to a small set, price competition decreases and procurement prices become much higher than necessary.

Practical aspects

The tender procedures should be transparent. Formal written procedures should be developed and be followed throughout the tender, and explicit criteria should be used to make procurement decisions. Broad-based committees should have the sole authority to make contract awards. Tender adjudication should be done properly and the award of contracts and issuing of orders should be completed within the shortest period of time possible. Information on the tender process and results should be public, to the extent permitted by law. At the very least, both bidders and health personnel should have access to information on the successful suppliers and the prices for all winning contracts.

3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

Justification and explanation

In order to ensure that drugs are available where and when they are needed, drug procurement must be carefully planned. Planners should consider factors such as access to suppliers; funding availability and timing; the number of levels in the logistics system; constraints of time and resources affecting procurement

functions such as drug selection, quantification, tendering and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport.

Practical aspects

A reliable management information system (MIS) is one of the most important elements in planning and managing procurement. Lack of a functioning MIS or the inability to use it appropriately is a key cause of programme failure. The MIS should track the status of each order and payment, and compile the information required for supplier monitoring, as discussed in Operational Principle 11. It is important that the MIS also tracks the number of orders placed, payments made, quantities actually purchased compared with estimates, purchases from all contract suppliers, and drug purchases from non-contract suppliers. In all but the smallest procurement systems, the procurement information system should be computerized in such a way as to facilitate tracking and reporting on performance by suppliers and by the health system.

The procurement office should be required to report regularly on key procurement performance indicators, selected by senior managers. Some standard indicators include the planned versus actual items and quantities purchased; prices obtained versus average international prices; average supplier lead-time and service level; percentage of key drugs in stock at various levels of the supply system; and report on stock-outs.

At least once a year the procurement unit should undergo an audit, either internal or external, to verify procurement office accounting records. The auditor should issue a statutory audit report in accordance with the legal regulations of the jurisdiction and in addition should issue a detailed *Letter of Comment* to the management of the organization and to the appropriate public supervisory body.

Drug Selection and Quantification

4. Public sector procurement should be limited to an essential drugs list or national/local formulary list.

Justification and explanation

No public or private health care system in the world can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure.

A nationally developed formulary or selection based on the essential drugs concept has been used in both industrialized and developing countries' health systems for more than twenty years. This allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or national list allows for concentrating on a limited number of products. Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs.

Practical aspects

Some public and private health systems strictly limit procurement to drugs listed on an essential drugs list. However, in most cases some mechanism exists to address special needs, allowing the occasional procurement of non-list drugs after approval by senior officials.

5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.

Justification and explanation

The INN is widely accepted as the standard for describing drugs on a procurement list or tender request. Although this is most obviously applicable when purchasing drugs which are available from multiple sources, generic description should also be used when purchasing single source products. When purchasing products which present potential problems with pharmaceutical equivalence or bio-equivalence the procurement request should specify the quality standards but not mention specific brands.

Practical aspects

This does not mean that brand-name suppliers should be barred from tender participation; they may offer the most cost-effective product, and in fact may offer more competitive prices for certain branded drugs than generic competitors. However, all drugs supplied to the public health system should be properly labelled in accordance with standards laid down by law (or in accordance with labelling instructions), including the INN featured prominently in addition to the brand name that may be on the label.

6. Order quantities should be based on a reliable estimate of actual need.

Justification and explanation

An accurate quantification of procurement requirements is needed to avoid stock-outs of some drugs and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract.

Practical aspects

Past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate. Such consumption data must be adjusted in the light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance. The downside of basing quantification only on past consumption is that any existing patterns of irrational drug use will be perpetuated.

In many countries consumption data are incomplete or do not reflect real demand because the supply pipeline has not always been full and drug use has not always been rational. In such cases the morbidity-based and extrapolated consumption techniques may be used to estimate procurement requirements. These techniques, particularly the morbidity-based method, should also be used periodically to check on the rationality of past consumption, by comparing actual consumption with the estimated need to treat common diseases based on standard treatment protocols and epidemiological data.

