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A STUDY TO ASSIST IN IMPROVING MANAGEMENT SKILL FOR PROCUREMENT OF PHARMACEUTICAL CHEMICALS, THEIR INTERMEDIATES AND DRUGS (PHARMACEUTICAL FORMULATIONS)*

Prepared by

the UNIDO Secretariat

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I. INTRODUCTION

The System of Consultations of UNIDO has held two meetings on the pharmaceutical industry in 1980 and 1983 respectively. These meetings served as a forum to discuss the major issues faced by the developing countries in the development of the pharmaceutical sector. One of the important issues discussed at length was the availability, pricing of pharmaceutical chemicals and their intermediates and transfer of technology for manufacture of pharmaceuticals in the developing countries.

The national goals for the pharmaceutical sector aim to improve and maintain the health care programmes. The provision of essential drugs of high efficiacy and safety at low costs is recognized as a vital component of global strategy to achieve health for all.

The developing countries face numerous constraints in making the drugs available to their population. These are economic, technical and managerial in nature and call for planned and concerted efforts at national and international levels to meet the challenge.

In response to recommendations made at the Second Consultation on the Pharmaceutical Industry on this issue, UNIDO has prepared two documents to assist developing countries towards better understanding of the industry and its development. The first document is a Directory of Sources of Supply for Pharmaceutical Chemicals and their Intermediates which aims to assist in providing wide sources of supply to achieve competitive buying. The second document is a study which deals with various aspects related to Procurement of Pharmaceuticals in finished forms as well as bulk pharmaceutical chemicals and intermediates.

Well designed procurement system to secure pharmaceuticals could certainly lead to development, strengthening of national capabilities and achievement of self-reliance. This study aims to analyze the subject of procurement and details various dimensions of the issue covering practices, marketing, investment, costs, transport, distribution, influence of modes of payment, prerequisites for better procurement and other steps involved in procurement, UNIPAC procurement system, sources of information on prices etc. and some conclusions aimed to reduce costs and improve the management skill for procurement.*

II. SUMMARY

Importance of drugs

Being essential component in health delivery programme, procurement of pharmaceuticals constitutes high degree of importance in developing countries due to following:

a) The relatively high ratio of expenditure on drugs in the country's total health care budget

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* Contribution of Mr. L. Thede of CHEMARCH, Sweden, in the preparation of the study is acknowledged.

b) Efficiently run procurement system to ensure satisfactory and sustained supply of drugs at different levels of health delivery system, in absence of which the effectiveness of the instituted facilities may be severely hampered.

WHO has evolved vital measures to improve usage, costs and quality of drugs in developing countries. A "Model List of Essential Drugs" of some 250 generic names has been prepared. Member countries are advised by World Health Organization to establish their own lists based on the WHO model list with due consideration to the local conditions. Using these lists the health care system will have better chances in meeting the needs of the population at lower costs.

WHO has also provided guidelines to ensure the quality of imported and locally manufactured drugs in form of a "Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce".

UNIDO has taken concrete steps to encourage and establish domestic production of pharmaceuticals in developing countries.

Production of Pharmaceutical Products

The decision to enter into drug manufacture should be based on several factors. These include not only the availability of sufficient finance and management capabilities but also access to relevant technology and skilled personnel. Only well-run factories, given adequate resources, can result in savings on cost of drugs. Besides industrialization and manpower developments, domestic production also provides benefits like self-reliance, continuity of supplies, etc.

Furthermore, local manufacture at economic cost may possibly induce non-local manufacturers to reduce the prices.

Preference of generic system resulting in numerical reduction of formulation offer economy in production through larger quantity purchases, longer production runs and better inventory controls.

Prices of Intermediates, Pharmaceutical Chemicals and Drugs

Cost evaluation of pharmaceutical chemicals and drugs is an involved issue and evaluations require long experience and regular liaison with the market.

The costs of imported pharmaceuticals depend on many factors, such as:

- Mode of purchase
- Monopolistic tendencies of suppliers
- Mode of payment
- Trade terms
- Size of orders and packing units
- Suppliers estimation of customer's "reliability"
- Mode of transport

This document also discusses the price fluctuations due to trade and payment terms. Existing conditions and procedures used for procurement in public sector of many developing countries are frequently less effective and contribute to unfavourable prices and other supply problems.

Comprehensive information on prices of pharmaceutical products is not generally available. Prices related to long term contracts or long established business relations are usually not published and can be only acquired from the concerned parties provided they agree to do so. Main published sources of price information for pharmaceuticals include:

a) Pharmaceutical Preparations

- Indicative Price list on Essential Drugs/Generics, published by UNICEF, indicating prices on CIF Copenhagen and covers UNIPAC procured drugs.

- National price lists published by pharmaceutical trade organizations/governments etc, e.g. Red Book, USA.

- "Price Lists" issued by some trading companies at regular intervals.

b) Pharmaceutical Chemicals

- Pharmaceutical Trading Companies issue "Price Lists" for pharmaceutical chemicals on monthly to yearly basis.

- Among more regular publications giving information on prices is the one published by the weekly Scrip World Pharmaceutical News and Chemical Marketing Reporter.

- National statistic bulletins on import and export in some countries e.g. India reveal information on prices.

- National Chambers of Commerce also issue information on prices routinely which cover a large number of pharmaceutical chemicals and intermediates e.g. Chamber of Commerce and Industry, Milan, Italy.

c) Pharmaceutical Intermediates

- Information on prices of intermediates can be found in papers like Chemical Marketing Reporter, Chemical News and other specialized journals.

Procurement

Well-functioning procurement is characterized by a scientifically organized mode of operation. The individual steps forming a "procurement cycle" are appended below:

- Collection of consumption levels and adjustment against inventories
- Revision of types and costs of selected drugs/chemicals
- Determination of order quantities
- Reconciliation of needs and available funds

- Provision of finance deficiencies
- Choice of procurement method
- Location and selection of suppliers
- Specification of contract terms
- Monitoring of orders
- Acceptance of arrived consignments and quality control
- Make payment

The procurement does not necessitate complicated procedures, but a disciplined management and established time schedules are essential components for an efficient system. Major problems are usually associated with bureaucratic and financial environment sustained by the procurement agency. Dwindling resources of foreign exchange, steps undertaken by the central banks and more stringent procedures result in additional obstacles to procurement. The influence of this factor and other constraints outside the control of the procurement agency have also been discussed in this document.

Some of the conclusions and recommendations are particularly directed to countries with shortage of adequate budgetary provisions in general and restrictions in the availability of foreign exchange in particular.

Pharmaceutical production and its role to fulfill the national economic and health-related goals, has been given due consideration. Efficiency in procurement of production inputs directly contributes to the success of domestic industry in competing with imported products.

It should be emphasized that improvements in procurement system must be well coordinated between agencies within the drug supply system.

Based on thorough and critical evaluation of existing procurement system, well designed programme should be established. Identification of major constraints and problem areas within the existing drug supply system will form a useful base on which the improvement of skills can be built. In some cases external support might be valuable, in others the problems are identified and merely necessitate local changes. The conclusions and recommendations referred at the end of this document are to be considered merely as foundations upon which a detailed system can be evolved rather than considering these as directly applicable measures.

III. PRODUCTION AND MARKETING OF PHARMACEUTICAL CHEMICALS AND DRUGS

Production - General

There are three distinct divisions in production of pharmaceuticals (active principles or active ingredienst), namely chemical synthesis, biotechnological methods such as fermentation and the extraction and isolation of naturally occurring compounds from plants and animal sources.

The industry differs radically from other sectors of chemical processing industry in several ways (such as batch processing) as it constitutes a greater variety of processes and more complicated chemical steps than most other sectors while biotechnological methods are widely employed.

The policies of Government for encouraging local production can induce greater growth of this sector. For details reference is made to UNIDO study on industrial drug policies. 1/ Other relevant factors such as market, size, technology, professional and technical personnel, access to raw/packaging material etc. are of significance to promote the establishment and growth of the industry.

Production of pharmaceuticals comprise two distinct levels. First one constitutes bulk production of active ingredients (pharmaceutical chemicals) while the second involves conversion of one or more active ingredients into dosage form suitable for administration.

Manufacture by chemical synthesis from petrochemicals

Petroleum is mainly used as an energy source and the production of petrochemicals takes a minor part of its consumption. In 1980 of the 8-10% petroleum was used in chemical production, some 7-9% of this was consumed for the production of the major petro-based products, viz.: plastics, synthetic fibres and synthetic rubber. The remaining 1-2% of the total petroleum consumption was used for the production of detergents, pesticides and pharmaceuticals.

Manufacture through fermentation

Fermentation process is chiefly used for production of antibiotics, etc., e.g. Penicillin V and G, Cephalosporin C, Streptomycin. The intermediates such as 6 Amino Penicillanic Acid (6APA), 7-Amino-deacetoxycephalosporanic acid (7ADCA) and 7-Amino-cephalosporanic acid (7ACA), are produced by transforming basic Penicillins and Cephalosporanics and these are used for production of pharmaceutical chemicals such as Ampicillin etc. The open market for these intermediates is roughly 1/3 of total production.

