Procurement of Pharmaceuticals in World Bank Projects

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by

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Abstract

World Bank financing for pharmaceuticals has grown to over US$ 300 million per year, and this trend is likely to accelerate because of the growing size of the population, health and nutrition portfolio. Pharmaceuticals generate particular procurement issues because the ways they are selected, purchased and distributed are very specific. This paper discusses issues related to pharmaceutical financing under Bank projects, presents Bank experiences to date, and outlines practical steps to help overcome common problems that can occur in drug procurement. The paper begins from the position that pharmaceuticals are essential inputs of any health system and must be considered within the global context of health and pharmaceutical policies. The paper further discusses when and how procurement through Bank projects can help in the reforms of the health sector that several countries are embarking on currently.
Introduction

1. World Bank financing for pharmaceuticals has grown to over US $300 million a year, and this trend is likely to accelerate because of the growing size of the population, health and nutrition portfolio. In order to address several issues that have emerged over the years with drug procurement, a package of "Standard bidding documents for procurement of pharmaceuticals and vaccines" was issued in September 1993, together with a procurement technical note (PTN 4.3.2, August 27, 1993). The purpose of this paper is to discuss the issue of pharmaceutical financing under Bank projects, to present Bank experiences to date, and to help overcome common practical problems raised by drug procurement using World Bank loans.¹

2. This paper is limited to pharmaceutical products, and does not cover medical and surgical consumable items, which are sometimes considered together with drugs. These items do not pose the same difficulties, especially because they are directly used by health workers, and are usually not prescribed to patients. Therefore, even if the discussion about the opportunity to finance health recurrent expenditures may apply to them, they are not considered in the following paragraphs.

3. Pharmaceuticals generate particular procurement issues: they are not ordinary consumption goods, and the ways they are purchased and distributed are very specific. This originality comes from several elements: (i) information asymmetries between producers and consumers are large; (ii) the user (patient) generally does not select the drug — it is prescribed by a physician or other health worker; (iii) when the user selects the drug, he or she lacks the specialized knowledge to make a critical comparison of various products; (iv) even health care workers are insufficiently trained to make a full assessment of drugs, and depend largely on the claims of the seller; (v) the user is often insulated from the price consequences of consumption decisions, as the public sector or private insurers often pay for the drugs; (vi) drugs have to be manufactured by specialized firms that operate within strict standards and are licensed and controlled; (vii) the pharmaceutical market does not correspond to the classical criteria for free market competition (atomicity, homogeneous products, free entry of new players).

4. The 1993 World Development Report emphasized the need for countries: (i) to develop an essential drug policy through a careful prioritization of medicines suited to their epidemiological needs; (ii) to improve their methods of procurement of drugs and vaccines through better selection of products and competitive purchasing and; (iii) to enhance drug prescription and consumption habits through better training and information. These recommendations are relevant to the pharmaceutical components of World Bank projects.

5. This paper is organized in two sections. The first section deals with the types of projects for which drug financing can be contemplated, the types of drugs that can be financed,

¹ This paper only addresses the issue of pharmaceuticals for human use: veterinary drugs are not financed through health loans, but usually financed through agricultural lending operations.
and the outcomes that can be expected. The second section considers the practical problems created by drug procurement in project implementation and the various options available to address them.

I. Bank Financing of Pharmaceuticals

6. Pharmaceuticals are usually considered to be recurrent costs. In some cases, however, they are a key component of a targeted health project (anti-malarial drugs in a malaria control project or STD drugs for HIV prevention, for example), and cannot be considered as being paid for from pure recurrent expenditure. In most other cases, procurement of drugs is performed in one operation and under serious constraints (i.e. much like investment items) and does not correspond to the procurement pattern typical of other recurrent costs such as salaries or maintenance. One of the objectives of the present paper is to define the conditions under which Bank financing of pharmaceutical procurement can be considered, and to analyze categories of projects that include such financing.

Limitations to Pharmaceutical Financing

7. Operational Manual Statement 1.21 (OMS) of January 1985 defines the conditions under which recurrent expenditures can be financed through Bank lending. Bank financing of recurrent costs is supposed to be limited to five situations:
   (i) in certain circumstances (see below), for incremental recurrent project costs, in addition to financing a portion of the capital expenditure;
   (ii) to overcome a backlog of deferred maintenance and to improve future maintenance operations by technical assistance or by institutional or policy improvements;
   (iii) in emergency situations created by national conditions such as drought;
   (iv) to rescue a crucial executing agency needing exceptional assistance to surmount an economic or financial crisis;
   (v) within SECALs, where all or part of a sector's import requirements are financed for a given period.

Cases (ii) and (iv) seldom apply to the pharmaceutical sector.

8. The "certain circumstances" described in 7.(i) include:
   (i) where the country has a serious shortage of budget resources for recurrent expenditure financing which makes it unlikely that the necessary funds for recurrent expenditure for a Bank project will be forthcoming;
   (ii) where a specific recurrent expenditure plays a crucial role in the success of the project and some Bank financing is desirable to ensure that the necessary funds are available on time.
In both cases, the Bank must be satisfied that the Government's economic policies are appropriately designed to move towards a solution of this problem, and disbursements for incremental recurrent expenditures should normally be on a declining scale over the implementation period.

9. Furthermore, the OMS states that if the Bank's project is aimed at a development objective which will require more time than the disbursement period of the loan, or may not yield its maximum effect on economic growth for many years, recurrent costs may be financed. The basis for disbursing for recurrent expenditures can be a more gradual decline, or if the amount is minimal in relation to the relevant budget, a constant proportion. That statement has often been interpreted in a wide sense, as nearly all health projects can qualify for that description. The present paper, however, discusses a more restrictive approach to pharmaceutical procurement, in view of the limited outcome of such financing in various countries.