When funds are not available to purchase all drugs in the quantities which were estimated to be needed, it is necessary to prioritize the procurement list to match available financial resources. Various techniques such as VEN (vital, essential and nonessential) Analysis, Therapeutic Category Analysis and ABC Analysis can be used to select priorities and reduce the quantities of less cost-effective drugs. A VEN priority list should be defined in advance of any decision related to reducing procurement. These tools are discussed in detail elsewhere.^{1,2}

Financing and Competition

7. 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.

Justification and explanation

Potential sources of funds for pharmaceutical procurement include government financing, user fees, health insurance, community co-financing and donor financing. These options vary in terms of their efficiency, equity and sustainability. The most important considerations for procurement are total funds available, adequate access to foreign exchange and the regularity with which funds are available. It is the responsibility of governments and senior managers to establish appropriate and reliable funding for public drug procurement as a high priority, and to implement mechanisms which provide adequate funding on time to support public sector procurement.

Efficient financial management systems are especially important if funds are limited and procurement priorities must be set. Being able to order drugs when needed and to pay for them on delivery has a very positive effect on reducing both prices and stock-outs and on increasing supplier confidence in the procurement system. Prompt, reliable payment can have as great an influence on bringing down drug prices as bulk discounts.

Practical aspects

Financial mechanisms such as decentralized drug purchasing accounts may help the procurement cycle to operate independently of the treasury cycle. Revolving drug funds can help achieve this separation by establishing their own bank accounts and their own working capital.

An aspect of financing which is sometimes overlooked is funding for the procurement process itself. Procurement services may be part of the warehouse and distribution operation or set up as a separate office. In either case, salaries and operational costs of the procurement office must be covered by the users. Options include:

¹ Management Sciences for Health in collaboration with the World Health Organization, Action Programme on Essential Drugs. *Managing drug supply*, 2nd ed. Edited by J.D. Quick, J. Rankin, R. Laing, R. O'Connor, H.V. Hogerzeil, M.N.G. Dukes and A. Garnett. Hartford, CT: Kumarian Press; 1997.

² World Health Organization. *Estimating drug requirements: a practical manual*. Geneva: WHO; 1988. WHO/DAP/88.2.

- support through the government budget;
- periodic payment from users at the beginning of the procurement cycle, based on the projected value of the total procurement, or at the end of the cycle, based on the actual value of total shipments;
- regular payment from suppliers, based on a percentage of the invoiced value of the shipment, although this method may be contrary to some countries' procurement integrity regulations;
- payment from users in the form of a flat annual fee, based on total expenses divided by the total number of areas and independent institutions served.

There is some risk in tying a procurement office's reimbursement to the value of purchases by user facilities, as this may create an incentive for the procurement office to increase, rather than decrease, prices and purchases. Therefore, if this sort of approach is used, checks and balances must be put in place, such as a requirement that all major procurement decisions be made by user representatives.

8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.

Justification and explanation

Larger procurement volume makes favourable prices and contract terms more likely, by increasing suppliers' interest in bidding and by providing them with an incentive to offer a competitive price.

Practical aspects

A higher volume for single items may be achieved through pooling of procurement volume from many facilities or from several States or countries, by restriction of the drug list or by elimination of duplication within therapeutic categories.

A large contract awarded to one supplier by no means implies that the entire volume must be shipped at once. Many procurement services specify, as part of contract terms, divided deliveries over the period of the contract or to multiple delivery points. Some supply systems use estimated quantity tenders, with orders placed throughout the contract period as needed. In decentralized procurement programmes, one way to sustain procurement volume is to negotiate prices centrally for a list of essential drugs and allow provinces, districts or health facilities to order the drugs as needed from the contract supplier. These strategies allow for optimal use of available storage and transport capacity, facilitate inventory management and ease cash flow constraints.

9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.

Justification and explanation

There are four main methods for purchasing drugs. Three of them are competitive: restricted tenders, open tenders and competitive negotiations. The

fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favourable pricing, the public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed. As discussed in Operational Principle 5, drugs which are available from multiple sources should be competitively purchased under their generic (INN) name.