The demand for good manufacturing practices (GMP) for pharmaceutical chemicals is now on the increase.

Production of dosage forms

Apart from pharmaceutical chemicals, a variety of ancillary materials are also required in the production of pharmaceutical formulations.

The pharmaceutical chemicals are generally not produced by every formulation manufacturing firm, and are bought from the original producers of the same.

WHO has established Good Manufacturing Practices (GMP) for pharmaceutical products with the help of experience gained in the developed countries. The requirements include criteria for building design, equipment, material qualities, manufacturing techniques, personnel, packaging, quality control, etc.

Large pharmaceutical companies are main contributors towards development of new drugs aiming at discovery of new remedies to expand their market.

1/ Factors having a bearing on Industrial Drug Policy - UNIDO document.

The R&D of the world pharmaceutical sector is concentrated in only few countries. It is estimated 1/ that 90% R&D expenditure is centered in France, Federal Republic of Germany, Japan, Switzerland, U.K. and USA. The same countries hold 46 out of the 50 largest pharmaceutical firms in the world. 2/

The development of new drugs has lately slowed down partly due to the increased requirement of drug registration from the approving authorities which results in extra costs of R&D and considerable time lag between the discovery and market availability of a new drug ranging usually up to ten years and more.

Although the cost of brand name products is considerable and despite ongoing debates in Western Europe, the prescribing habits of medical profession remain in most countries overwhelmingly leaning towards brand products even when cheaper alternatives and generics are available. 3/ 4/ There are growing signs of a more clear split of the drug market into generic and brand areas. The brand market is predominated by large companies, while the generics are produced by companies with relatively limited R&D and marketing. However, signs of an increase in generic subsidiaries of the large producers of brands, in sympathy with increased generic market 5/, has been observed in recent years.

Generics are taking substantial shares of the market in some countries. For instance in Canada 6/, the generic prescriptions are now some 40% of the total. Public schemes where generic prescriptions are obligatory, have been launched in the UK 7/ and reported to offer substantial savings.

IV. INVESTMENTS, CAPACITIES AND COSTS OF PHARMACEUTICAL PRODUCTION

Petrochemicals and Intermediates

Investments involved in the production of most basic chemicals are very large. The undertakings for production of intermediates also necessitate high capital costs.

Pharmaceutical Chemicals and Formulations

Production costs and prices of late intermediates, pharmaceutical chemicals and formulations can not be forecasted accurately by a universally acceptable general formula because of many variables influencing the market:

1/ OECD: "Gaps in Technology: Pharmaceuticals", Paris, 1980.
2/ Scrip World Pharmaceutical News Nr. 653 and 54.
3/ Walker H.D.: "Market power and price levels in the ethical drug industry", Indiana University Press, 1971.
4/ Lilja J.: "Price differences between different brands of multisource drugs in Sweden, Journal of Social and Administrative Pharmacy, Vol.3, No.1, 1985.
5/ New York Times, August 11, 1985.
6/ James B.B.: "The marketing of generic drugs", London 1981, p.81-82.
7/ Scrip World Pharmaceutical News of 2/12/1985.

- Late intermediates have often more extensive uses outside the pharmaceutical area and consequently prices can be influenced by demand pattern from other markets.
- In many cases there are different synthesis methods for the production of same intermediate so the costs of raw materials and utilities used in different methods may vary considerably.
- Monopoly by manufacturers of some intermediates and pharmaceutical chemicals influence their prices.
- Considerable difference in indirect cost such as R&D, marketing etc. between the generic and brand name drugs, is a significant factor to influence the prices.

In market economies the raw materials usually amount to about 20-50 % of the sales value of pharmaceutical formulations while total production cost is estimated at 35-65 %. The lower figures are found in companies with extensive R&D and marketing and vice versa. A fair portion is assigned to R&D activities. However, no single formula of cost can be evolved, these indications should be treated with caution.

Prices must bear a reasonable relationship to costs. Costs depend on factors including cost of intermediates, pharmaceutical chemicals, volume, transport, distance, taxes, exchange rates and local conditions.

V. COSTS OF TRANSPORT AND PACKAGING

Low cost transportations have been developed in industrialized areas. Sea tankers, railway wagons with bulk-loads of specific chemicals, reduce the transportation cost of larger shipment.

The transport systems for chemicals has been governed by ever increasing rules and regulations for protection against accidents and environmental hazards. The IMCO (International Maritime Consultative Organization) for sea transport is widely acknowledged code.

The conditions for packaging, allowed mixtures in collective loading, maximum allowed amount per consignment etc. considerably enhance the transport costs of "dangerous" chemicals.

Raw Materials in bulk

The freight rates are directly dependent on the demand-supply situation and change frequently. For most bulk chemicals the freight is based on the volume occupied.

The freight rates are governed by variables like specific gravity/storage factor, needed transport temperature and IMCO-class. The transport-rates for dangerous chemicals are usually three times the normal rate.

Raw Materials and Intermediates in smaller quantities

Chemicals packed in drums or bags to be carried over long distance, might need extra packaging in form of containers or wooden boxes. Container costs around $ 40-60 per m^3, which is roughly double the cost of wooden sea-worthy packages. Depending on volume/weight of the

contents, the extra costs incurred in transports to distant locations will be around $ 50 (wooden boxes) to 100 (container) per ton with no return freight. Dangerous chemicals are debited some 20% extra.

The cost of transportation of rather bulky raw materials required to produce pharmaceutical chemicals is high enough to be taken note of.

Dosage forms

A sometimes overlooked cost-component of pharmaceutical dosage forms is transport. Packed pharmaceuticals are generally bulky. The choice of unit packs, packaging materials and forms of packs will have influence on the drug costs.

VI. DISTRIBUTION SYSTEMS AND CONSUMER PRICES FOR DRUGS

The costs of distribution and handling up to the consumer within "market" and "centrally planned" economies vary widely, also between country to country. The consumer prices are generally more stable in centralized economies. High levels of export/import exchanges of drugs characterize the market economies in comparison with centrally planned economies, usually 15-25% of their needs depend upon imports.

Different forms of price control are applied in market economies within the wholesale-retail chain. The margins in the wholesale link are around 6-10%. The pharmacies are allowed varied margins, as the national system of the pharmacy trade varies considerably. In most market economies the indicative consumer prices are published in "red book" type of publications, some of which are referred in Appendix III.

VII. MODES OF PAYMENTS AND THEIR INFLUENCE

The prices of pharmaceutical intermediates, chemicals and formulations are also influenced by the modes of payment. Prices offered in developed countries are generally based on "cash" or draft payment terms of 60-180 days, in the latter (deferred payment) interest is included. The interest charge generally is 2-4% higher than the national discount rate.

VIII. SOME BASIC PREREQUSITES FOR BETTER PROCUREMENT OF PHARMACEUTICALS

National Drug Policy - Rational Selection of Drugs

A procurement system of intermediates, pharmaceutical chemicals and drugs will be facilitated by clear national drug policies, including a national formulary or "list of essential drugs" with periodic updating, wherein the number of drugs and dosage forms are kept at a minimum and it is predominantly oriented towards non-proprietary or generic drugs coupled with objective policies to promote domestic manufacture (Ref. Appendix I).

Limitation in the numbers of drugs will generate larger purchases of fewer items at economic prices, facilitate quality control, warehousing, more convenient shipment and distribution involvement. Local production of quality pharmaceuticals will also benefit equally.

Use of generic names helps to reduced complications due to multitude of branded inventories of the same drug and facilitates in communication with the pharmaceutical sector internationally. The INN (International Nonproprietary Name) nomenclature has received general acceptance and is employed in the WHO "List of Essential Drugs" 1/.

The WHO list of essential drugs has generally been recognized as a useful and rational basis of drug procurement at national level and for establishment of drug requirements. Recommended measures include the steps listed in Annex I.

The practical availability of fewer drugs in the beginning may be met with resistance by the prescribers. Launching of an essential drug list should be accompanied by a more objective and full information on the drugs to remove such resistance.

Quality Assurance System

The purpose of quality assurance is to make certain that each drug reaching a patient is safe, effective and acceptable. Quality is warranted at all steps: manufacturing plant environments, active and inactive ingredients, equipment, manufacturing process, packaging, warehousing, storage and shipping conditions. The establishment and maintenance of quality control laboratories is an expensive and difficult task. WHO has recognized the problems in relation to essential drug programmes and introduced "Certification Scheme on the quality of pharmaceutical products moving in international commerce" 2/ to safeguard the quality of imports to developing countries with no quality control facilities. There is a proposal by the international industry to WHO that this certification scheme may be broadened to offer importing countries, in addition, full information regarding drugs indications, dosages, precautions, contra indications and side effects as required by a developed country's drug authority. Developing countries without comprehensive facilities can utilize the services of foreign quality control laboratories. Appendix IV gives a list of laboratories, which carry out analysis at request.