10. One of the reasons for this restrictive approach is that Bank financing of pharmaceuticals never represents a matter of life and death for the populations. It has often occurred that drug procurement has been authorized upon requests by Governments claiming dire shortages, and requiring the Bank to authorize procurement for a wide range of products. But clearly, there is no case where a Bank project would take in charge financing of the whole pharmaceutical requirements of a country. This statement has repercussions on the choice of drugs. In particular, there is never any rationale for the Bank to finance certain types of drugs such as potentially addictive substances (morphine derivatives, for instance), as other sources of finance such as country budgets can always be used for their procurement. Nor should the Bank take the risk of financing excessively large quantities of drugs for which the country's need and/or market have not been carefully evaluated. Quantities financed under Bank projects should remain less than one year's forecast consumption, as there is no case of a country not being in a position to procure additional pharmaceuticals using funds from the budget and/or through the private sector.

11. Even in the rare instances when Bank financing may have covered a large portion of the annual needs of the public sector\(^2\) (especially if the procurement and disbursement process takes less than one year), recommendations not to finance certain types of drugs will not put the population's health at risk, since they will relate to the least essential items. Other options for financing drugs that the Bank would not accept for procurement are always open to countries, and the Bank would not accept that the public budget for drug procurement be met by a lending operation. Furthermore, in all countries where the public sector has been unable to purchase drugs in sufficient quantity, ensuing shortages have always been partially offset by the private sector.

\(^2\) In contrast with Bank practice, the EEC has provided funds to cover the entire annual pharmaceutical needs of the public sector in several African countries (Cote d'Ivoire, Niger), within the framework of budget support operations.
sector, formal or otherwise (including donations from various sources); and Bank support, though often critical, has never been vital.  

12. The problem of emergency situations (para 7.(iii)) is different, but their consequences on Bank financing in the pharmaceutical sector have to be better clarified than hitherto. It usually is a misconception to consider that drug procurement through World Bank loans can help in acute emergency situations. The length of the project cycle and the strict World Bank procurement rules are hardly compatible with emergency situations. Although drug procurement using Bank financing can help improve the situation in the years that follow an acute emergency or drug shortage, it should not be contemplated for the purpose of offsetting it. Various NGOs are able to react fast and efficiently to emergency situations; UNICEF can deliver small quantities of emergency essential drugs in 72 hours and other assistance programs are also capable of fast mobilization. Several Bank projects have attempted to address the issue of emergency drug requirements (see Box 1), but usually they were not successful in alleviating shortages at short notice.

13. To make emergency procurement efficient, Bank procurement procedures authorize waiving most of the requirements for competitive bidding, and streamlining disbursement procedures. Still, drawing full benefit from such arrangements would require that the list of essential drugs to be provided be "standardized" and agreed with the country very rapidly, and that procurement be performed from an acceptable procurement agency, such as UNIPAC or IDA, that already hold the products in stock. That would also require fast project processing, fast contracting agreements with the procurement agency, simple and fast payment procedures, and accelerated delivery procedures. All these requirements, though not impossible to meet, are not easily complied with within the framework of Bank projects.

When Should Pharmaceutical Procurement be Included in Bank Projects?

14. So far we have considered those cases where pharmaceuticals should not be procured using World Bank loans, i.e.: (i) in cases of emergency, in spite of the specific procurement arrangements authorized by the World Bank in such instances; (ii) when the Bank would need to finance the entire pharmaceutical needs of a country; and (iii) when a recipient country requests products which are not essential (see para 34). Drug procurement should also not be considered if project financing would significantly finance non incremental recurrent costs. That means that financing of the normal drug budget of a country through a Bank loan should not be considered in ordinary circumstances. In exceptional circumstances, such financing could only be envisaged in combination with an in-depth reform of the pharmaceutical policy (para 33-36, and Sectoral Adjustment Loans).

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3 It is difficult to assess in financial terms the pharmaceutical needs of a population, as they depend on the population structure and the epidemiology. Pharmaceuticals usually represent 0.7 percent to 1 percent of the GDP of any country, and consumption per capita ranged in 1992 from less than US $1 in Mozambique to US $420 in Japan. The average drug consumption in sub-saharan Africa (South Africa excluded) was estimated at US $ 3.2 per capita in 1992, comprising consumption in both the public and private sectors.
15. However, drug financing is often requested by countries, especially within the framework of health projects. There are three major cases where drug financing should be considered: (i) when a project or project component addresses one specific disease in cases when its eradication (or decrease in prevalence and/or incidence) would represent an investment in human capital; (ii) when a project or project component directly addresses the pharmaceutical policy of a country; and (iii) when a project is supporting the start-up of a cost recovery (or other drug financing) program. Furthermore, pharmaceuticals can also be financed through critical import loans. In all cases, it is important that task managers pay special attention to the selection of the drugs on the procurement list, and make sure adequate information on these drugs is provided to health personnel and patients, as part of the total package.

**Box 1: How Fast Can a Country Procure Drugs Using Bank Financing?**

- "Rehabilitation Loans" have been made to various countries of the Former Soviet Union, mixing Balance of Payment Support and financing of pre-identified critical imports, including pharmaceutical products. The Rehabilitation Loans were processed at a fast pace, and were designed for quick disbursement. Conditionalities only pertained to Bank procurement procedures. However, the time span between submission by the health authorities of a first list of drugs requested for Bank financing (in general during the pre-appraisal mission) and the first delivery of pharmaceuticals procured through the projects has never been less than one year:

<table>
<thead>
<tr>
<th>Country</th>
<th>Time Span</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithuania</td>
<td>14 months</td>
</tr>
<tr>
<td>Latvia</td>
<td>14 months</td>
</tr>
<tr>
<td>Estonia</td>
<td>13 months</td>
</tr>
<tr>
<td>Russia</td>
<td>18 months</td>
</tr>
</tbody>
</table>

- The Romania Health Rehabilitation Project also included financing for taking care of an emergency situation of shortage. The first list of drugs was submitted to the Bank by the Romanian Ministry of Health in February 1992, and the first shipment arrived in Bucharest in December 1993.

