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PURCHASING QUALITY ESSENTIAL MEDICINES

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1. INTRODUCTION

Purchasing Quality Essential Medicines at an affordable price and ensuring a regular supply to the health care institutions is among the major functions of Ministries of Health. During their interactions with WHO/SEARO, Member countries have frequently requested information and technical assistance on this issue. It should be noted that the medicines provided need to be used rationally to achieve the ultimate objective of maintaining and improving the health of the population. This paper however, focuses on the purchasing of quality essential medicines.

A simple end-point but a complicated journey

The simple end-point of purchasing and providing essential medicines of adequate quality however requires policy decisions, involves complex technical and administrative issues, expertise and trained human resources and knowledge of the pharmaceutical market and the pharmaceutical industry. Essential medicines is an issue that has been examined and reviewed repeatedly; it was discussed at the Health Ministers Meeting in Maldives in 2001 and was also the subject of a Regional Committee Resolution in 2002. While the Region has the capacity to manufacture the essential medicines requirements for its population, there are major problems in maintaining quality, supply and distribution.

Strategies and Solutions will vary

There is no overall solution for purchasing quality medicines at affordable prices. Countries must adopt strategies according to their needs; some have capable domestic industries; others are entirely dependent on imports and the rest obtain their medicines through a mixture of domestic production and import. Tools such as purchasing procedures (including pre-qualification of manufacturers) have been used successfully to ensure quality. To solve problems in distribution, purchases have been made centrally but the medicines had to be supplied to the districts. Each country needs to choose from the strategies and tools that are available and learn from the experiences of other countries.

2. SUCCESSFUL EXAMPLES

Vaccines for the Expanded Programme on Immunization

What are the successful examples in the Region where essential medicines or vaccines of adequate quality are being purchased at affordable prices and supplied by ministries? Countries have either purchased or requested the procurement of the six vaccines for their Expanded Programmes on Immunization. These six vaccines were obtained from the pre-qualified manufacturers in the UN scheme for pre-qualification of vaccine manufacturers. WHO and other UN organizations have been closely involved in this scheme in evaluating the manufacturers for quality; negotiating prices, ensuring delivery to the countries as well as assisting in the cold chain necessary for distribution within the countries. The technical expertise within the organizations ensured quality, the consolidated requirements of the countries also meant economies of scale and a huge purchase which, in turn, made it attractive for the manufacturers.

Other Schemes

Other schemes such as condoms for the AIDS programme in the early 1990s, The Global Alliance to Eliminate Lymphatic Filariasis (focusing on two drugs) managed to ensure quality through pre-qualification of a limited number of suppliers. At present, schemes such as the Global Fund to Fight AIDS Tuberculosis and Malaria (GFATM), the Global Drug Facility (GDF) for tuberculosis function or plan to function within the framework of large purchases (by consolidating country requirements) of a limited number of medicines from a pre-qualified list of manufacturers; this has resulted, and for the newer schemes, will result in medicines of acceptable quality at affordable prices.

Countries in the SEA Region have used these schemes; the most widely used scheme has been the six vaccines for the Expanded Programme on Immunization. Bangladesh, India, Indonesia and Myanmar have been approved for GDF support. Countries in the Region are now processing the GFATM funds, a sizeable proportion being for medicines to treat these diseases. Thus for these diseases, countries have achieved and in the case of the newer schemes will achieve their objectives of medicines/vaccines of acceptable quality at affordable prices. However, the critical issue is whether these schemes can be applied to the much larger number of essential medicines that are required for the health care needs of a country.

Applicability of these examples to the essential medicines requirements in a country

While all these schemes demonstrate that it is possible to achieve essential drugs/vaccines of adequate quality at affordable prices, the schemes dealt with a very limited number of products with a few manufacturers for each product. On the other hand, the essential medicines requirements of a country are very much higher. Even a small country would require a minimum of 200 medicines (quite possibly more) and most medicines would have more than 5 suppliers each. The resources for this are simply not available and it would not be possible to either scale up or develop new schemes for the essential medicines requirements of a country.

Therefore, the major player in purchasing quality essential drugs for a country would remain the Ministry of Health; strengthening the medicines procurement capabilities of the ministries is the most sustainable option. However, important lessons could be learnt from the experiences of these schemes; the two most important ones are quality and price when purchasing essential medicines.