Practical aspects

As long as drug quality and service reliability are assured, competition should be increased to the point at which drug prices are as low as possible. The “rule-of-five” for pharmaceutical pricing holds that generic prices generally reach their minimum when there are at least five generic alternatives on the market and that prices in tendering systems are at their lowest where there are at least five bids per item; adding more bids generally does not result in further lowering of prices.

In situations where most or all of the products in a therapeutic category are single-source or branded products, the number of different drugs in a therapeutic category can be reduced through cost-effectiveness analysis. Competition can be induced by therapeutic class tendering. For example, among the newer antibiotics there may be several which are therapeutically similar, at least for specific indications. Therapeutic class tendering means that offers are requested on two, three or more therapeutically similar but generically different products. The selection of the most cost-effective drugs within a therapeutic category should be done by the national essential drugs committee, not by the procurement office.

10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

Justification and explanation

Except in those systems where each health facility negotiates prices and purchases drugs individually, public pharmaceutical procurement systems are seen as *purchasing groups*. Normally, group purchasing achieves lower prices than would be available to the same group of health facilities if they purchased individually. These discounts are based on the fact that facilities which are part of the purchasing group will purchase contract items only from the selected contract supplier, as long as that supplier is able to perform. This is called sole-source commitment. If group members are free to make separate deals for contract items with other suppliers at will, the suppliers who participate in tenders will have little incentive to offer the best possible discounts to the purchasing group.

Practical aspects

Sole-source commitment must be monitored and enforced. Monitoring is particularly important in systems where prices are negotiated centrally and ordering is done by individual health facilities. Suppliers that do not win contracts in a competitive tender may offer more competitive prices on a short-term basis in an attempt to split the purchasing group. If group members do not

resist such price dumping, the prices at subsequent tenders will rise to previous unfavourable high levels.

Supplier Selection and Quality Assurance

11. 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.

Justification and explanation

Pre- and post-qualification procedures help to eliminate substandard suppliers, if properly managed. Pre-qualification is the procedure of evaluating supplier capacity and reputation before bids are solicited for specific products. This is the preferred procedure, especially for ongoing drug procurement systems. Although substantial time is required to establish an initial list of pre-qualified suppliers, once this has been done the lowest pre-qualified tenderer for each product is deemed to be qualified, which expedites adjudication and contract award.

Post-qualification evaluates the suppliers after bids have been received. If there are numerous offers from unknown suppliers there may be long delays in awarding contracts, as it will be necessary to validate suppliers' capacity to supply good-quality products.

Practical aspects

Most established procurement systems use some form of restricted tender with pre-qualification, soliciting bids only from suppliers that have been pre-qualified. Procurement systems using restricted tenders with pre-qualification should make continuous efforts to seek out potential new suppliers in order to maintain competitive pressure on established suppliers that had been pre-qualified previously. Drug regulatory authorities may provide relevant information regarding new suppliers.

The process for evaluating new suppliers can include formal registration, formal inspection, reference checks with past clients and international agencies, test purchases in small quantities and informal local information-gathering. Countries that do not have functional regulatory agencies and drug quality control laboratories must make vigorous efforts to check references of new suppliers and should buy only from those suppliers that are known to provide quality products. One important aspect of quality assurance is the concept of "traceability". The supplier must be able to trace the product to the finished product manufacturer, and the latter must be able to trace the ingredients to their producers, all in a transparent manner.

In addition to using pre- or post-qualification procedures, successful procurement offices ensure continued good supplier performance through a formal monitoring system which tracks lead time, compliance with contract terms, partial shipments, quality of drugs, remaining shelf-life, compliance with packaging and labelling instructions, etc. A cumulative file for each supplier should have copies of registration papers, references, special correspondence, complaints and other anecdotal supplier information. The information system should track chronologically the number and value of tender contracts awarded,

and the value of total purchases from the supplier by year and performance for each tender.

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

Justification and explanation

Four components make up an effective quality assurance system:

- selecting reliable suppliers of quality drugs;
- using existing mechanisms, such as the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce;
- establishing a programme of product defect reporting; and
- performing targeted quality control testing.