**Drugs in projects covering a specific program**

16. Projects addressing one or several specific health conditions usually include financing for pharmaceuticals, which are treated as investment costs rather than recurrent costs. As reducing the burden of these specific diseases is considered an investment in the human capital of the country, drugs necessary for achieving such a result are then understood to be part of that investment, and not recurrent expenditure.

17. Such projects are fully dedicated to disease control, or have one component aiming at specific diseases, or only target a limited part of the population. They include actions for the control of malaria, leprosy, schistosomiasis, Sexually Transmitted Diseases (STD) and

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*Brazil: Amazon Basin Malaria Control Project; Madagascar: Health Sector Improvement Project; Sao Tome and Principe: Health and Education Project; Equatorial Guinea: Health Improvement Project*

*India: National Leprosy Elimination Project*
AIDS, etc. With the growing importance of the AIDS epidemic and other diseases, more such projects may be prepared in the future. Several agricultural projects have included such components, usually for the control of endemic diseases in the areas targeted by the project. Some projects only wish to address the health of mothers and children, or include the procurement of contraceptive drugs within a family planning project.

18. In the cases of malaria or schistosomiasis and to a lesser extent leprosy and tuberculosis, the appropriate drugs with which to treat the disease can be well identified, and their procurement generally leads to their use in treating only the condition in question. That is not the case for antibiotics used for sexually transmitted diseases, which are less specific and can be used for a wide range of other types of infections. Similar considerations apply to drugs for children (which can often also be used in adults) and some drugs with a large spectrum of indications (anti-pyretics such as acetylsalicylic acid or paracetamol, corticosteroids or pain relievers). In "mother and child health" project components, the only specific products would be those used during infant delivery and vaccines; most other drugs could also be used in other populations. In all these cases, the drugs may very well end up being used for purposes other than those for which they were intended, and the issues targeted by the project may not be fully addressed. It is thus preferable to include mostly specific drugs for Bank financing in such projects, and to leave less specific drugs to other sources (other government procurement, private sector).

19. Projects dealing with specific diseases may include financing for diagnosis and follow-up of these conditions, and the problem of effective drug distribution should be addressed during the early stages of preparation. Full cooperation of national and regional authorities and/or private channels of distribution must be secured for the best possible effectiveness of these projects. Such projects only finance a very limited list of products, making procurement easier. A strict respect for Bank procurement procedures — which allow single source items, such as ivermectin for onchocercosis, for instance — should be enforced by recipient countries.

20. Financing of pharmaceuticals for a project targeting specific disease control should be contemplated only after the epidemiology of the disease is fully understood and its incidence and prevalence have been evaluated, after therapeutic protocols have been agreed upon and drug

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6 Egypt: National Schistosomiasis Control project

7 Uganda: Sexually Transmitted Infections Project; Zimbabwe: Sexually Transmitted Infections Prevention and Care Project

8 Somalia: Farahaane Project, Sudan: Emergency Drought Recovery Project

9 Such as in the Ukraine: proposed Health Project

10 Drugs for such conditions are relatively "pathology-specific" and can hardly be used in other diseases; it is then easier to consider them as investment costs. Vaccines are an even better example, as they can only prevent the disease on which they are targeted. Contraceptives generally fall in that category too.
quantities corresponding to the use of the protocols in the given disease have been calculated. Such projects should include a component regarding dissemination of information on the disease and its treatment. They should also include a training component for health personnel in charge of implementing the project. It is advisable that the supervision plan should, wherever possible, include a drug utilization study to determine the actual end-use of the drugs supplied (at mid-term evaluation, for example); this could be handled by local experts using some of the methodologies developed by WHO.\textsuperscript{11}

*Financing Drug Procurement in the Framework of Pharmaceutical Policy Reform*

21. Many countries have a wasteful pharmaceutical policy as regards public expenditure, or fail to correctly address issues of drug efficacy, safety, cost-effectiveness and rational use. As pharmaceutical expenditures can represent more than half of the total health expenditure of a developing country, such a policy is worth addressing within the framework of a health project, as it can yield major improvements and large savings. Such policy reforms can be supported by a drug procurement component in the project, provided that enough funds from Bank lending are allocated to the process of reform and institutional strengthening and under the condition that procurement procedures correspond to Bank requirements.

22. Projects supporting pharmaceutical policy reform must: (i) address the issue of drug regulations, with special reference to registration regulations (especially as regards generic drugs), quality assurance, and enforcement; (ii) address the issues of training of health personnel (both prescribers and regulatory staff) and dissemination of information about pharmaceuticals; and (iii) help borrowing countries to design and/or update lists of essential drugs and formularies by type of health facility (limited lists of drugs for primary, secondary and tertiary care), and assist in the implementation of a sound public sector procurement system. Drug procurement under such projects has to set an example for the reform of public sector purchases.

23. One of the key issues such projects should address is that of drug financing and price setting. Projects can support cost recovery programs, such as community financing, cost sharing and direct out-of-pocket expenditures. If the option of price controls is selected (to help improve access of the population to essential drugs by containing the profit margins at the levels of manufacturers, wholesale distributors or retail distributors), these projects can provide financing for a sound system of price monitoring. Distribution and pricing of drugs procured through such projects should set standards in these matters.

24. Logistics of distribution have to be addressed in such projects, in a way that supports private sector and community involvement. In the case of vaccines, the safe operation of an adequate "cold chain" is essential. Ensuring an adequate distribution of project drugs through the private sector may be highly efficient, but that will always require that the system of incentives prevalent in the private sector be studied and revisited to provide adequate

\textsuperscript{11} M.N.G. Dukes: "Drug Utilization Studies," WHO 1992
stimulations. Pricing of essential drugs for the most disadvantaged groups also has to be addressed.