Utilization of domestic production facilities is frequently hampered due to fear of sub-standard quality of locally manufactured drugs as compared to imported ones. In the absence of a reliable quality control laboratory at a national level, public health related schemes might avoid domestic suppliers.

1/ "The selection and protection of international nonproprietary names for pharmaceutical substances", A. Wehrli, WHO Chronicle, Vol. 35, No.6

2/ "Certification scheme on the quality of pharmaceutical products moving in international commerce / with up-dated list of participating countries", WHO, September 1985.

Analysis are performed in conformity with the standards laid in the national pharmacopoeias. The work on future editions of the international pharmacopoeias has given priority to essential drugs in the WHO list, based on classical methods. WHO has also issued a standard plan for a small laboratory in this connection. 1/

Budget and other provisions

The working of many procurement agencies in developing countries is adversely affected due to the scarcity of foreign exchange and adequate funds for domestic purchases. Although this situation should not hinder the efficiency of procurement, the rigidity and slackness in flow of funds often result in loss of objectivity.

Inadequate resources of foreign exchange force governments to introduce stringent controls. Such measures are hard to sustain due to processing of thousands of applications. The allocation authorities face difficulties in judging the genuity of individual requests. Since the allocations are made mostly in proportion to the available funds, it is likely tha. some realistic and well founded application may not be catered for justifiably.

The procurement planning is thus based on uncertainty in the quantum of forthcoming funds, and the basic figures do often reflect a need for higher allocation. An additional difficulty arising from scarcity of foreign exchange is uncertainty as to what extent the needs for interlinked industries (domestic drug units, packaging material factories) will be satisfied to permit forecasts of local production.

Foreign exchange is generally allocated annually in developing countries. The subsequent procurement activities therefore intensify within a specific duration causing excessive build up of work pressure.

The modes of payment used by procurement agencies in many developing countries include guarantees by the domestic bank. Slow or erratic payments to suppliers or foreign banks will result in difficulties to reach favourable agreements with more reliable suppliers. At time the foreign banks will even refuse to accept the irrevocable and confirmed letter of credits, resorting to expensive alternatives. These matters are discussed in detail in chapter VII.

At the national level, the foreign exchange spending are of more concern than local spending. Rational usage of foreign exchange in the procurement of drugs should therefore be geared towards encouraging local pharmaceutical industries which require less foreign exchange to substitute the imports. The budget and allocation procedures should therefore be so harmonized that the total pharmaceutical sector, including domestic production, is treated in an integrated manner allocating due share to local pharmaceutical and allied industries.

1/ WHO Technical Report Series, No. 704, 1984.

Procurement in relation to national drug supply system

National drug supply systems comprise various types of arrangements, which differ as regards government influence and division of procurement responsibilities. Some main models are:

A. Centralized drug procurement. All procurement are vested with one state agency, but with separate distribution systems for the public and the private sector.

B. Two separate systems. The public sector confined to one agency, while a parallel system operates for the private sector. The private sector might operate within a restricted drug list for its procurement.

C. Two separate systems. The public sector also procures through the private sector under certain circumstances.

D. Private sector supplying the whole of a nation.

Every system has its own advantages and disadvantages and is governed by the priorities given by governments to such factors as foreign exchange expenditure, satisfaction of demand and just distribution of drugs under prevailing circumstances.

Centralized Drug Supply System

Legal provisions are required in cases where change of the drug supply to a centralized system is under consideration. UNCTAD has studied such problems and has compiled a legal frame work for pharmaceuticals.

As in any system, the centralized procurement should be based on adequate basic data of the areas, population and existing health facilities to be covered. Drug requirements at each level of the health care system should be assessed carefully and as accurately as possible.

The kind of distribution system must be agreed. Evaluation of various distribution systems shall include factors like fair allocation of drugs and making use of existing distribution possibilities. In situations where the demand of drugs is likely to significantly exceed the supplies, there is a risk that the drugs may be exhausted at hospital levels. Direct deliveries or prepacked "kits" to the rural health facilities may be a better option to achieve an equitable distribution.

The most important factor for a central procurement system to function efficiently is availability of adequate facilities. Expendient procedures for clearance, storage, buffer areas and high security, must be installed before a centralized system is introduced. Poor facilities, unwanted or obsolete stocks of drugs, absence of handling capabilities and untrained, undisciplined and unmotivated personnel are not likely to offer the desired results.

Advantages of Centralized Pooled Purchases

Countries that have adopted a system of centralized and pooled purchases in the place of fragmented procurement systems which exist in many developing countries, have been able to effect economics, diversify sources of supply and regulate distribution of the bulk drugs and raw materials to an appreciable degree at advantageous prices. The centralized purchase of drugs limited to a national list of drugs, in addition to rationalizing purchasing procedures, would also help to rationalize storage, distribution, prescription, quality control and dissemination of objective drug information to health workers. Experience of some of the developing countries has shown that centralized purchase and distribution has several merits e.g. India, Sri Lanka, Costa Rica etc. Some of the developed countries also have benefited. The experience of the American Food and Drug Administration has shown that bulk buying under generic name have achieved considerable savings in drugs purchased and dispensed under the Medicare and Medicaid programmes.1/

Agency for Procurement

A centralized procurement agency should preferably be a separate public corporation, not necessarily a Government department. It should be run on commercial lines, managed by staff trained in business and management practices relating to trade, storage and inventory control. Initially, such an agency may act merely as a clearing house, but as the work develops, it may have to establish its own warehousing facilities. The agency may be assisted by an independent committee to advise on the quality aspects of the products. The prerequisites for centralized purchasing are a restricted list of drugs and the exclusive use of generic names. It will then be necessary to work out estimates of the quantities required annually or bi-annually. An appreciable savings could be made by centralized purchases.1/ 2/

A centralized purchasing system may be established in every developing country, whatever its level of development. In nearly all developing countries health care is delivered by both the public and private sectors. Centralized procurement may, therefore, initially have to be for public sector requirement only. After a period of time, when the system functions well, it could extend its operations to cover private sector requirements as well. To maximize its bargaining power, the purchasing agency should build up a market intelligence unit.

Regional Pooling

The total drug requirements of a number of small developing countries are too small for them to take advantage of economies of scale merely by centralizing the procurement system. A way of resolving the problem would be for such countries in the same region to pool their drug purchases through a regional centre.

The prerequisites of a regional pooled purchase programme are:

1/ Case studies in the transfer of technology, pharmaceutical policies in Sri Linka (TD/B/C.6/21) and technology policies in the pharmaceutical sector in Costa Rica (UNCTAD/TT/37)

2/ Guidelines on technology issue in the pharmaceutical sector in developing countries (UNCTAD/TT/49)

b. the drawing-up, on the basis of trade information (the volume and price of individual transactions), of a restricted list of products to be subject of pooled purchases;

c. the making of pooled purchases on the basis of international invitations to tender and with, so far as possible, the according of priority to suppliers;

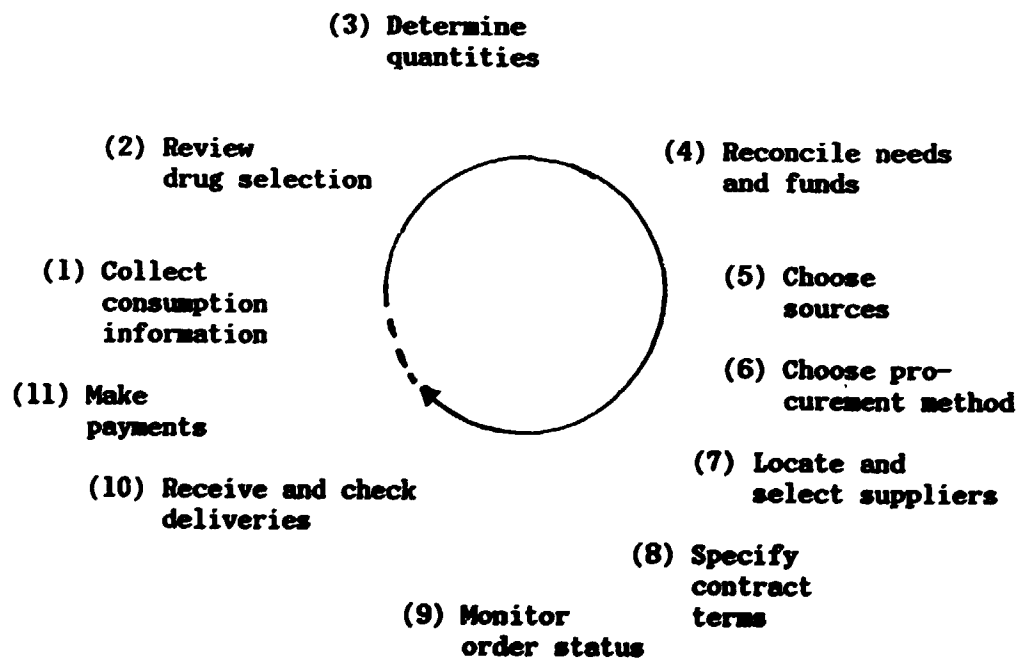
d. the gradual assumption by the institutions already in existence or to be created of responsibility for quality control in relation to the entire range of drugs subject to pooled purchasing;

e. study and determination by each group of countries when setting up its pooled purchasing programme of the status and powers to be conferred on the regional procurement agency and the means of financing both the necessary investments (e.g. warehouse, stocks) and current operations (e.g. the collection of credits/debits).

