WHO/EDM/PAR/2003.3

Guidelines for price discounts of single-source pharmaceuticals

World Health Organization
Joint United Nations Programme on HIV/AIDS
United Nations Children's Fund
United Nations Population Fund

Acknowledgements

Status of this document
This is a statement of the Interagency Pharmaceutical Coordination Group[1], issued on behalf of the Group by the WHO Department of Essential Drugs and Medicines Policy, Geneva.

Development process of these guidelines
A first draft was written by Dr Hans V. Hogerzeil of WHO's Department of Essential Drugs and Medicines Policy (EDM) in collaboration with Dr Maria Neira and staff of the WHO Cluster of Communicable Diseases (CDS). This draft was discussed with members of the International Pharmaceutical Coordination Group (UNAIDS, UNFPA, UNICEF, WHO and the World Bank) at their meeting of 28 September 2000, and their comments taken into consideration.

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The final text of the statement was approved by the IPC at their meeting of 12 November 2002.

[1] The IPC group consists of the pharmaceutical policy advisers of UNAIDS, UNFPA, UNICEF, WHO and the World Bank. More information on IPC is available on the following web site: www.who.int/medicines

Introduction

Access to essential medicines for developing country populations is crucial to maintaining and improving health. Access to essential medicines depends on four factors: rational selection, affordable prices, sustainable financing and reliable health systems. They are best secured through development and implementation of a national drug policy and an essential drugs programme. Medicine donations and price discounts, when clearly justified, carefully planned and properly managed, can be applied as additional policy instruments to improve access. They can contribute to reducing the cost of health care, and help to reduce unnecessary suffering and save lives. However, their impact on and relation to the other factors also need to be considered.

There are several good examples of long-term donation programmes, including the ivermectin programme that has been active for over 25 years and has drastically reduced the incidence and prevalence of river blindness. Long-term agreements also exist for the donation of ivermectin and albendazole for lymphatic filariasis, for azithromycin for trachoma and for nevirapine for the prevention of mother-to-child-transmission of HIV/AIDS. Experiences with discount agreements are more recent, and more mixed. Some drugs for the treatment of multi-drug resistant tuberculosis are successfully being offered at large discounts. On the other hand, the offer by five pharmaceutical companies for discounts on medicines needed for the care of HIV/AIDS patients has not been taken up very widely. A recent discount agreement for lumefantrine-artesunate against malaria has not yet been evaluated.

Target audience

These interagency guidelines are designed to maximize the benefit of price discount arrangements. They are intended for policy-makers and technical staff in international and bilateral agencies active in international health development support, for pharmaceutical companies, and for governments and NGOs in recipient countries.

Objectives of these guidelines

- Maximize the benefit to recipients of price discounts for single-source products;
- Help prevent unnecessary misunderstandings and delays;
- Promote the integration of efforts leading to price discounts of single-source products within long-term programmes, in order to improve access to essential medicines for priority diseases.

Link between price discounts and equitable pricing

Equitable pricing is the adaptation of prices to purchasing power in different countries. This aim can be achieved in many ways, such as (1) increased competition, generic policies and bulk purchasing; (2) voluntary price agreements and discounts; (3) voluntary licensing with transfer of technology and geographic restriction; (4) non-exclusive compulsory licensing and (5) systematic patent waivers. Voluntary price discounts are therefore only one way to achieve the wider objective of equitable pricing.

Link to guidelines for drug donations, scope and review of these guidelines

This document should be read in conjunction with the interagency *Guidelines for Drug Donations,* which give the general principles for drug donations. The present guidelines are intended to cover the additional specific aspects of price discounts of single-source pharmaceuticals. Although generic equivalents may exist in some countries, single-source pharmaceuticals are usually patented products and the discounts are usually offered by or negotiated with one single pharmaceutical company. These guidelines are not international regulations but are intended as a checklist of important issues to consider when planning, executing, supporting or evaluating a programme of price discounts of single-source pharmaceuticals in the public and/or private sector. The guidelines will be reviewed in 2005.