25. Such projects should also prepare systems of follow-up on the implementation of the pharmaceutical policy. Funds may be used for institutional strengthening, training and technical support, as these projects should stretch over a long enough period to make monitoring of the effects possible during the project life-span.

26. In spite of sometimes strong borrower pressure, it is not recommended to finance pharmaceutical procurement in health projects that create or upgrade health care facilities, on the basis that they cannot operate without a minimum supply of drugs and other consumable items. The recipient country first has to agree to a set of reforms regarding drug policies. Even if such reforms are not financed through the project, they should become conditions of lending, as they are necessary to ensure the sustainability of drug supply (and operations of health facilities) in the future.

**Financing Drugs for Start-up of Cost Recovery Mechanisms**

27. Cost recovery for drugs in the public sector has been introduced in several countries over the last 10 years, and the changes in the country procurement system created by that new approach to drug financing have sometimes been supported by Bank projects. Several drug revolving funds have been started using Bank financing, the intention being that the sales of drugs to the population should generate enough income for new purchases and stock financing. The key to the success of such projects in low-income countries, once actual drug requirements have been identified, is procurement of cheap essential drugs that can be afforded by the population, especially when mechanisms for support of the poor are not very developed.

28. In such cases, the Bank may finance the setting-up of a procurement agency (in general as a para-public entity): drugs financed under such a scheme are considered as start-up costs which are eligible for project financing, and are not considered recurrent expenditures. Such projects require a very careful design of the procurement organization, including legal status and economic viability, and a thorough review of distribution mechanisms. Such agencies must be financially sustainable, and operate like commercial wholesalers.

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12 If the private sector of drug distribution operates with a system of fixed percentage mark-ups directly proportional to the buying price of drugs, they may be reluctant to distribute cheap drugs such as the ones procured through an International Competitive Bidding (ICB) process, as their profit would be lower than with more expensive products. It is nearly always cheaper and more effective to help a country change its pricing regulations than to set-up a new public drug distribution network.

13 A good example of such an approach is given by the Guinea: Population and Health Project

14 Benin: Health Services Development Project; Burkina Faso: Projet de Développement des Services de Santé.
29. Drug procurement agencies should have access to extensive market information. The only way in which these agencies can negotiate with producers on an equal footing is to have as complete as possible a knowledge of both what is produced by the market to fulfill their needs and who the producers are. In order to achieve that, it is essential that the procurement agent have: (i) a wide technical knowledge (and preferably include staff fully trained as pharmacists); (ii) a comprehensive access to pharmaceutical market information; and (iii) current technical data on drugs. World Bank financing should include funds for such documents, including the World Directory of Pharmaceutical Manufacturers (IMS), other directories and price lists (UNICEF, IDA, M.S.H. International Drug Price Indicator Guide, and at least one pharmaceutical journal), and cover the costs of training for some staff of the procurement agency.

30. The procurement agency has to adopt strict procedures for the procurement of drugs using Bank financing. When the procurement agency uses its own funds or other sources of financing, however, it is not essential that procurement through ICB be an absolute rule, because: (i) direct purchases without competition are the only possibility for patented drugs (which the procurement agency may also need); and (ii) direct purchases can also be used for other products as well — procurement is then based on direct negotiations, the result of which can be very satisfactory if the purchaser has enough knowledge of the market. Direct purchases with competition (shopping) can also apply to all types of products. Offers are requested from a limited number of producers, and the whole procedure (excluding delivery) can take less than 18 weeks (against more than 6 months for an ICB procedure). Throughout the world, the most efficient procurement agencies use a combination of negotiations and various forms of competition for their purchases and neither they nor the Bank limit the process to ICB.

31. When the procurement agency also holds stocks, it is important that the project include a warehouse management component: rehabilitation and equipment of physical facilities; implementation of inventory management techniques and training of staff. However, the three functions — procurement, wholesale and distribution — do not have to be combined in one single agency and it may often be preferable to separate them. For example, use of the private sector for transporting drugs from a central warehouse to various health facilities is nearly always more economical than keeping that function with the procurement agency.

32. Finally, projects financing drugs within the framework of a cost recovery mechanism must address the issue of pricing policies. It is preferable that the cost recovery system be organized in such a way that selling prices cover the cost of stock replenishment, logistics, management and reserves. Drug revolving funds or cost recovery programs paying for more than drugs (Bamako Initiative) are highly dependent on the quality of procurement procedures, the pricing system, and the planning of orders and deliveries to avoid shortages.

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15 Such price lists should be used at appraisal to determine the value of the pharmaceutical package to be procured from the loan.

16 Comoros Islands: Health and Population Project
Financing Drugs Within Critical Imports Loans

33. Several lending instruments provide financing for imports, the eligibility of which is assessed using either a positive or a negative list, and can cover pharmaceuticals. Sectoral Adjustment Loans, which finance recurrent costs against policy reform conditionalities (para 7.(v)), may finance imports of pharmaceuticals (especially when dealing with the health sector) because drugs are never included in the negative lists of imports to be financed under Structural Adjustment Loans. They have often been included in critical import financing programs and in the recently developed Rehabilitation Loans for Republics of the Former Soviet Union. Such loans represent a support to the balance of payments in times of crisis, and are seldom repeated.

34. In general, the list of drugs to be financed using such loans tends to be wide, and not to target specific diseases. Such projects usually do not lend themselves to detailed policy conditionalities as regards the pharmaceutical sector, and it is important that they address two issues: that of procurement and that of drug financing. Conditionalities can be imposed as regards strict enforcement of Bank procurement procedures in such projects.