IX. PROCUREMENT PROCESS AND ITS COMPONENTS

"The Procurement Cycle"

Good and efficient procurement comprises standardization of procedures, which should be carried out scrupulously. The necessary steps of procurement cycle are described below 1/:



1/ "Managing Drug Supply", Management Sciences for Health, Boston, Massachusetts, USA. Second Printing 1982

Some components of the "procurement cycle" have already been covered from a macro-national point of view (drug selection and public funding of purchase). The management of the procurement agency is dealt in detail hereunder:

In principle the description covers the procurement of drugs, but it can be applied to pharmaceutical chemicals as well. Where desirable, the pharmaceutical and other auxillary chemicals have been dealt separately. The description is more related to procurement under the scarce foreign exchange availability and administrative routines of a more centralized public procurement.

(1) Collection of consumption information - inventory control

Inventory control systems are introduced and maintained to optimize the available funds, balancing the demands and the resources. A good inventory control system helps to prevent phenomena such as stock out of inexpensive and vital drugs at the same time as more expensive or expired drugs are piling up. The basic information for the processing of such control systems require an even flow of consumption data forwarded from lower to higher levels.

An inventory control system for drugs is a must for getting maximum benefits at lowest cost. There are several different systems, managed by manual stock cards or with cheaper computer systems, but the underlying

principles and working methods are the same. The stock or inventory of each drug is kept at a level which, within available budget limits, to the largest extent possible prevents stock-outs, maximizes purchasing power of available funds, gives optimal base for transportation efficiency and adequate information on changes in consumption pattern. Well run inventory systems will further provide a strong security against pilferages and frauds. Appendix V gives a short outline of how inventory control systems functions.

Once the system is functioning, it will show over and under-stocking, give signals for ordering and become a major tool to increase the efficiency of procurement. A regular up-dating of all cards on which the information is kept, is imperative. Without disciplined officers, following some basic working procedures, very little will be achieved.

In the context of inventory control, a major problem area is obsolete goods in combination with limited storage area, worsened by slow write-off procedures for public property. Goods destroyed in handling or by climate, as well as expired materials, have a tendency to be hidden and recorded as valid assets. The obsolete materials might in a few years increase to unmanageable size in that the stipulated government procedures can not be carried through any more.

The likely results from high levels of obsolescence are slackening discipline, chaotic storage conditions and dissolution of responsibilities. The best way to resolve such problems is to introduce more regular write-off occassions, more easy implemented write-off procedures and the appointment of officials with delegated authority from the often high-ranked and busy officers included at ministry level. Higher limits for write-off by responsible officers of the procurement agency might also be introduced.

(2) Review drug selection

A rationalized list of drugs for procurement will facilitate the work and in addition give the benefits stated elsewhere in the document. The compilation of such a list, based on the WHO List of Essential Drugs and information on the consumption patterns at different levels of the health care system, is a big task, which however will pay off quickly and for a long time.

Reviews of the list and primarily selected drugs shall be made at regular intervals. Based on field experiences and latest drug information, revisions shall be made to reduce further unnecessary or costly drugs and dosage form. In accordance with individual drug consumptions at different levels of the health care system, such evaluations are likely to show that some 20 % of the actual volume of drugs procured or consumed will correspond to some 80 % of the value. This gives a base on which a more efficient procurement can be made.

The so called ABC-Value-Analysis devides drugs by their annual usage (unit cost times annual consumption) into Class A items (the 10 to 20 % of the items which account for 70 to 80 % of the funds spent), Class B items (with intermediate usage rates), and Class C items (the vast majority of items which account for less than 25 % of the funds spent). ABC analysis can be used to:

- Reduce inventory levels and costs by arranging for more frequent purchase or delivery of smaller quantities of Class A items.

- Seek major cost reductions by concentrating on finding lower prices on Class A items, where savings will be more noticeable.

- Assign import and Inventory Control staff, to assure that large orders of Class A items are expeditiously handled.

The VEN System is a system of categorizing drugs by their health impact. It can be useful in setting purchasing priorities, in determining safety stock levels, and in directing staff activities. Categories are:

V - VITAL drugs which are potentially life-saving, which have significant withdrawal side-effects such that regular supply is mandatory, or which are included in basic drug lists (e.g., vaccines);

E - ESSENTIAL drugs which are effective against less severe, but nevertheless significant forms of illness;

N - NON-ESSENTIAL or normal usage drugs for minor or self-limited illnesses, drugs which are of questionable efficacy, and drugs which have a high cost for a marginal therapeutic advantage.

After inclusion of shelf-life data and other non-financial considerations, the procurement can be economized by applying different methods for the various groups. The A-type might preferably be openly tendered and "subordered" more often and also given the bulk of the administrative work. B-types can be ordered after selected tender say twice a year and C-types procured directly once a year.

An ABC-analysis or the VEN-method referred in the following paragraphs for classification of drugs after another type of priority ranking, will form a useful basis on which the procurement can be made. There is, for instance, little use in spending work-demanding open tender procedures for C/N-items, but this is still often the case.

Further rationalizations of transports might equally be obtained by ordering drugs in unit-size packs and boxes, which correspond to the basic consumption patterns at different levels of health facilities, e.g. the present Essential Drug programmes in East Africa are based on the forwarding of "Standard Kits" to the rural areas, where standard basic amounts of the most used drugs are forwarded on monthly basis to all facilities.

(3) Determine quantities

In most developing countries, statistical information on health related factors are often scattered and unreliable. Depending on the information available, the requirements of individual drugs can be calculated with different methods viz.: Population-, service- and consumption-based estimates. Appendix.II gives summarized descriptions of these methods.

(4) Reconcile needs and funds

The financial means available to most health care systems in developing countries are at present diminishing. Why are any of the above methods likely to give a total value of drugs for which adequate funds are missing? Necessary cuts in purchase must be made and additional funding possiblities sought.

A rational way to make cuts in drug purchase must be found so that simply equal portions are not taken away from all drugs. This is likely to strongly harm the health demands. The first measure to cut expenditures is to introduce an Essential Drug List, if this has not already been made. Thereafter, the so called VEN-system, by which the drugs are given priorities in form of Vital, Essential and Non-essential value, can be applied to better optimize the balance between health demands and available funds. The most vital drugs are bought first of all and a systematic procurement schedule is used for additional purchases[1/].

The procurement skills will not benefit from a procurement planning giving volumes, which cannot be fulfilled. The use of a VEN-system at different levels of expected and realistic available funds can help.

The procurement planning in a deteriorating economy might thus comprise two levels of expenditure, one at safe level, say 80 % of the last two year's level and one at the same level as previous year. The allocation authorities might as well present a lower but dependable and realistic amount for the national drug procurement on which the planning can be firmly based.

(5) Choose sources

Procurement sources use to be stated as purchase, donation and manufacture in own units. Sources of procurement under the conditions of scarcity of foreign exchange might be listed as:

1/ "Managing Drug Supply", Management Sciences for Health, Boston, Massachusetts, USA. Second Printing 1982.

- Purchase of finished drugs with foreign exchange
- Purchase of locally manufactured drugs with local currencies
- Subcontracting local industries with supply of raw materials
- Donations requiring local counter value
- Donations free of charge

The total national need for drugs in developing countries might therefore preferably be planned on basis of both foreign exchange and local currency.

Purchase of locally manufactured drugs in local currency

Some existing formulation units in developing countries are running at low capacities or standing idle. Even new investments in formulation capacities are ailing, due to reasons such as:

- There is no coordination of the domestic pharmaceutical production potential and imports of drugs from abroad in the national allocation procedure for foreign exchange. The potential import substitution often used in feasibility studies on which implementation was once decided, is not a major variable for use in allocation procedures in most cases.

- This may partly be due to high prices for locally produced drugs, which causes problems for the health expenditure budget. High customs duties levied on pharmaceutical raw materials, but not on finished drugs, is an exceptional way in which imports are favoured. The main problem behind high local prices use however to be the dual lack of foreign exchange and overvalued local currencies. Lack of foreign exchange brings small allocations for purchase of raw materials which gives a low capacity utilization. The fixed costs in the industry must then be distributed on a smaller production, giving high prices. These high prices in local currency can not be contained within the health budget and imports will look cheaper, especially in the case of highly overvalued local currencies.

The imports of finished drugs are generally dealt under the heading of Health Services by the Ministry of Health in the annual budgeting, while production of drugs is dealt mainly under the budget of Ministry of Industries. An integration of raw materials for domestic production and imported drugs plus donations in the planning and allocation processes at higher levels should therefore be made.

Put into practise, the production units might be "subcontracted", whereby payment from the procurement agency is made in the form of raw materials and auxilliaries in an amount, which is equivalent to the import price of the drugs. The "surplus" raw materials can, after transformation into finished drugs, be sold outside the public sector at prices, which give a chance to cover local production costs.