Guidelines for price discounts of single-source pharmaceuticals

When planning or negotiating offers of price discounts of single-source products, the following issues need to be considered. These are presented in accordance with the four components of the WHO framework for access to essential medicines (rational selection, affordable prices, sustainable financing and reliable health systems).

1. The discount programme should aim to assist countries in promoting access

The discount agreement should aim to assist countries in their efforts to achieve equitable and sustainable access to essential health care, including essential medicines. The programme should not be mainly promotional in character, nor should it be designed primarily to increase market opportunities for the company involved to the detriment of others.

Justification and explanation
Discount agreements should not constitute a tool for market penetration, for influencing national therapeutic choices, or for rewarding certain national pharmaceutical and development policies.

Practical implications
The underlying aim for the company should be, and should be perceived to be, to make a genuine contribution to a public health objective which is not otherwise being addressed. If this is not paramount, the justification for the pricing offer needs to be reviewed. The programme should not result in preferential access to pharmaceutical policy decision makers, or be used to influence government health policy or procurement decisions.

2. The eligible population should be selected on the basis of agreed criteria

The countries and patient populations for which the pricing offer is made should be jointly selected on the basis of agreed justifiable criteria, such as health needs, expression of interest, political commitment, economic status, health system infrastructure and potential for sustainability.

Justification and explanation
The grounds for selecting countries for discount agreements have not always been transparent. This article is intended to prevent national, international or non-governmental agencies being perceived as colluding with industry to reward or punish countries on commercial, international property rights or other criteria.

Practical implications
If a discount agreement is executed together with a UN institution, the selection criteria should be justifiable and the process should be transparent. The final selection of countries and patient populations should be a joint process between the relevant UN institution, the company concerned and recipient countries or organizations which have expressed an interest in the offer.

3. The product should be registered for the relevant indication in the country of destination

Justification and explanation
Single-source products are sometimes not (yet) registered in the recipient country. Such registration is needed to ensure that the appropriate regulatory body in the recipient country has reviewed the safety, efficacy and quality of the product.

Practical implications, possible exceptions
Products should preferably also be registered for the relevant indication in the country of origin; and they usually are. However, if this is not the case, an acceptable explanation should be provided. If the evidence on efficacy, safety and quality for the relevant indication is strong enough, it should be confirmed by the drug regulatory agency in the recipient country. If it is not, the data need to be developed through proper studies. For new products, pharmacovigilance systems may need to be put in place.

4. The medicine should be recommended in a recognized clinical guideline

The medicine should offer a cost-effective and safe treatment for the disease, and be recommended by an officially published WHO treatment guideline or included in the *WHO Model Formulary*. The medicine should preferably be included in a national or organizational treatment guideline and in the national list of essential medicines.

Justification and explanation
Some new products are not yet fully evaluated on their safety and efficacy under field conditions in developing countries, and on their cost-effectiveness and public health relevance. This statement is intended to encourage the relevant international and national bodies (such as the national drug and therapeutics committee) to define the place of the medicine in national or organizational treatment schedules.

Practical implications
If the medicine is not (yet) part of an official treatment recommendation, it could be utilized within an operational research project with the necessary planning and safeguards (for example, formulation of research questions, an approved research protocol and ethical clearance).

5. The discounted price should be compared with prices of equivalent medicines

The discounted price offered should be compared with the prices of the generic and therapeutic equivalents legally available on the world market.

Justification and explanation
Negotiators in recipient countries may not always be aware that the discounted price could still be above the price of generic or therapeutic equivalents legally available on the world market.

Practical implications
If the product is not under patent in the recipient country, importation or production of generic equivalents may be possible, provided they have been registered. Therapeutic alternatives may also be available and should be considered.