35. Financing of critical imports can only have a beneficial effect on policy practices if the procurement process is improved significantly over the country’s usual procedures, and if prices obtained through Bank procurement are significantly lower than usual in the country. In order to reach such a target, it may be useful for the Government to consider contracting a reputable private firm or a UN agency such as UNICEF to undertake drug procurement in strict accordance with Bank procedures (and be paid accordingly). As many countries do not routinely use international tenders for drugs, Bank financing provides a good opportunity to amend the country’s procurement procedures and to train staff. (The cost of such training may be covered by the Bank’s loan.)

36. Adjustment operations (national or sectoral) finance critical imports under the condition that major policy reforms be undertaken by the country. Health sector adjustment operations should include an individualized pharmaceutical policy component, consistent with a comprehensive health financing package, to make sure that this sub-sector is correctly reformed. However, national adjustment loans can also address issues relating to the pharmaceutical sector. The Burkina Faso Economic Recovery Credit (1994) provided an opportunity to revise the system of drug price subsidies and the mechanisms of determination of distribution mark-ups. In all cases, adjustment operations usually require a set of conditionalities that may delay procurement: practically, time needed to fulfill these conditions should be used for the establishment of a procurement unit, the preparation of tender documents and the advertisement of the procurement process.

Selection of a List of Drugs for Procurement

37. Because of insufficient planning and poor understanding of the population’s drug requirements, several countries have requested Bank financing for drugs which have not corresponded to their most important needs. Even when agreements have been reached during
project preparation, it is not uncommon that drugs lists presented for "no-objection" at the time of the procurement process fail to correspond to earlier agreements. Several reasons can be given for such variations, some of which may be valid: change in the epidemiology or morbidity profile in the country (a rare but possible occurrence); change in the perception of health priorities; influence of specific medical groups (often tertiary care doctors); and even pressure from pharmaceutical manufacturers. The result is that drug lists often vary from the early stages of project preparation to the moment of actual procurement.

38. In all cases, drug procurement using World Bank funds should be limited to essential drugs only. Essential drugs are pharmaceutical products that meet the needs of the majority of the population and can help treat the majority of conditions in that population. Also, essential drugs are products with a long and satisfactory history of efficacy and safety, are nearly always available under a generic form, and are generally cheap and cost effective. The concept of an essential drug has been widely developed and disseminated by WHO, which publishes regular updates of a model "Standard list of essential drugs" (the latest edition was published in 1992). WHO has provided guidelines for countries to establish their own list of essential drugs, adapted to local morbidity patterns, training and experience of health staff, health care organization and financial resources. Although most countries have established an essential drug list, only some update it regularly and use it for the implementation of their public health policy.

39. On several occasions, World Bank projects have financed essential drugs not included in the recipient country’s list, generally because that list was too old, or because it was not considered good enough. It is important for the Bank, however, to support the countries' essential drug lists and to finance drugs from such lists: for instance, it is better for reasons of "ownership" of the project and to be coherent with local regulations, that a project finance only a subset of the country’s essential drug list rather than alternative products that are not on the list. Exceptions include: (i) cases where the essential drug list still does not include contraceptives and/or essential micronutrients, which should still be considered for Bank-financed procurement; and (ii) cases where the list includes drugs that should not be financed by the Bank, i.e., drugs which have been found to be unduly hazardous or to have a high risk of side effects in other countries, drugs which have been found inefficient, or potentially addictive substances. In both cases, the project should support the updating of the country’s list. Such an update may become a project covenant.

40. Limiting procurement to the essential drug list of the country, and not considering other drugs for financing under Bank projects may sometimes be resented by health authorities. It should be emphasized, however, that countries remain entirely free to procure other drugs using other resources. As Bank financing never covers the entire drug needs of a country (see para

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17 Such changes may include the outbreak of an epidemic, as was the case with cholera in several countries of Latin America in the early 1990s.

18 Essential drugs are generally off patent. Product patents protect companies which discover new products by giving them a position of temporary monopoly during which they can sell at a relatively high price.
10), the option of restricting procurement to essential drugs does not represent a limitation of the country's freedom of choice regarding pharmaceutical purchases. On the contrary, it supports the Government's Essential Drug List, which is not always implemented fully for public sector procurement, with consequences such as lower cost effectiveness of procurement and loss of credibility for the Government and its pharmaceutical experts.

41. All essential drugs financed through World Bank loans should be procured under generic name, i.e. using their International Non-Proprietary Name (INN). For practical reasons, it is recommended to restrict the procurement to drugs that do not require specific administrative authorizations for international trade, i.e., potentially addictive substances (such as morphine derivatives).

Quantities of Drugs to be Procured

42. The quantities of each item have to be determined by the client, preferably using an objective assessment of the population's drug requirements as a guideline. Because of the length of the procurement process, the level of current stocks in the country usually does not have to be considered, as it is likely those stocks will have been consumed by the time drugs procured through Bank financing are delivered. Quantities for each product have to be large enough to attract bids from as many manufacturers as possible, as prices tend to decrease when quantities are larger and competition wider. If the quantities requested are too small, the risk of relatively high prices will increase because fewer producers enter the competition and the relative cost of logistics rises. In the worst cases, there may be no evaluated bid for several of the products, and the credibility of the procurement process is called into doubt.

43. On the other hand, it is important to avoid large amounts of stock; this can be ensured not through reductions of quantities but through scheduled deliveries. As tenders tend to generate over-stocks for a limited number of drugs, it is preferable that more than one delivery be organized for any large volume of drugs procured. It is also necessary to keep the cost of logistics low: transportation has to be by sea, then by land; air transportation is normally not needed, as there is no emergency that would justify the higher costs. Most procurement

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19 International non-proprietary names (INN) are assigned through WHO based on general principles set forth by the WHO and published in multiple languages in the WHO Drug Information. A committee, which operates under the umbrella of the WHO expert committee on Specifications for Pharmaceutical Preparations and is represented by members of national nomenclature commissions from USA, Britain, France, Spain and Russia, meets every 6 months to assign the INNs.