It is to be noted that procurement of domestic products must take into consideration the lead-time required for production after arrival of raw materials. Domestic purchase should therefore be planned for later deliveries, unless stock at hand is available at the factory.

Donations

Donations should conform with the national needs and be adopted to the national formulary or Essential Drug List. Most donations are distributed through voluntary organizations and they constitute sometimes a substantial part of the total volume of drugs. Vaccine programmes in some countries are such an example. In quite a few cases, the donations might cause additional problems and be a burden to the health care system.

Donations passing outside the national procurement system should anyhow be reported and used in the national planning. A reporting system in form of collected import licenses or packing lists might suffice, provided that these contain adequate information on type and volume of each drug.

(6) Choose procurement method

The main methods for procurement used by developing countries are:

- Open tender also called public/unrestricted bid
- Restricted/selective tender or closed bid
- Negotiated procurement
- Direct procurement

Open tenders are invitations to quote from any interested supplier on terms and conditions stipulated by announcements in the local/international press. The method necessitates high formality and strict time-tables and is work-demanding. Therefore, open tendering shall preferably be used for the A-items mentioned earlier in the study. There are various national government regulations of procedures, which must be followed. The final decision is commonly made by a Central Tender Board, which selects and compiles a list of "awarded" suppliers. Only dependable suppliers shall be selected, which prerequisites a rather deep knowledge and that records on the performances by appointed suppliers are kept. As quotations given on open tender usually comprise bid values, accusations of fraud are likely and strict adherance to stipulated rules must therefore be kept.

Closed tenders comprise invitations to quote from a limited number of suppliers. Quality concern might be a reason for use of this type of tender, also where A-type of drugs are procured. Access to a supplier registration system or an own list of approved suppliers is a prerequisite. See further details under selection of suppliers.

Negotiated procurement is a way of procurement, by which a selected number of potential suppliers are contacted and direct negotiations are carried through until an agreement is reached. The method can be very useful when bargaining power can be executed by the buyer and the supplier is interested in longer term relations or contracts. In many developing countries this method is restricted in use, due to government regulations.

Direct procurement is chosen where only one supplier exists or when orders are small in value. In case of branded drugs with one supplier, there is no other option than to pay the offered price.

In the choice of procurement methods, the lead-times to cater for delays resulting from official procedures must be included. Government regulations might stipulate open tender procedures for a majority of purchased drugs, but scarcity of foreign exchange might at the same time make the tender conditions impossible to fulfill. This is a major problem area in many countries, as tender procedures are followed, but procurement is made more or less direct at much higher prices. An invitation to tender should not be made until there is a definite and firm commitment of funds from the central bank. In other cases, government regulations might preferably be changed to better reflect the real conditions prevailing.

Trade terms

The main bases on which procurement can be made by developing countries comprise generally:

- Ex works (at factory), used for local suppliers
- F.O.B. basis (free on board)
- C & F basis (cost and freight included in price)
- C.I.F. basis (cost, insurance and freight included in price)

The trade terms are defined by the IMCO-terms of 1953 and later amendments like IMCO-terms 1980. The main responsibilities as regards freight and insurance are divided between the buyer and seller in different ways by the above referred trade terms. The price and leadtime will also be influenced.

CIF-terms are commonly used in international trade, when the buyer/supplier is unknown. The seller includes freight and insurance in his price and the buyer takes over the responsibility at the point of arrival. The CIF-price thus includes denotation of the point of arrival, like "CIF Maputo". All administrative work for freight and potential claims for damages up to the arriving point is handled by the supplier.

C&F-terms are equivalent to the CIF ones, but the buyer insures the goods himself. Where national insurance possibilities exist, many developing countries force the use of C&F by central bank stipulations. In the case of national scarcity of foreign exchange, insurance recoveries are likely to be paid out only in local currency, which cannot be used for replenishment.

FOB-terms give the supplier the responsibility to deliver the goods on board the freighter. Freight and insurance is covered by the buyer. In many cases the supplier is requested to quote the price, specifying the individual costs of CIF-price in terms of FOB-price, freight costs and insurance, so that the buyer can calculate if an arrangement of cheaper freight and insurance rates is possible to achieve. It is also common to quote CIF with a fixed FOB-part and later deliver freight and insurance bills in accordance with real costs. FOB-terms might be chosen when the supplier is unfamiliar with the local transportation structure or when the government wants to support local shipping lines and clearing/forwarding agencies.

Exworks (ex.gate/ex.factory) etc. is mostly used when a collection of the goods can be made at the supplier's factory within a country.

(7) Locate and Select Suppliers

A. Pharmaceutical Drugs

An efficient procurement agency must know how to select low-cost suppliers and how to assure desired quality and service levels. Classifications of potential suppliers can be made as follows:

- Original producers of brand products, foreign and local
- Original producers of generics, foreign and local, government and private
- International procurement organizations (UNIPAC, etc.)
- Private/public procurement organizations (Crown Agents, ECHO etc.)
- Private trading companies (sometimes subcontracting production of orders)

A procurement agency will benefit much from keeping track of and at regular intervals, update its records of all kind of suppliers. This benefits factors like: lower prices are more likely to be found, less reliable suppliers can be more quickly dropped, special dosage forms more easily found and, in emergency situations, the deliveries can be made at shorter notice.

Developing a system of determining suppliers, reliability and eliminating those whose performance is clearly substandard, is an essential task and needs adequate attention and monitoring.

The decision makers should possess or have access to technical expertise necessary to evaluate arguments concerning quality and substitutability. Should have ability to act promptly and with integrity.

The means of locating suppliers are numerous, viz:

- International tendering
- Contacts through local sales representatives
- Contacts via foreign embassies in the country
- Contacts via own embassies abroad
- Inquiries through national trade associations
- Inquiries through international organizations

B. Pharmaceutical Chemicals, Intermediates and Basic Chemicals

UNIDO Directory of Sources of Supply 1/, chemical directories such as 2/ and journals like Chemical Marketing Reporter and Scrip World Pharmaceutical News are the main sources to find information on suppliers of this category of goods. In addition, the modes listed above suggest ways which should be useful.

The original producers of pharmaceutical chemicals and other auxilliary chemicals are invariably difficult to find. Some are in fact "non-pharmaceutical" producers and could be found listed under the producers of "fine chemicals".

1/ "Directory of sources of supply of pharmaceutical chemicals, their intermediates and some raw materials included in the UNIDO list", UNIDO (ID/WG.393/2/Rev.1)

2/ "Directory of World Chemical Producers", 1985/86 Edition, International Information Services Ltd. Publishers, P.O.Box 61, Oceanside, NY 11572, USA.

Trading companies should not be ruled out from giving their quotations, as these might be the swiftest suppliers. Many original suppliers will further refer to trading companies when asked for quotations. Units with production programmes including many products will have to order a great number of items and it might therefore make sense to utilize trading companies for supplies in many cases. Some trading companies also have good connections with reputable East European and Asian suppliers of interest.

One can point out the need for a competent experienced and trustworthy consultant at the buyers side, preferably dosage form manufacturers in developing countries with an annual turnover of $ 10 million or more (for instance example are Epharm in Ethiopia or Imarsel in Nigeria. Similarly advice of experienced sellers with extensive business experience in developing countries is worth consideration.

C. Price Comparisons

Price comparisons must be made on equal conditions for all quotations, that is, the terms of trade should be equalized in comparisons. When it comes to currency fluctuations, the problems are bigger. In the utilization of public funds, speculations should be avoided, and it is therefore recommended to compare the prices at the day of opening the tender or at a determined set of exchange rates. In some cases advice from the Central Bank will be needed. Whatever system is used, it must be followed in order to give the necessary consistency for suppliers' participation and relevant procurement basis for future.

It is desirable not to allow price fluctuation schemes as regards one year contracts, a principle used in utilization of World Bank loans.

(8) Specify Contract Terms

Contracts can either be periodic contracts, where an approximate amount can be purchased over the contract period, or quantity contracts for specified quantities. The former type is generally more advantageous to both parties, as the supplier can more easily plan production and the buyer can adapt to financial changes and storage capacity. In countries with troublesome allocation procedures (foreign exchange, import licenses and letters of credit) the periodic contracts might solve many problems, that is, if the central bank accepts suborders or similar conditions, which is not always the case.

Essential items for inclusion in contracts are:

1) Contract prices and trade terms
2) Specifications of the material incl. expiry date
3) Quantity and quality of the material, incl. packaging/labelling
4) Delivery period, latest date of shipment
5) Removal by supplier of rejections
6) Freedom of buyer to procure from elsewhere in case of default
7) Bad quality and damages therefore
8) Terms of payment
9) Prohibition of transfer of contract to other suppliers
10) Service of notice
11) Indemnity cover for patents, trade-marks, design etc.
12) Price escalation clause (should be avoided)
13) Force majeur incl. bankruptcy of supplier

Standard contract terms shall be forwarded in tender procedures, so that the supplier quotes accordingly and agrees to conditions set from the beginning.