The selection of suppliers that are known to provide high-quality products as discussed in Operational Principle 11 is the primary key to ensuring drug product quality. When using new suppliers whose products are not familiar in the country, the procurement system must be particularly alert to product quality issues.

Practical aspects

Some products vary substantially in formulation and bio-availability from supplier to supplier. When this difference is therapeutically significant, purchasing offices should be cautious about making changes in supplier from year to year, and particularly about accepting unknown suppliers. Even when new products are completely equivalent in content and effect, changes in dosage form can be problematic, requiring patient and provider re-education. For drugs used in chronic diseases there should be a significant cost benefit before changes are made.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is a way of exchanging information on the supplier between the regulatory authorities of the exporting country and those of the importing country. It does not constitute an absolute assurance of product quality but does provide a mechanism for ascertaining that a drug product comes from a reputable source. The certificate is as independent and reliable as the regulatory authority that issues it.

All shipments from suppliers should be physically checked on receipt. A formal system should be established which encourages health workers to report potential problems with poor product quality, ideally using pre-printed, simple reporting forms. All reports should be carefully assessed to establish the need for laboratory testing and appropriate follow-up action must be taken, including product recall if warranted. The reporter should be informed about the results and the action taken, even if products are not defective, in order to encourage continued participation in the reporting programme. Product defect reports and results should be recorded as part of the supplier monitoring system.

If supplier selection is managed effectively it is not necessary to carry out quality control testing on every batch of every drug received. Many procurement

agencies limit routine testing to new suppliers and to sensitive products. However, all public drug supply systems should have access to quality control laboratories to test suspect drug products.

Unfortunately, not all governments have been able to sustain government-operated laboratories. In some countries a college of pharmacy or an independent laboratory may have the required testing facilities. Also, quality control laboratories in industrialized countries will provide drug analyses against payment. If analyses must be performed by foreign laboratories, foreign exchange problems may be reduced by requiring the suppliers of suspect products to pay the laboratory directly, with the arrangement clearly described in the purchase contract. Financing for quality control testing is a difficult problem in many countries, and governments and donors should collaborate to find viable solutions.

4. Practical implementation issues

The twelve operational principles for good pharmaceutical procurement practices aim to improve pharmaceutical procurement by ministries of health, supply agencies, nongovernmental organizations and other organizations involved in drug supply. When introducing and using these principles, the following should be kept in mind.

The operational principles should be used to develop standard operational procedures

These twelve principles constitute the minimum conditions for a reliable and cost-effective drug procurement system. They should be used as the basis for developing a set of more detailed standard operational procedures, taking into account the specific institutional circumstances and market conditions under which the system must operate.

Standard operational procedures must be actively implemented and monitored

The operational principles and the standard operational procedures must be supported by the national drug policy, regulations and legislation. International agencies and other external organizations which give technical or financial support to the national drug supply system should be asked to support and promote their implementation.

Good drug procurement is only possible within a well-managed drug supply system

Standard operational procedures can improve drug procurement only if they are implemented within a well-managed drug supply agency. This agency may be a classic government central medical store, an autonomous or semi-autonomous supply agency, an independent nongovernmental agency or some other form of supply agency. Critical factors for the performance of drug supply agencies include: qualified senior management; adequate personnel policies; a broad-based board for planning and following up the overall work; proper contract terms between the government and the contractor; and reliable financing and accounting systems.

The right purchasing and inventory control model should be chosen

Procurement can be done through a single annual tender, through a schedule of periodic tenders throughout the year, through a perpetual inventory system in which procurement is initiated as soon as stocks fall below a certain level, or through a combination of such systems. The choice depends on a variety of factors, including the type of drugs used (expensive drugs, short shelf-life, high or low consumption rate), the geographical situation, local production capacity, total consumption and others. The geography is important since more isolated areas tend to purchase less frequently. Local production capacity allows greater flexibility and more frequent deliveries. High-volume items may be purchased

more frequently throughout the year. The choice of purchasing and inventory model affects the direct cost of the drug, staff requirements (frequent purchases need more staff time) and inventory costs (less frequent procurement requires more warehouse space).