20 Limiting the number of drugs on a tender list also allows for larger quantities of each drug, thus making a real difference as regards essential drug availability. Larger quantities of fewer products also make contracting and disbursement operations simpler.

21 That problem has happened in some Bank financed projects (such as the Albania: Health Rehabilitation Project), when quantities to be procured were too small and/or when the procurement process was not well enough advertised.
agencies do not have enough knowledge of drug consumption history and are not able to
determine how demand would vary with a better availability of stocks. Projects supporting
procurement agencies would help them to acquire experience on stock management and the
respective costs of procurement and ownership.

**Drug Information**

44. It is necessary that projects include a component on information to prescribers and
distributors to make sure that the drugs will indeed be prescribed and sold to patients (or
distributed in hospital pharmacies). Often, products procured through Bank tenders are bought
under generic name, and are manufactured by companies that are not familiar to doctors and
pharmacists, and do not advertise in the country. The only way to make sure that the stock of
such drugs move is to sensitize all the actors; otherwise old prescription habits and various
commercial pressure may cause physicians and patients to mistrust the new items.

45. In order to improve the information needed by prescribers and distributors, projects may
include financing of several types of tools: (i) production of an information booklet (including
a simple therapeutic guide) on the drugs to be procured under the tender, or more generally on
the use of essential drugs; (ii) production of a small "dictionary of equivalents" matching the
generic names of drugs procured with the commercial names of equivalent products already
known in the country; (iii) financing the updating of the country's drugs nomenclature, once the
drugs procured under the project have been registered. It is often useful to have the production
of a formulary (prescriber information about a limited list of drugs available for purchase for
the public sector) financed through the project, so that future public procurement can be
rationalized. A formulary may be wider than the national list of essential drugs, because of the
inclusion of hospital or dietary products.

46. It is also often useful to include under the project's financing a sub-component for the
information to be provided to patients, especially as regards generic drugs. Techniques of social
marketing have to be used there, to convey the message that generic drugs are as good and safe
as brand name products and, that patients have the right to ask for these cheaper drugs and be
sold generic products if they wish (and provided local regulations allow).

47. The cost of information policy is not negligible, as it is desirable that all doctors and
pharmacists receive the information provided, preferably without charge. Costs include those
for design and publication of documents, production of texts, and costs of dissemination. Such
costs can be born by the project (and financed by the Bank). Then, the project can also
represent an opportunity to start (or upgrade) a drug information unit in the Ministry of Health,
with appropriate hardware and software and training.
II. Practical Procurement Issues

48. Once the decision has been taken to include financing for drug procurement in a project, it is important to determine the conditions by which that procurement process will take place. Since the early 1980s, the share of the pharmaceutical market taken by generic drugs has increased steadily, and most essential drugs can now be procured under conditions of open competition. During the last 5 to 10 years, several companies manufacturing a wide range of high quality generic products have gained respectability (and a large market share), and some of the multinational companies which used to raise the issue of poor quality of generic products no longer do so, particularly since they often have also launched their own production of generics.

49. High quality generic drugs are now produced in a large number of countries, and the Bank recommends ICB as the most appropriate, but not the only, procurement procedure. The Bank requires that for ICB, its standard Bidding Documents be used. Exceptions such as "orphan drugs" or single source items can still be procured using the Bank’s Standard Bidding Documents, and be included in the general specifications of an international tender. Because of the specific nature of pharmaceuticals and the problems raised by drug quality (see paras 54-59), further discussion is necessary on the practical organization of ICB for drug procurement and on alternative options.

Procurement Agency

50. Most procurement operations tend to be handled by the Project Implementation (or Coordination) Unit, which usually does not have sufficient expertise for the organization and evaluation of a pharmaceutical tender. A procurement agency for drugs not only must have the technical and pharmaceutical know-how for the evaluation of tenders, but also for the preparation and follow-up of purchases. As mentioned above, a Bank loan can finance a large proportion of public sector pharmaceutical requirements and not be limited to the mere procurement of pharmaceuticals (components on drug information, pricing, etc.). These require specialized attention, the absence of which may lead to serious procurement and/or disbursement problems.

51. When the operation leading to drug procurement includes the establishment of or support to a National Procurement Agency, it is essential that the agency handles the entire process directly. Support in the form of technical assistance during the preparation, and evaluation of the first few international tenders is often needed, and in several countries long-term technical assistance (one year) has been highly beneficial for the implementation of adequate procurement mechanisms and the acquisition of useful market intelligence.

52. UN organizations (such as UNICEF or UNFPA) can be considered as suppliers in case of emergency for amounts less than US$10 million or can be appointed as procurement agencies provided they strictly comply with Bank procurement procedures (see Box 2). It is better to only appoint such procurement agencies in cases where the procurement process itself is not part
of the policy improvements targeted by the Bank operation, i.e. when the project's long term objectives do not stress the importance of public sector procurement whereas its short term objectives require efficient drug procurement. UN agencies can be used for programs addressing a specific disease or objective (such as family planning programs), for which they are usually faster and more efficient than local procurement agencies. They are also a good choice for projects in which drug financing is accepted, but where there is no pharmaceutical component (within the framework of agricultural or industrial projects, for example). UNICEF's requirement of 100 percent advance payment may not be always favorably considered by borrowers, but other payment mechanisms are available under Bank financing, and can be negotiated with UNICEF on a case by case basis.

53. UNICEF is usually one of the best possible choices for procurement of vaccines, as it is the single largest purchaser of vaccines in the world (60 percent of the world production of vaccines covered by the Expanded Program of Immunization are purchased by UNICEF). In that case, procurement should not be considered "single source" (but procurement from a UN agency). It has often been recommended that this exception to Bank procurement procedures should be explicitly stated in the Loan agreement. Vaccines supplied by UNICEF are generally well accepted and do not typically create complex problems of registration, as is the case with drugs.