6. Distribution and other costs should be estimated and funding assured

Current and future additional funding requirements for the product and its transport, distribution, training and use should be estimated in advance and the funding should be assured. This also applies to additional costs to national and international organizations involved, such as meeting costs, travel costs and country visits.

Justification and explanation
Besides costs for transport, distribution and special reporting systems, other costs may include those for diagnostic facilities, laboratories, training and supervision of health workers, surveillance, etc. These costs are usually not included in the price offer and the need to cover them from other sources should be weighed against the need to fund other important public health interventions. National and international organizations, such as United Nations institutions, could contribute to the programme by providing a political entry point, policy guidance and technical assistance. However, the additional costs to these organizations can be considerable and can rarely be met from the regular budget.

Practical implications
All additional costs should be estimated and funding arrangements be made between the parties concerned. It should not automatically be assumed that the recipient government, nor the national or international organizations involved, will be able to absorb all such costs from their existing budget, as this may imply that personnel and/or funds are diverted away from more important programmes. In general, new activities should be funded from new funds. The use of development loans to finance running costs is not recommended.

7. The scope of the offer should be clearly specified

The scope of the discount (e.g. geographical areas, patient categories, products, volume and duration) should be clearly specified. If the discounted price is limited in scope or in time, these limitations must be clearly defined, and the needs of other patients and the long-term sustainability of the programme must be addressed.

Justification and explanation
Many discount arrangements are limited in time or in scope, e.g. limited to certain types of patients, to special delivery arrangements, or to public sector facilities only. This may lead to an increased demand from other patients (for example, patients in the private sector) or to a need for continued use in the case of life-long treatment.

Practical implications
It is important to clearly define the patient selection criteria and duration of the programme. Recipient countries should determine how the demand from other patients not covered by the agreement will be addressed, and whether there will be a continued need for the medicines after the programme is completed. All programmes should include measures to promote long-term sustainability, including sustained production capacity. Multi-year commitments should be given preference over programmes with shorter commitments.

8. Diagnostic and clinical guidelines must be promoted, and treatment facilities available

Diagnostic criteria and clinical guidelines for the effective use of the medicine must be defined and promoted. Health workers must have been trained and a supervision system must be in place. Diagnostic and treatment facilities must be available or be developed.

Justification and explanation
Many discount arrangements involve medicines which are not (yet) widely used in the recipient country and for which training and supervision are therefore needed. New diagnostic and treatment facilities and training may also be required.

Practical implications
Diagnostic and treatment facilities, and programmes for training and supervision must be put in place before the medicine can be distributed and used. The financial requirements for developing and running such facilities need to be estimated and addressed (see also guideline 6).

9. Systems for supply and reporting must be defined

The systems for supply, distribution, monitoring and reporting must be defined in advance. These systems should not create an undue burden for all concerned and should, as far as possible, be integrated within existing systems.

Justification and explanation
It is important for the company, the UN institution(s) involved and the recipient country or organization to clearly define the administrative systems required to manage the programme. A pragmatic balance must be struck between the need to promote rational use of the products and reduce the risks of improper use, waste and theft, and the need to minimize the administrative burden for all parties concerned.

Practical implications
As much as possible the supply, distribution, training, supervision, monitoring and reporting on medicines subject to the discount agreement should be integrated with existing systems. If special safety monitoring (for example, on use in pregnancy) is necessary but not possible, the medicine should not be used.

10. The content of the discount agreement should be public

Information regarding the content of the discount agreement and the experiences with the programme should be accessible to the public.

Justification and explanation
Information regarding the content of discount agreements is often not accessible to the public, and the experiences with these programmes are rarely published independently. In matters related to public health, and when public institutions are involved, openness is essential.

Practical implications
When discount agreements have been concluded, the terms of the agreement, including the selection of countries and patient populations, the agreed price, the type and quantity of the goods and services, and the duration of the agreement, should be published. The same applies to evaluation reports on experiences with the programme and its impact.