(9) Monitor Order Status - (10) Receive and Check Deliveries

Once a contract is signed, a complete set of procedures is needed to keep the supply situation under control. The monitoring comprises administrative work with local banks (import license, letter of credits etc.) and adequate communication with the supplier. Standard letters and stringent procedures shall be followed in the communication with the suppliers, as such measures will ease the work-load considerably and alert the supplier to do his best.

ABC or VEN categorization of drugs might preferably be used in monitoring of orders, so that priority of work can be established. A system with cards, covering all steps from selection of suppliers and procurement method up to the final stocking in own warehouse and release after quality control etc. might preferably be included. Possible steps for a system related to letter of credit payment can look as follows 1/:

1) Request for import license
2) Notification of award to selected suppliers (preferably by telex)
3) Answer from supplier
4) Start to open letter of credit on basis of import license
5) Send order and other needed documents to supplier by mail
6) Send standard letter of request to confirm terms by copy for quick answer by supplier
7) Copy of order placed with the inventory control system
8) At time of established letter of credit, notify the supplier by standard letter of this plus additional documents required (e.g. certificate of analysis, last day of shipment etc.). The supplier answers by filling in copy of letter.
9) Send standard letter on status of order etc. to supplier, asking for information regarding freight, ETA, any balances left etc.
10) Answer from supplier by filled in copy of letter
11) Last standard letter (status of order) sent to supplier at determined number of weeks before the shipment day asking for last details in shipping and banking procedures, if quality certificate has been posted etc.
12) Answer from supplier - information sent to inventory control and clearing and forwarding department/agency
13) Shipping documents arrive. Check correctness against order
14) Follow up clearing at port
15) On arrival of goods, check quality, packing etc. collect harbour documents
16) Release the goods if in order, otherwise immediately notify supplier and send necessary documents relating to damage, shortlanding etc.
17) Record supplier performance in special register according to standard procedure.

1/ "Managing Drug Supply", Management Sciences for Health, Boston, Massachusetts, USA. Second Printing 1982.

The consignment shall be inspected on arrival in harbour or airport, and the quality established. In case of own analyzing facilities or if an agreement has been reached with a foreign independent laboratory, it is imperative that the samples taken for analysis are picked according to a standard and established sampling procedure. Each part of the consignment holding a separate batch number shall further be sampled for testing. The costs of analysis is often high, the number of batches per consignment be kept reasonable.

In some instances, part of the payment might be withheld as a performance bond which is paid out only after full compliance of contract terms. Inspection by agencies as General Superintendents (SGS) in the port of on-loading may also be stipulated in letter of credit or in the contract. Such inspections will directly cost roughly 2 % of the value of the consignment.

(11) Make Payments

Suppliers in international trade are paid in three main ways:

1. Clean Payment in practical terms mean that the bank in buyer's country releases the document without any condition, or the documents are directly mailed to the buyers, e.g. 90 days credit from the date of arrival, documents, goods, ship in port etc.

2. Cash against documents means that buyer's bank will release documents only upon payment of the total value invoiced.

3. Irrevocable and confirmed Letter of Credits (L/C) means that buyer must pay the total value of the goods to suppliers bank before the shipment is made.

The buyer's or government's ability to pay in accordance to international practice is very important in maintaining good prices and reliable suppliers. The suppliers will otherwise react by referring to trading companies, withdrawing completely or compensate themselves for the expected risks and troubles with much higher prices in future. Procurement agencies in many developing countries suffer from many factors outside their control. Good procurement procedures are much harder to maintain under such circumstances, but if the bureaucratic lead-times can be estimated and thus included in the planning, there are still ways to compensate for such constraints.

X. COST OF PROCUREMENT IN DEVELOPING COUNTRIES

A. Price Levels of Pharmaceutical Chemicals and Drugs

As explained earlier in the document, cost is influenced by purchasing in bulk quantities, processing greater proportion of generics, reducing the number of therapeutically equivalent drugs, improving procurement procedures to encourage competition. Whether the prices paid by procurement agencies are favourable or not, use to be the main question placed to officials concerned

with the procurement of pharmaceuticals. The prices offered in open tenders can still be high in comparison with the average levels paid in the industrialized countries. From the foregoing, it can be infered that prices offered to developing countries invariably depend on various sets of factors, such as:

- The supplier's former experiences as regards the buyer's reliability in making payments, communication of relevant information for shipments and as a whole the buyer's "dependability" and swiftness in finalizing his part of the trade.

- Costs of the trade and payment terms stipulated.

- The extra administrative work included for fulfillment of referred terms above.

In countries with non-convertible currencies, the mode of payment will often be in form of Letters of Credit plus bank charges. The quoted prices are however in many cases higher than the increase due to bank charges. Several European suppliers become desinterested in quoting to some countries after having been involved in L/C-troubles. Such suppliers of pharmaceutical chemicals and drugs might direct enquiries to trading companies, which are more experienced in handling L/C-transactions.

In comparison with payment on "cash basis" or commercial terms, payments on L/C basis push the prices high. Elements contributing possibly to escalations in prices in comparison with a buyer in developed countries are:

1) Bank charges (approx. 1-2 %, in some cases of unconfirmed nature financing secured L/C even more)

2) "Delay" interests (10-15 % for expected delays in the range of 4-6 months)

3) Security for expected changes of the requested currency of payment (bank advice, very difficult to state, but in range of 4-5%)

4) Increased costs for expected extra administration in handling the order (around 1-3 %).

Thus a price increase of 10-20 % is likely to be included in offers based on L/C payment by a developing country with a bad trade balance and erratic procurement procedures in comparison with "cash"-paying customers in the neighbourhood.

If there are special adverse clauses in the L/Cs, the suppliers will add extra margins to cover the administrative costs incurred. Such clauses include confinement of transport to one line or certificates of Special Goods Storage-inspections etc. Another increase of 2-3 % may be expected.

The "reliability" of the customers is often stressed in discussions with producers and suppliers of pharmaceutical chemicals and drugs. In order to achieve good prices, shorter term credits, prompt deliveries etc., the customer must be deemed able to receive and handle his part of the deal in an agreed and expected manner without many changes or delays, which are likely to cause disturbances in the production and administration at the supplier's end. Long-term contracts or relations with regularity in the deliveries are much appreciated. Consequently, a disjointed procurement system will hamper the supplier's willingness to quote favourably or help in difficult situations.

Long lead-times in procurement makes it hard to fulfill the suppliers' wishes as regards "reliable" customers. In most centrally controlled developing countries the lead-times for the different steps of procurement are generally long.

A private purchaser, who is well acquainted with the trade and is located in the industrialized countries normally needs a short time for placing an order. Within the government agencies, which use tender procedures, a period of 1.5 months will be sufficient for this purpose, while administration in developing countries (at times worsened because of scarcity of foreign exchange) generally may require periods of 4-6 months for the same decision to be made. Suppliers in the developed countries have difficulties in handling such lead-time and react accordingly in pricing.

B. Price Information on Pharmaceutical Drugs and Chemicals

As stated earlier, price information must be scrutinized from several angles. The main problem is the lack of relevant and continuous basic data for most chemicals and drugs.

Price information on pharmaceutical preparations, mostly in branded form, can be found in national "red-books", where consumer prices are published. As explained earlier, the wholesaler's purchase prices can not be deducted by one general formula, as the pharmacies are organized in various ways and allowed different margins in each country. By studying one of the red-books mentioned in Appendix I and deducting the margins allowed or prevalent in the country in question, approximate prices can be obtained. An approximate deduction at times could be at the rate of 35 %.

UNIPAC, the UNICEF Procurement and Assembly Centre, procures drugs for some $ 40 million per annum and publishes the prices paid for Essential Drugs on a more regular basis. This "Indicative Price List" is at present the best guide to the lower levels at which drugs are sold. UNIPAC is likely to procure in future large number of pharmaceutical chemicals and auxilliary materials. For further information on UNIPAC see chapter XI.

Many trading companies issue "Price Lists" of the most common essential drugs and over the counter preparations, as well as monthly newsletters on pharmaceutical chemicals. Among such companies a sample include Halewood, Selectchemie, ICC-Trading, Marsing, Helm, Siemsgluss, Blau, Dolder, Dangschat, EMA, FBA, MMM, etc, also ATI's Price Indicator for essential drugs, Berlin, serves as source of information. For further details regarding suppliers, reference may be made to UNIDO Directory of Sources of Supply and other publications on the subject.

Prices of some basic chemicals (including pharmaceutical chemicals and their intermediates) are published regularly in Chemical Marketing Reporter and similar journals. Information as regard pharmaceutical chemicals and some of the intermediates are toutinely published by Chambers of Commerce and Industry for instance Milan, Italy, and are at times covered in periodic issues of Scrip-World Pharmaceutical News. UNIPAC is planning to issue a periodic indicative price list for pharmaceutical chemicals. Some trading companies such as Dangschat, Siemsgluss, Dolder, Helm, Selectchemie etc. (for details reference is made to UNIDO Directory of Sources of Supply which provides information about the suppliers and manufacturers of pharmaceutical chemicals who could be contacted for price lists) issue price lists for a number of pharmaceutical chemicals.