The Issue of Drug Registration

54. The issue of drug registration is complex, and must be dealt with carefully. Most developed countries would not agree to procure and use drugs not registered at the national level, and have tight regulations regarding exceptions (such as drugs not yet registered which may be imported for exceptional cases, or for tests and clinical trials with a view to future registration). The registration process is intended to protect the country's population from unsafe drugs or from undocumented claims of efficacy. However, in many countries, the registration process is also a protectionist tool used to bar entry to new drugs.

55. The registration process is usually different for new molecules and for generic drugs. New molecules have to pass through a complex and lengthy process of studies, in vitro and in vivo, before being registered. International agreements (such as in the European Union or the Nordic States) sometimes make it possible for drug manufacturers to avoid repeating this complex process in each country where they wish their drug to be registered. Generic products

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22 UNICEF procures vaccines from various sources, using a combination of tenders, international shopping and direct contracting. The issue of vaccine quality control is very carefully addressed by UNICEF, and purchasers may avoid duplicating such tests.

23 This type of policy does not always protect local industries only. It sometimes gives an unfair advantage to drugs imported from various sources by preventing competition from other foreign suppliers. That situation may arise from traditions of purchase and prescriptions, or from other motives: in several countries, there is a serious issue of governance in the pharmaceutical sector.
only have to prove they are equivalent to an already registered form of the same molecule, and the registration mechanisms for generics should normally be simpler and shorter.

56. The Bank's "Standard bidding documents" require that all drugs be manufactured in compliance with Good Manufacturing Practice (GMP) regulations, and that bidders produce a copy of the most recent GMP certificate issued by their national regulatory agency. The World Health Organization has organized a certification scheme that refers to the quality of pharmaceutical products manufactured for export. It is actually an export certificate which tells the importing country whether the product is licensed in the country of origin (with a few exceptions, e.g. drugs against tropical diseases) and whether the manufacturer complied with the internationally accepted standards of Good Manufacturing Practice (GMP). However, as some countries do not monitor GMP as closely as they should, this certificate, issued by the "exporting" government on the request of "importing" governments, may not represent an optimal guarantee. Despite several potential advantages, the WHO certification scheme is poorly understood, poorly enforced, and has failed to represent a guarantee of quality for importers.

57. The Bank recommends a system of "postqualification," which means that registration of the drug in the borrowing country is a condition of contract award, and not of bidding, i.e. that there is no condition (prequalification) to submit a bid. Countries are recommended to establish a fast-track registration process (see Box 2) by which, upon presentation of a set of documentation requested in the bidding documents, including proof of registration and approval in the country of origin, the drugs of the lowest estimated bidder can be automatically registered. However, that recommendation requires that documents approved by the country of origin be considered dependable. That is not always the case, and the WHO certification scheme does not replace inadequate regulations or their enforcement. Therefore, it is not surprising that authorities in several countries deny registration to some bidders on the basis that their certificates do not originate from what they consider a dependable source. Such attitudes have to be reviewed case by case, as there cannot be a standard policy. It is still the Bank's policy, however, that the contract should not be financed by the Bank (misprocurement) if registration is unreasonably denied to a qualified bidder.

58. Where a country does not have the means to test the quality of drugs for their registration process, it should normally use the services of a foreign facility, the cost of which would have to be financed from the loan. Such an option is not cheap, but not all the drugs have to be tested: only products for which there may be a doubt about quality and where

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24 Some exporting countries have actually issued the certificate irrespective of the manufacturer complying with the GMP guidelines allowing export of substandard drugs and causing both hazards to consumers and unfair competition in the market.

25 Quality control at registration is often questioned. Generally, manufacturers always produce samples that fully comply with quality requirements, and testing them is often considered tedious, expensive and unproductive. Surprise quality tests on batches selected among drugs delivered are usually more cost effective.
Box 2: Romania Health Rehabilitation Loan

This project provided an opportunity for the Romanian pharmaceutical community to improve their market intelligence and their access to reliable sources of cheap quality drugs. It was decided all drugs procured through competitive bidding would be registered in Romania, so that after project completion, Romanian importers could still routinely buy and distribute the same products.

A specific regulation was introduced by the Prime Minister for a "fast track" registration process of the project's pharmaceuticals, and support (equipment and spare parts) was included to the National Drug Quality Control Institute through the project.

Drugs financed under that project were purchased using UNICEF as a procurement agent. The tender documents issued by UNICEF required that all interested bidders submit an offer including all documents necessary for the fast track registration process. Although registration of the generics procured by UNICEF was not always as rapid as expected, less than 10 percent of the drugs were not adequately registered at project mid-term. Market studies after two years showed that some importers had contacted the suppliers selected by UNICEF and were now regularly purchasing their products.

Documents are not conclusive need be tested. Another difficulty is the time it takes to have such quality tests performed. The best option for a borrower is to take these costs into consideration during tender evaluation, even if it may result in the lowest bidder not being selected, if the cost of making sure the lowest bidder is of high enough standards exceeds the price difference with the next lowest bidder.

59. In order to be able to perform tests (either locally or abroad) and examine the acceptability of proposed products, the procurement agency should require all bidders to submit samples with their offer. Samples have the advantage that they provide information that can be evaluated: quality of packaging, quality of containers, quality of labelling. Furthermore, simple tests (such as dissolution time of a tablet in water) can be performed on samples without the need for a sophisticated laboratory. Samples must be supplied in small quantities and be labelled as such, so that the risk of their being used otherwise is reduced.

Product Labelling

60. Because of the relative simplicity of technical specifications for pharmaceuticals, the labelling component of these specifications often tends to be overlooked. It is actually very important that packaging and labelling specifications be carefully designed in order to avoid major problems during tender evaluation and at delivery of the drugs.