3. QUALITY

The cost of quality

Quality has to be the bedrock of any procurement system for medicines in a country; all other factors including price must play a secondary role. A cheap medicine of poor quality will ultimately cost more than a medicine of adequate quality that is more expensive. Cheap medicines of poor quality will not cure and will thus be money wasted.

It must be remembered that “Quality has a Price”; thus the price of a medicine should include the raw material, transport and the cost of systems to ensure quality. All too often there are manufacturers who produce medicines without ensuring quality. Thus, when evaluating offers for medicines, the procurement system must rightly reject offers that are too expensive but must also be careful about medicines whose prices are unrealistically

cheap. If the cost of quality is not paid when purchasing medicines, the costs to health may have to be paid.

Choosing the Medicines to Buy and Ensuring Supplies

Countries in the Region have a very creditable achievement in this area; all the countries have developed their National Essential Medicines List and therefore clearly demonstrated their commitment to the Essential Medicines Concept and, for the manufacturers, indicated what medicines would be purchased. Manufacturers will thus operate in a predictable market which has benefits to them and also ensures that there will be suppliers of essential medicines in the country.

Quality of Essential Medicines

Evaluating quality in essential medicines should not be difficult; the medicines are well-established effective products for which there has been long experience in manufacturing and most of the issues, difficulties and practical aspects are known. The technical (pharmacopoeial) specifications for essential medicines are widely known and therefore do not pose a problem. It is the trained human resources necessary to evaluate the documents and the facilities for the quality control tests that are a problem.

WHO Good Manufacturing Practices (GMP) Scheme

The WHO GMP scheme for pharmaceutical manufacturers provides a standardized method for inspection and documentation thus making it easy for buyers to evaluate the medicines that are produced. While the scheme provides a good beginning for quality, the working of the scheme is entirely dependent on the National Drug Regulatory Authority of a country. WHO provides guidelines but it is the National Drug Regulatory Authority which inspects, documents and issues the certificate. Hence, the quality of the inspection and documentation depends upon the expertise of the National Drug Regulatory Authority. Thus, ministries of health when importing medicines, should use the WHO GMP scheme as a minimum requirement but will often be required to evaluate further. Building such capacity within a national procurement system is crucial.

Local Manufacture of Essential Medicines

Local manufacture of essential medicines provides the opportunity for a country to promote its national industry as well as increase pharmaceutical expertise within the country. As the National Drug Regulatory Authority would be able to supervise and monitor the quality of the locally manufactured medicines more effectively than products that are imported, it could potentially provide a better mechanism for ensuring quality. In addition local manufacturers have a financial advantage too. Most countries provide a price margin for local manufacturers above that for imported products, as these industries contribute to the national economy. The principle of this margin for national industries has been formalized and institutionalized even by multilateral agencies such as the World Bank. Although this margin could result in slightly more expensive medicines in the short term, the long term benefits of increased pharmaceutical capacity and a continuous supply of quality essential medicines from local manufacturers would more than offset this.

Needless to say, all these desirable advantages of local manufacture must not compromise the first requirement of purchasing quality essential drugs – Quality. All too

often, National Drug Regulatory Authorities will ignore quality and other problems in order to promote local manufacture. This benefits no one; national industry learns that lower standards are acceptable and sees no reason to improve, patients get poor quality medicines and the funds for medicines are wasted. On the other hand, maintaining quality benefits all.

Incorporating the Cost of Testing in the Purchase

On some occasions ministries would like to test the quality of the medicines purchased but cannot identify the necessary funds. Some of the international schemes have addressed this problem by specifying that the budget for purchasing medicines should include a small fixed percentage for quality testing. This, while funding the quality testing, would also send a very strong signal to the suppliers that quality is being taken seriously. However, the obstacles to such a percentage maybe internal; ministries of finance in their effort to get the maximum medicines from the limited funds may not permit it. Ministries of health would have to argue this case based on the long term benefits and cost-effectiveness.

4. PRICE

It is not entirely Price but Cost-Effectiveness too

All health systems in the world are constrained by funding, therefore Ministries of Health would naturally be concerned with the price of medicines. It is not the price of medicines alone that is important; it is equally important to ensure that the funds are being used cost-effectively. For example, strategies to improve the use of medicines by using good drug information and strategies to decrease waste and pilfering will have their initial costs but ultimately be cost-effective in ensuring medicines are used correctly and are not wasted.

