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INTERCOUNTRY COOPERATION IN SUPPLY OF ESSENTIAL DRUGS

CONTENTS

1. INTRODUCTION

Medicinal drugs are indispensable for the prevention, control, treatment and amelioration of a number of maladies that affect human beings. Communicable as well as non-communicable diseases are amenable to pharmacological actions of therapeutic agents. Hence it is important to ensure that essential drugs, which are important for the health of the majority of the population, are available and accessible at all times in sufficient quantities and in proper dosage forms.

WHO has been assisting Member Countries in the formulation and implementation of national drug policies in order to reduce morbidity and mortality from common illnesses by promoting the availability of and accessibility to essential drugs. Towards this goal, a major thrust has been placed on promoting the essential drugs concept, drug supply management, quality assurance and rational use of drugs. Furthermore, other aspects of the national drug policy relating to drug legislation and regulatory control, essential drugs production according to the current good manufacturing practices, dissemination of drug information, drug financing, training of human resources and technical cooperation among countries of the region, among others, are being supported in accordance with the priorities of the countries.

Even though national drug or pharmaceutical policies have been developed in the countries of South-East Asia, accessibility to essential drugs varies from place to place within a country. Such differences can also be observed from country to country within the Region as a whole. These variabilities become prominent at the time of an economic crisis since drug supply management is disrupted due to financial and economic factors. In the circumstances, intercountry cooperation in sustaining the supply of essential drugs becomes a critical issue as this strategy can ameliorate the shortage of essential drugs in the health care facility.

2. MANAGING DRUG SUPPLY

In order to have an efficient drug supply system, four components are critically important. They are:

- Selection of appropriate drugs,
- Procurement,
- Distribution
- Rational use.

Among these four components, intercountry cooperation has been commonly seen in the area of procurement. Countries have been able to collaborate successfully in pooled procurement or group purchasing with obvious benefit to the countries due to economies of scale. Examples of pooled procurement can be seen in the following Table.

Table. ***Existing intercountry cooperation in pooled procurement of drugs and other medical supplies***

Procurement group	Year started	Type of agreement	No. of countries	Participating countries
African Association of Central Medical Stores for Generic Essential Drugs	1996	Declaration of Intention	5	Burkina Fasso, Chad, Mali, Niger and Senegal
Maghreb Commission for Bulk Purchasing	1989	Proposal	5	Algeria, Libya, Mauritania, Morocco and Tunisia
Gulf Cooperative Council	1978	Health Ministers' Meeting	6	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and United Arab Emirates
Eastern Caribbean Drug Service(ECDS)	1981	ECDS Agreement	8	Antigua and Barbuda, Dominica, Grenada, Montserrat, St. Kitts and Nevis, St. Lucia, St. Vincent and Grenadines, and British Virgin Islands
South Pacific Pharmaceutical Project	1997	Rarotonga Agreement	4	Fiji, Kiribati, Nauru and Tuvalu

3. EXISTING INTERCOUNTRY COOPERATION IN SUPPLY OF ESSENTIAL DRUGS

There are a number of successful pooled procurement schemes in different parts of the world. The schemes now in operation are – African Association of Central Medical Stores for Generic Essential Drugs (abbreviated in French as ACAME); Maghreb Commission for Bulk Purchasing by the Arab States; the Bulk Purchasing System of the Gulf Countries; Eastern Caribbean Drug Service in the West Indies, and South Pacific Pharmaceutical Project among the Pacific Island countries.

A Generic Model of Pooled Procurement/Group Purchasing Scheme

It can be seen from the above-mentioned pooled procurement schemes that intercountry cooperation in the supply of essential drugs can be realized through the establishment of a viable system. Such a system is usually initiated with the Agreement of the participating countries, which subsequently leads to the development of a programme. The programme includes, among other things, establishment of:

- objectives of pooled procurement
- policy framework
- administrative infrastructure
- responsibilities and functions of office-bearers
- tendering system
- financial management, and
- legal provisions in case of dispute.