61. It is potentially dangerous and normally forbidden to deliver pharmaceuticals without appropriate product information in the language of the end-user (packaging and inserts). Labelling and information regulations are part of Good Manufacturing Practice, and must be given as much emphasis as drug quality requirements. When drugs procured under Bank financing do not get distributed appropriately, it is often because packaging materials are not provided in the language of the country, or that doctors and patients feel they cannot trust them.
In some countries, it is difficult to ensure that suppliers provide adequate labelling, especially if the language is not widely used and the local drug market small.

62. The regulation relating to labelling creates a specific problem as regards the samples provided by bidders. If the tender documents require samples to be labelled in the language of the country: (i) it is nearly impossible for a pharmaceutical manufacturer to produce and ship samples in the correct language in the time available for a drug tender (4 to 6 weeks), and it is a costly procedure (the additional cost would be about 5 percent for tablets and 2 percent for vials) and; (ii) drugs with labels in the new language would no longer be registered in the country of origin, and would no longer comply with the obligation of being "strictly identical" to the one with a registration in the country of origin. Manufacturers and distributors are forbidden to modify anything to the form that has been accepted for registration. To change the language of the labeling, the manufacturer would have to require a new registration, which would not be profitable under the punctual conditions of a tender. If samples are in the language of the manufacturer, they do not, strictly speaking, correspond to what should be delivered at the time of shipment, and cannot, in theory, be considered as samples of contracted goods. However, this latter solution has to be accepted.

63. The amount of information to be produced on the packaging and inserts is a decision of the borrower, and details have to be provided in the registration documents. However, for the borrower's decisions to be enforced, all relevant details have to be provided with the tender documents, including, if necessary, translations of all compulsory data into the end-user's language. Countries using more than one language may require the information to be provided in several languages, but they have to be aware of the additional costs and delays that such a requirement may create.

Advertisement Procedures

64. The efficiency of the ICB process hinges on a wide dissemination of the invitation to tender in order mobilize competition, especially in small countries where only a restricted number of drug manufacturers have commercial activity. Too often, in countries practicing restricted tenders, the prequalified firms belong to the small group of usual suppliers of the procurement agency. An efficient ICB procedure requires wide advertisement, through notices in newspapers and in specialized international publications. In several cases, however notices have been published only in the local press (and there are examples where only the Sunday edition was used), whose diffusion abroad was negligible, and hence only few bidders have participated, leading to high prices. Whatever the procedure used, the procurement agency should ensure that it reaches the international market. In some cases, the agency will not be able to contact potential interested suppliers and to get them bidding documents on time, because it does not know them well enough. Using embassies (as is usually the case for dissemination of information on tenders) has a very low efficacy. The best solution would be for drug procurement agencies to have an updated directory of producers, which to date is very seldom the case. Such directories represent a minimal investment that may be financed through the Bank loan.
Technical Evaluation

65. Technical evaluation has to be undertaken by a specific committee, with an appropriate competence mix. In the case of large tenders, it is better that specialized software be used for the evaluation. In the case of pharmaceuticals, protests and complains by unsuccessful bidders are common, and it is not unusual for the legality and fairness of the evaluation process to be questioned. The contract should be awarded to the lowest evaluated bidder, i.e. the firm offering the lowest price of all the bids submitted in full conformity with the tender documents and proposing products of acceptable quality. It is reasonable to set a maximum price that the procurement agency is willing to pay for each product, and to declare unsuccessful a tender for which all the offers are at a higher price. However, such an approach requires a certain level of market intelligence (see para 29), that may not always be available. One possibility is to compare prices with those of international catalogues (which should also be used at project appraisal — see para 29).

66. It is not uncommon for a large proportion of offers to be rejected at this stage because of such technical failings as the presentation of bids in single envelopes, unfilled forms, missing documents, missing samples, etc. In most cases, rejection at opening comes from insufficient attention from the bidders (World Bank standard bidding documents are clear and detailed). Debates can be arduous over the rejection of the offer and the request for additional information from the firm. In general, it is in the interest of the client to keep as many offers as possible in the competition (as it increases the chance of low prices); it is, however, necessary to evaluate offers by the rules that are set in the bidding documents, and to treat enterprises fairly. Bidders who have not taken the trouble to put together a complete and good offer should not be treated on the same terms as those who have.

Conclusion: the Outcome of Drug Procurement

67. Even with adequate international bidding procedures, prices may vary considerably from one procurement to another. Figure 1 shows the price of an essential drug, cotrimoxazolé, after ICB procurement (believed to have been fair and correct) using Bank financing, in various countries in 1992-93. Prices vary with a factor of nearly one to five. This figure gives an example of the complexity of pharmaceutical markets, which are fragmented and heterogenous, and for which there is no real "world price."

68. Discrepancies between countries can be explained by various reasons: the quality of the advertisement process (see para 64); the perceived strategic importance of the borrower's market for manufacturers (in 1992-93, the Baltic states may have been perceived as promising markets, and manufacturers may have considered a low price as way to gain entry); the quality

\[26\] Software should take into consideration discounts, grouping of products, and other elements of evaluation such as manufacturing and delivery time, reputation of the supplier, etc.
of tender evaluation; the distance for deliveries (comparisons in the figure are established on CIF prices); etc. It is still legitimate to use UNICEF catalogue prices as a reference, even if there are other price catalogues and although they are obtained through slightly different procurement procedures.

![Procurement of Co-trimoxazole (400/80 mg)](image)

69. More than the price of drugs through correct procurement using World Bank financing, it is the sustainability of the supply process and the actual access of the population to essential drugs that matter most. These preoccupations explain the restrictions to financing of drug procurement recommended in this paper. Pharmaceutical products are essential inputs of any health system, but should not be considered outside of the global context of health and pharmaceutical policies. Their procurement through Bank projects can help in the reforms of the health sector that many countries are embarking on, provided it takes into consideration the specific features of pharmaceuticals.
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