XI. UNIPAC PROCUREMENT SYSTEM

UNIPAC (UNICEF Procurement and Assembly Centre) is an organization which procures, packs and delivers health related basic goods of broad range to developing countries as part of various UNICEF programmes. The main activities are carried out in UNIPAC premises in Copenhagen, Denmark.

UNICEF/UNIPAC got more heavily involved in the procurement of drugs around 1980 in cooperation with WHO and DANIDA. The introduction of various essential drug programmes necessitated regular availability of inexpensive pharmaceutical formulations. The procurement of these was assigned to UNIPAC, which is now a major purchaser of drugs for developing countries and currently procures drugs for over $ 40 million.

UNIPAC - procurement follows rules and regulations laid by UNICEF board. The corresponding prerequisites for the procurement of drugs comprise:

- Procurement shall preferably be part of an essential drug programme.
- All orders above a value of $ 5,000 are handled through international tender. Payments are made under normal business conditions, usually net 30 days.
- No purchase is made before funds are made available to UNICEF/UNIPAC bank accounts.

For instance, in the essential drug programmes in East Africa are handled on regular basis by UNIPAC. DANIDA/SIDA funds have been placed with UNIPAC and the programmes are treated as normal UNICEF projects. Prices are mutually negotiable on an annual basis in case of price changes for pharmaceutical chemicals. The average prices of the 30-40 essential drugs supplied to East Africa have been kept more or less constant for the last 3-4 years.

UNIPAC selects suppliers with own production facilities. Invariably, UNIPAC suppliers of pharmaceutical drugs are about 90 % from West European countries while the balance comprise North America, China, Japan and Eastern Europe.

UNIPAC is at present commonly regarded as the most viable and efficient procurement agency for developing countries. The costs of the operations are covered from the interests generated by deposited funds and debited standard fees.

Standard fees, added to the FOB-value of the drugs, are as follows:

A UNIPAC fee of 3 % irrespective of the fact whether the shipments pass UNIPAC warehouse or not. A warehouse overhead charge of 10 % for set packing and consolidation. Freight and insurance costs are additional.

The prerequisite that UNIPAC deposited funds must be present before procurement can be made, has in practice meant that few L/C transactions have been carried through. A formal decision has now been taken by the UNICEF executive board to establish a Revolving Fund for developing countries to perform purchases with payment on delivery rather than with order. Modus operandi for the same is being worked out by UNICEF.

So far UNIPAC has not been involved in any major procurement of inputs for pharmaceutical industries. One major reason is the stipulation that transactions giving the recipient a profit is ruled out by the UNIPAC regulations for procurement. During the last WHO meeting on Essential Drugs in Nairobi (December, 1985) UNICEF has expressed an agreement in principle to procure inputs for pharmaceutical industry.

UNIPAC is likely to partly utilize trading companies for the procurement services for pharmaceutical production activities.The prices for pharmaceutical chemicals and auxilliary inputs will in time also be published in form of an indicative price list along with the pharmaceutical drugs. It is further expected that UNIPAC in the purchases from trading companies will be able to charge the lower fee of 3 % as mentioned above and this utilization of trading companies will give the producers advantage of getting all necessary inputs in one consignment, thereby cutting down lead-times in production. The prerequisite is, of course, that the pharmaceutical industry places order of "balanced" quantities of the needed materials for formulation activities.

XII. STORAGE

Adequate storage and regular distribution of pharmaceutical chemicals, intermediates and pharmaceutical drugs are imperative for effective operation of any procurement scheme. Due consideration should be given to factors such as access, ventilation, drainage, security, water, electrical and telephone services while selecting a site.

XIII. CONCLUSIONS FOR CONSIDERATION

The procurement of drugs and pharmaceutical chemicals is in many cases constrained by externally imposed procedures and regulations. An important task for the procurement agency or responsible ministry is therefore to identify and comment on such constraints to responsible authorities in order to get changes for the better. Constraints of major importance are:

a) Unlimited number of drugs or pharmaceutical chemicals gives low purchase volume per item and hinders purchasing at reasonable prices. A rational and restricted List of Essential Drugs, following WHO recommendations is likely to be a major step forward to better procurement.

b) Long lead-times between applications and approval of necessary documents for imports of drugs and chemicals are common. In case of scarcity of foreign exchange appropriate allocations of funds be made for making timely payment as price levels otherwise will escalate.

c) There should be full coordination between accessing needs for drugs and available donations/making allocation for procurement through local sources or import.

d) Complicated and irregular write-off procedures as well as stipulated regulations for procurement should be investigated and altered where necessary. Tender procedures should be concentrated on the items of the largest value and ABC/VEN-classification allowed to govern the procurement method and other stringent or complicated procedures.

e) Quality control supporting programmes may be started in close cooperation with foreign reputable laboratories.

Procurement Agencies

First of all, internal constraints of drug supply systems should be investigated. Such investigations may be carried out with the assistance of foreign, well-known and reputable procurement and training agencies. The support may be sought from bilateral aid-agencies (request for consultancy studies) or directly from organizations like WHO, UNICEF/UNIPAC, World Bank, UNCTAD, UNITAR, IFPMA etc.

Among the more costly components of the procurement activities, the following are likely to have big potential of savings and increased efficiency:

a) Selection of drugs: This can be rationalized by introduction of a restricted number of drugs named or classified under a generic system. If such a list has not already been put in practice, the introduction is likely to give the biggest savings of all measures.

b) Inventory control: Emphasis must be put on the possibility to reduce the stocks, not only through a rationalized list of drugs, but also by means of a more continuous procurement/distribution system, in which methods like the ABC or VEN-system will facilitate its management.

c) Quantities consumed: The procurement agency should make efforts to have periodic information on regular basis on the consumption pattern and inventories at the consuming points.

d) Finance: The procurement personnel should plan their requests within the likely budget limits. The execution of the plans can then at large be followed and the planning exercise become useful as a working tool. In countries with scarcity of foreign exchange and low availability of funds, these two variables be kept apart in the planning to integrate the potential domestic supplies.

e) Sources of supply: Donations can form an important part of the procurement, provided that they are governed and recorded within the limits set by national interests. Domestic production units should as well be utilized and "subcontracting" might here be of interest in case the local prices are hard to accommodate.

f) Procurement method: Procurement should as much as possible be carried out with priorities set for the procured items, if this is possible within the stipulated procedures of an agency. Open tenders are recommended for the limited number of items (the A and V-type items of the ABC/VEN-methods) which have the biggest share of the expenditures.

g) Trade and payment terms: An adoption should be made to the terms under which advantageous procurement is made in the industrialized countries. Payment without delays and long lead-times are likely to give advantageous prices as discussed in chapter X. If bilateral aid funds can be obtained, their placing in foreign bank accounts, from which payment can be made more quickly, may be considered. Such a measure and utilization of secured ways of cash-payment is likely to give benefits of pricing.

h) Contract: Should be comprehensive, clear and timely without complicating the transactions of the supplier, as he is likely to charge for complications.

i) Personnel: Providing on the job training may be considered for the weak areas discovered in an initial investigation. Support can be sought from the same sources as mentioned earlier in the study. In the context of personnel, it is prudent not to overstaff procurement agencies. Especially public agencies sometimes tend to have too many people for the tasks assigned.

Training: Training aiming to increase knowledge, change attitude, improve skill and job behaviour among policy makers, mid level managers and line personnel would go long way in managing procurement. In the area of procurement module content of curriculum may include procurement cycle, purchasing methods, scheduling purchases, terms of payment, selecting suppliers, payment mechanisms, organizing procurement services, make or buy decisions and quality assurance aspects etc.

UNITED NATIONS AGENCIES:

Local production of pharmaceuticals offer a number of advantages enumerated elsewhere in the document. UNIDO should continue updating the Directory of Sources of Supply for the pharmaceutical chemicals required for the manufacture of pharmaceutical drugs included in WHO model list of essential drugs and consider inclusion in the Directory of auxilliary materials required by pharmaceutical industry.

UNIDO may investigate the possibility of cooperation with UNIPAC and WHO in the area of price information on drugs and pharmaceutical chemicals. Information in the UNIPAC Indicative Price List, and other competent sources could be compiled and published on regular basis by the United Nations agencies for guidance on lower price levels in the first place and steps may be taken towards the establishment of an information system.

United Nations agencies' assistance may be asked in establishing and strengthening national procurement agencies.

United Nations agencies may consider providing fellowships for training managers in developing countries in various aspects of management of drug supply and control systems. These organizations should hold seminars and workshops and encourage bilateral and other training schemes.

United Nations agencies may assist in establishing collective procurement centres for pharmaceutical formulations as well as active principles and auxillary materials on regional basis.

United Nations organizations may encourage regional approaches for training and dissemination of information on procurement.

APPENDIX I

"TEN STEPS TO DEVELOPING A FORMULARY"

Extract from "Managing Drug Supply" 1/

1. Obtain support for an essential list of drugs within Ministry of Health, from the organized medical community and among local health care workers.