The key findings in pooled procurement of pharmaceuticals are the following:

- Reduction in the cost of drugs and other medical supplies
- Improvement in quality assurance
- Increase in local production due to greater scope of supply
- Increased collaboration of pharmaceutical sectors among countries including harmonization of drug registration.

There are a number of advantages in the pooled procurement scheme, the most important being the reduction of drug cost due to economies of scale. Due to greater quantities of purchase compared to those done by individual countries, there is better service and attention given by suppliers. There is also a decrease in the administrative workload of the individual countries. Another advantage of the pooled procurement scheme is harmonization in drug registration among countries since the same products are imported at approximately the same time. Production for regional supply instead of national supply is also an added advantage.

There are a number of key conditions for successful implementation of pooled procurement. They are:

- Political will
- Commitment of participating countries to the scheme
- Formal agreement among the relevent countries
- Well-defined regulations and procedures
- Permanent and independent secretariat, and
- Stage-by-stage development.

The political will of the participating countries and commitment of the secretariat are critical elements in making pooled procurement a success. Pre-qualification and registration of suppliers are important in better selection of suppliers. A realistic number of drugs to be purchased and a limited number of participating countries in the initial stages of development of pooled procurement are contributory to the effectiveness of the system.

4. ENABLING FACTORS IN A POOLED PROCUREMENT SCHEME

In addition to the establishment of a pooled procurement system, sharing of information among participating countries pertaining to drugs for procurement, such as sources and suppliers, prices of drugs, and ways and means to ensure the quality of pharmaceutical products, are indispensable in instilling confidence in the system.

4.1 Sharing of Drug Information

Exchange of drug information is a cost-effective way of utilizing available resources. It is particularly important in country situations where there is a limitation of technical, administrative and/or human resources. Exchange of information can cover many areas in

the field of essential drugs but the following issues are considered to be important in improving the supply of essential drugs:

- Sources of essential drugs, import prices and conditions of contract
- Decisions of drug regulatory authorities pertaining to procured drugs
- Quality of the drugs.

4.2 Information on Regional and Global Price Indicators

It is well known that there is wide variation between prices of essential drugs procured by various organizations. In order for Member Countries to help reduce such variations, the Regional Office for Africa, in collaboration with WHO headquarters, is in the process of publishing “Prices of Essential Drugs” in the Region on an annual basis. Data on prices are to be collected from all Member Countries of the Region. The data are analysed by experts and compared with prices of international drug suppliers. It is important to have the participation of all countries in the data collection process and to use the data so generated in the tendering and procurement of pharmaceuticals, especially in the case of essential drugs.

At present, there are international prices of essential drugs published by UNICEF, International Dispensary Association, Foundation for Non-Profit Procurement of Medical Supplies based in the Netherlands, and International Drug Price Indicator Guide published by Management Sciences for Health (located in the State of Virginia, USA) and the World Bank.

4.3 Harmonization in Drug Quality Assurance

Drug quality assurance is a prerequisite for any supply of essential drugs. There are various critical procedures by which quality of drugs can be assured. They are:

- Product selection – selection of products with longer shelf life, powders for reconstitution rather than oral suspension and selection of products with no bioavailability problems.
- Supplier selection – supplier pre-qualification, valid GMP certification, supplier monitoring, limitation of purchase of non-critical products from new suppliers.
- Product certification – through GMP certificate, requirement of certificates of pharmaceutical product and batch (as recommended by WHO).
- Contract specifications – quality standard according to pharmacopoeia, labelling requirement, minimum shelf life, packaging standard.
- Inspection of shipments – physical inspection of all shipments, sampling for analysis of suspect products and random sampling for testing.
- Laboratory testing – therapeutically critical drugs, drugs with known bioavailability problems, new suppliers, suppliers with past quality problems.
- Product problem reporting system – having a system for reporting suspect or problem drugs.
- Application of the WHO Certification Scheme – very useful tool for certifying the quality of pharmaceutical products moving in international commerce.

5. A MODEL FOR INTERCOUNTRY COOPERATION IN SUPPLY OF ESSENTIAL DRUGS

Because of the emergence of economic crises in the Region in recent years, the Regional Director initiated steps to promote intercountry cooperation for the provision of quality drugs at competitive prices.