At a certain stage, an effective computerized system should be introduced to manage inventory control. This should probably be done in phases, with the system developed or backed up by a local company. A well-functioning manual inventory control system can be converted into a computerized one.

Legislation and regulations may need to be adapted

National legislation and regulations provide the necessary legal foundation for procurement procedures, contract enforcement, financial authority, staff accountability and other critical aspects of procurement. Existing legislation and regulations may be fully consistent with the twelve core principles. Often, however, legislative or regulatory changes will be needed.

A common problem is that the general rules for drug procurement by the public sector do not take account of the specialized procurement requirements of buying pharmaceuticals. The challenge may be not only to identify the changes which are needed, but also to convince the relevant legal and financial authorities that pharmaceutical procurement does in fact require a different approach. Some examples of specific requirements are: separation of the key procurement functions, the need for financial audit, mandatory use of generic names, the need for product registration (which should also apply to the public sector but is often ignored) and formal supplier qualification. Other related issues are pricing policies and ethical criteria for drug promotion.

Capacity needs to be built

Pharmaceutical procurement is a specialized professional activity which requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement positions be well trained and highly motivated. Training may be organized through national or international courses, through apprenticeships with international supply agencies or supply agencies in other countries, or by enlisting experienced short-term or long-term support from external technical advisers.

International and bilateral agencies should support the national procurement system

Development assistance through loans, grants and other financial mechanisms is intended to contribute to long-term health sector development. External technical assistance is intended to build local capacity and to develop sustainable systems, and should therefore be consistent with the policies of the country.

It is essential that development assistance reinforces good pharmaceutical procurement practices and aims at sustainability, rather than undermining or delaying the national development of such practices. From a development point of view, investing in teaching good procurement practices may be more

important than just procuring the drugs. Thus international, multilateral and bilateral agencies may need to review their own procedures, requirements and technical advice in the light of the present document. In the same vein, WHO's *Guidelines for drug donations* or their national adaptations should be respected by external agencies.

Procurement in decentralized systems needs special arrangements

Health system functions are increasingly being decentralized to provincial, district or local health services. In the pharmaceutical sector experiences with decentralization have been mixed. Proper drug selection, price reductions from bulk purchasing, quality assurance and accountability may all be threatened in decentralized procurement.

In principle, the twelve core principles for good procurement apply in decentralized systems as well, but they may need to be adapted in practice. For example, separation of key functions may be difficult with limited local staff. Bulk procurement may be possible only if districts and major health units pool their requirements and negotiate one contract. Under a system of direct delivery, drugs are then delivered to and paid for by the district or health unit. Finally, it may be difficult for local authorities to verify the quality of the drugs. Some decentralized systems rely on a list of qualified suppliers provided by national authorities.

To achieve good drug procurement practices in decentralized systems the role of the central government should be made clear. It would usually be its responsibility to guarantee the safety and efficacy of all drugs circulating in the market and in the health system, and to monitor the performance of the decentralized procurement system. In addition, the central government may tender for the prices of the drugs, for direct delivery systems.

Other operational issues

In addition to the above, there are other possibilities for improving procurement performance, which should be considered. These include:

- the use of international drug supply agencies, such as the Equipment for Charity Hospitals Overseas (ECHO) organization, the International Dispensary Association (IDA) and UNICEF. Their services can especially be beneficial when small quantities of a product need to be procured;
- access to information on prices and supply sources. Comparative price information is currently available to countries through the *International drug price indicator guide* (Management Sciences for Health and World Bank, 1999);
- primary and secondary systems for pre-registration and post-registration of suppliers;
- managing mixed systems of procured and donated drugs, especially in countries where donations form a large part of drug supplies. In such countries an active donor policy, clear indications of drug needs to potential donors and early announcement and registration of drug donations in the pipeline are extremely important in order to derive the maximum benefit

from the donations and prevent overlapping donation requests and drug orders.

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