Where pilferage is a common problem in the Government sector, a State logo stamped on tablets and capsules would identify the source of the drugs and thereby significantly reduce pilferage. The small extra cost involved could be more than recovered in the decrease of pilferage from the State system. Ministries of health often purchase medicines in large quantities such as a thousand tablets/capsules in a bulk pack rather than individual file/strips or package. While providing economies of scale, it does create problems of poor storage, misidentification and poor quality dispensing. Individual packaging does have an advantage in clear identification of the medicines, potential reduction in pilferage and loss, and better stability. Patients too prefer such individually packed medicines and there is a perception of higher quality. Again, there would be an extra cost for individual packaging but this would be more than offset by the better use of the medicines.

Essential Medicines as a Group are Inexpensive

Essential medicines as a group due to being long established products with multiple suppliers are inexpensive; therefore ministries should be able to purchase their requirements at very affordable prices. Prices from year to year at a minimum should be stable, and, for some, should decrease. Monitoring prices of essential medicines being purchased would be a useful tool to identify inappropriately high prices. Data on essential medicines prices are available widely on the Internet as well as in publications. In addition, there are services which provide the raw material prices of essential medicines, which, in turn, provide a very good basis for the ministries to assess whether they are paying the appropriate prices. It must be stressed again that “Quality has a Price” and inappropriately low prices may mean low-quality products.

Financial Procedures in Purchasing Medicines

"Open Procurement of Medicines", allowing many suppliers of varying capability to tender, is a known unsatisfactory method of purchasing medicines. A manufacturer being registered in a country only means his product has been evaluated for quality. It does not mean the manufacturer has been evaluated as a supplier, which is as important when large amounts are being purchased. Thus, manufacturers need to be evaluated for their ability to supply large quantities and often on whether quality could be maintained in such situations. The most widely used method is to have a list of suppliers that have been pre-qualified which ensures quality as well as competitive bidding.

Often, pre-qualification through ensuring quality, by limiting manufacturers is against the general regulations of the Finance Ministry of a country. The Ministry of Health may therefore need to argue and justify exceptions to the general rules in order to ensure quality. For large purchases, if the two lowest acceptable offers are very close, it might be useful to split the award thus removing the risk of depending on a single supplier. Again, this may not be allowed due to financial regulations.

Clear regulations implemented in a transparent manner with timely payment will influence the prices that are offered in a tender. Suppliers will provide better prices when regulations are unambiguous on what documents are needed, the specifications for the product are clear and transparent accountable decisions are made. Publicizing the tenders and procurements on the Internet would be useful in attracting good suppliers which would increase competition and result in decreased prices.

Some of these procedures could be implemented by the ministry of health whereas others may need cooperation from the ministry of finance. Removal of inefficiencies in the procurement procedures will have an effect on the prices that a ministry will have to pay for medicines.

Influence of Technical Specifications on Price

The price of medicines can be affected by the technical specifications of the medicines. For example, manufacturers in the Region manufacture to the specifications of the pharmacopoeias of the Region. Specifications from pharmacopoeias outside the Region may mean that manufacturers would need to make special batches which would increase the cost of medicines. Hence, unless there are special reasons, the technical specifications for medicines should be what are widely used in the Region.

5. CONCLUSION

1. Purchasing essential medicines of adequate quality and providing them to health care institutions is one of the highest priorities of ministries of health. Ministries of health in the Region have purchased quality medicines and vaccines at affordable prices from schemes which are overseen by WHO and other UN agencies.
2. These schemes have dealt with a limited number of products and a small selected list of pre-qualified list of manufacturers. While useful strategies and tools could be adopted from these schemes, it is not possible to generalize such schemes to the much larger number of medicines that are required by the health system of a country. The ministry of health in a country is and will continue to be the major player in ensuring quality and purchase of drugs.

3. Quality should be the first priority in any procurement system for drugs and all other factors including price should be secondary. “Quality has a Price” and this will be reflected in the cost; inappropriately cheap drugs may have been manufactured without ensuring quality.

4. Ensuring the quality of essential medicines requires a combination of strategies, expertise and facilities. Local manufacture, including the cost of quality testing in the purchase budget are some of the possibilities.

5. Although price is important, cost-effectiveness is equally important. Strategies to increase cost-effectiveness may have short term costs but these will be more than compensated by the long term savings. Clear regulations, transparent decisions, prompt payment will result in better prices being offered. The special nature of medicines may require that exceptions be made to the general procurement regulations,

SEARO hopes that this discussion of issues in purchasing quality essential medicines will help member countries to improve their systems of procurement. The Regional Office, as always, is willing to provide technical support and facilitate the country efforts in purchasing quality essential drugs.