2. Establish Drug Selection Committee with appropriate representation

3. Gather and analyse information on:

   a. Prevalent morbidities
   b. Drugs available
   c. Patient characteristics
   d. Types of health care personnel at each level
   e. Local manufacturing activities
   f. Existing drug lists
   g. Pharmaceutical logistics problems

4. Make decisions regarding

   a. Structure of formulary
   b. Format of formulary
   c. Selection criteria

5. Select drug products

6. Include prescribing information

7. Have draft reviewed by

   a. Nationally recognized specialists
   b. Local health care personnel

8. Undertake educational campaign for

   a. Practicing health care personnel
   b. Patients

9. Promulgate regulations

10. Conduct annual update of formulary

1/ "Managing Drug Supply", Management Sciences for Health, Boston, Massachusets, USA. Second Printing 1982.

APPENDIX II

ESTIMATION METHODS FOR DETERMINATION OF DRUG QUANTITIES

There are three basic methods for estimation of drug needs:

I. Population-based estimates:

a) Demographic datas are used to identify the average composition of the population in regard to "age-groups" as follows: Children under 4 years of age, children of 4-14 years, men aged 14-44, women aged 14-44 years and adults over 45 years of age.
b) Collect and compile morbidity/mortality rates for the above groups.
c) Calculate the frequency of occurrence of each disease for 1 million inhabitants on annual basis.
d) Estimate type and frequency of treatment for each disease.
e) Multiply standard norms for treatments with type and frequences of treatment to arrive at drug requirements per year and 1 million inhabitants.
f) Add domestic lead-times and expected wastages.
g) Multiply with actual estimate of millions of inhabitants.

The population-based method gives generous quantities and prerequisites more available funds for procurement than other methods. To cut down the estimated requirements necessitates that epidemological problems are given priorities.

II. Service-based estimates:

a) Collect and compile service records for each type of existing health facility or provider and compile a list of the 20-30 most common diagnosis and note their frequences over a whole year to avoid seasonal changes.

b) Establish standard norms of treatment.

c) Calculate the drug requirements for the 20-30 most prevalent diseases per facility or prescriber.

d) Multiply with existing and planned expansion of programme. Schedule the requirements in time and add lead-times and wastages.

The service-based method is used for programmes, where the number of services provided are adjusted to financial and other frames. The method will not take the total need for health-care into consideration, but give identifiable targets (programme will treat 50 % of all malaria etc. in a certain area).

III. Consumption-based estimates:

a) Records of consumptions of drugs are compiled and studied on annual basis. Alternaltively are import and production datas used for arriving at annual consumptions of each (at least major) drug.

b) For each item, the trend in consumption is studied and new estimates made for future.

The consumption-based method prerequisites that the health-case services show a steady trend and are not undergoing rapid growth or decrease. The method only reflects what can be expected under unaltered conditions and not what should happen. The imports/production patterns may not reflect the actual disease pattern or a wise consumption of drugs.

APPENDIX III

EXAMPLES OF NATIONAL FORMULARIES AND OTHER SOURCES REFERRING TO PRICES

1. Switzerland:
Arzneimittel - Kompendium der Schweiz 198X
(Editors Josef Neugebauer and Jurg Morant, Basel)
Verlag Documed AG, Basel

2. West Germany:
Rote Liste 198X
Bundesverband der Pharmazeutischen Industrie e.V.
D-6000 Frankfurt/Main

3. U.S.A.:
Red Book 198X
Medical Economics Company Inc.
at Oradell, NJ 07649

4. France:
Dictionnaire Vidal 198X
11, rue Quentin-Bouchart
75384 Paris Cedex 08

5. Italy:
L'Informatore Farmaceutico 198X
Organizzazione Editorale
Medico - Farmaceutica S.R.L.
Via Edolo 42
20125 Milano

6. Denmark:
Laegemiddel Katalogets Prisliste
Laegemiddelkataloget
Norre Voldgade 106/1
1358 Kopenhamn K

7. Sweden:
FASS
Läkemedelsinformation AB
Box 1319
11 83 Stockholm

Some examples of sources of information on prices for pharmaceutical chemicals:

- Chemical Marketing Reporter
100 Church Street
New York, NY 10007-2694
USA

- Scrip
18-20 Hill Rise
Richmond, Surrey, TW106UA
UNITED KINGDOM

- Chamber of Commerce and Industry
Public Relation Office
9B Via Meravigli
20123 Milan
ITALY

- UNIPAC
UNICEF Plads
Freeport
DK-2000 Copenhagen
DENMARK

- Companies as listed in UNIDO Directory of Sources of Supply and in other publications

APPENDIX IV

EXAMPLES ON GOVERNMENT TYPE OF LABORATORIES FOR QUALITY CONTROL

Belgium:
Service de Controle
des Medicaments
137 rue Stevin
B-1040 Brussels
BELGIUM

Canada:
Drugs Research Laboratories
Tunney's Pasture
Ottawa
Ontario K1AOL2
CANADA

Poland:
Institute of Drug
Control
Chelmska 30
00725 Warsaw
POLAND

Switzerland:
Office Intercantonal
de Controle des Medicaments
Erlachstrasse 8
CH-3000 Bern 9
SWITZERLAND

United Kingdom:
Governmental Chemist
Cornwall House
Stamford Street
London SE1 9NQ
UNITED KINGDOM

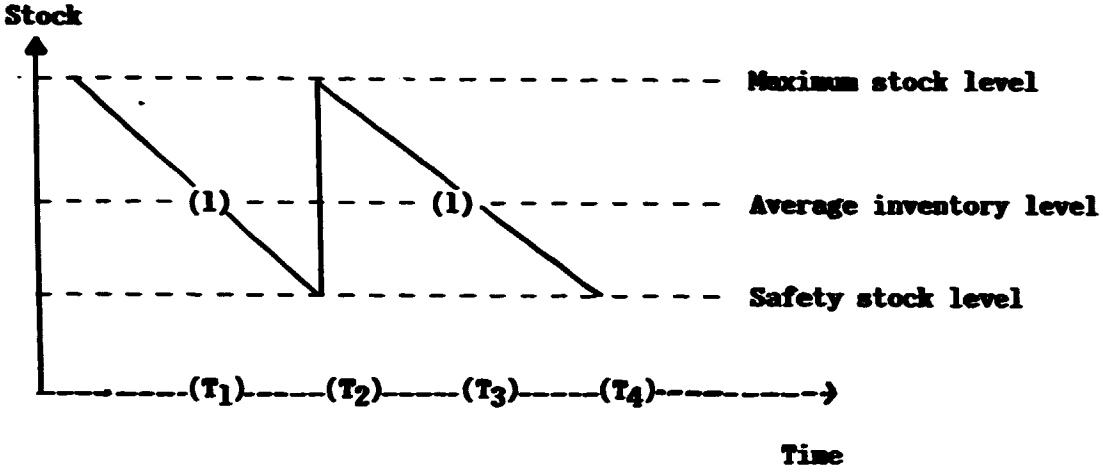
Societe Generale de
Surveillance S.A.
Chemicals Division
Case Postale 898
CH-1211 Geneva 1
SWITZERLAND

USA:
FDA
Pharmaceutical Testing Laboratory
Bureau of Drugs
Department of Health and Human Services
Public Health Service
Washington, DC 20204
USA

APPENDIX V

INVENTORY CONTROL SYSTEMS - A SHORT OUTLINE

1. An ideal inventory control model looks as follows:



The ideal curve above shows, how a new consignment of the item in question is initiated when the stock has reached a level of (1) at time T_1.

The time for carrying through all procurement activities until a new consignment is in stock is called the "lead-time" and is represented by the distances $(T_2 - T_1)$. Lead-time is generally the time it takes for an order or action to be finalized.

When the new order has been received and stocked, the inventory will reach its highest level, corresponding to safety stock + ordered amount.

The curve above shows an ideal behaviour with constant deliveries taken from the stock. As soon as the stock has diminished to an "order level" (1), an order is placed. Ideally the new consignment arrives when the stock level has diminished to "safety" level. The safety stock takes care of unexpected delays and prevents stock-outs.

The average inventory can be diminished by placing smaller orders at shorter intervals, which save storage area needed and give a more continuous flow of goods and higher readiness to changes in consumption, but higher administrative work. Centralized procurement in developing countries often orders every 12 months, corresponding to the government's financial year. Depending on the way in which the inventory control is managed, different types of purchasing can be obtained:

- Annual purchasing is a common, but potentially costly system, which gives a very uneven workload.

- Scheduled purchasing (quarterly, semiannually) is an option, which gives a more even work-load and is cheaper than the above.

- Perpetual purchasing is based on regular check-ups of stock and orders of drugs in relation to consumption. Demands much administrative work, but is also economical.

- Modified optional replenishment is more complex than the above and mostly used in well established and large systems, supported by computer aid.

The pro's and con's of the above methods are described in "Managing Drug Supply", which also contains thorough information on how calculations are made.