Member States of SEAR are, to some extent, in a similar situation with Member States in other regions described above with respect to constraints in the accessibility to essential drugs at different levels of health care. However, SEAR Member States are also in a unique position in that eight of the ten Member Countries have drug production facilities as well as capability and capacity to manufacture essential drugs. Furthermore, there is also the availability of good quality raw materials from a number of Member States of the Region. Bangladesh, India, Indonesia, DPR Korea and Thailand are producers of a certain number of raw materials as well as a wide range of pharmaceuticals from the national lists of essential drugs.

This model is focused on intercountry cooperation in the supply of raw materials for the production of essential drugs. To help achieve this aim, the following mechanisms may be introduced to ensure that only good quality raw materials are made available from the exporting country.

5.1 Careful Selection of Manufacturers and their Raw Material Products

The track record of the manufacturer of raw materials is a prerequisite for ensuring the quality of their product. In this regard, GMP (Good Manufacturing Practice) certificate of the manufacturer and approval of their products by well-developed regulatory authorities, such as the United States Food and Drug Administration, the Medicines Commission of the United Kingdom or the Therapeutic Goods Administration of Australia, are useful indicators. Furthermore, the producers must also have a good record of timely delivery of goods.

Supply of raw materials from within the Region would be a useful mechanism in intercountry cooperation in improving the supply of essential drugs through their production. Providing information regarding availability of raw materials in the international market can also facilitate national production. The International Trade Centre of the World Trade Organization, in collaboration with the Action Programme on Essential Drugs of WHO headquarters, publishes such information on a monthly basis. It is known as Market News Service for Pharmaceutical Raw Materials/Essential Drugs Report. The report contains unit price of packing, minimum quantity for order, delivery time, quality standard, country of origin of the raw material and price trend indicating whether it is increasing, decreasing or is static. Communication with the supplier can be established through the International Trade Centre.

5.2 Assurance of Good Manufacturing Practice (GMP) and ISO Standards

The manufacturers must have a GMP certificate as recommended by WHO. These certificates are issued by national regulatory authorities and form part of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Hence it is the prerogative of the importer to request the required certificate from the exporter or its representative in the importing country. Such a certificate may also be requested from or verified by the national control authority of the country where the manufacturer is located.

Recently, the International Standards Organization (ISO) has established requirements for internationally-accepted standards of quality system, which deals with the organizational structure, procedures, processes and resources needed to implement quality management. It is implemented through a quality manual, which covers relevant ISO standards and GMP requirements. It also describes how the quality system is managed.

5.3 Random Checking of Raw Materials

It is important to randomly check samples of raw materials at a recognized laboratory for quality assurance of pharmaceuticals. A system for random selection of samples for testing has to be instituted.

6. CONCLUSIONS

Intercountry cooperation in the supply of essential drugs (manufactured products) as well as raw materials for the manufacture of essential drugs can be accomplished if there is a complement of three basic and indispensable components. These are:

- Political will and commitment of relevant decision-makers to procure raw materials, regionally or internationally, based on cost-effectiveness,
- Assurance of quality through a well-defined mechanism, and
- Sufficient financial resources to ensure the availability of adequate quantities of essential drugs and other medical supplies.

7. POINTS FOR CONSIDERATION

The following issues may be taken into consideration in regard to intercountry cooperation in the supply of essential drugs:

- Intercountry cooperation is seen in the form of pooled procurement or group purchasing as a common strategy for improving drug supply to regional groups of countries. Is this a step towards intercountry cooperation in this Region?
- A recent survey in SEAR has shown that raw materials for the production of essential drugs can be obtained more cheaply from within the Region. Is procurement of raw materials from within the Region a step towards intercountry cooperation in this Region?
- Are enabling factors in pooled procurement schemes, such as information sharing on suppliers of essential drugs (finished products), their prices and quality a step towards intercountry cooperation in this Region while leaving procurement as the national prerogative?
- Are there other more desirable options for intercountry cooperation in this Region?

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