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Guidelines for Drug Donations

Revised 1999

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Caritas Internationalis
Churches' Action for Health of the World Council of Churches
International Committee of the Red Cross
International Federation of Red Cross and Red Crescent Societies
International Pharmaceutical Federation
Joint United NationsProgramme on HIV/AIDS
Médecins Sans Frontières
Office of the United Nations High Commissioner for Refugees
OXFAM
Pharmaciens Sans Frontières
United Nations Children's Fund
United Nations Development Programme
United Nations Population Fund
World Bank

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I. Introduction

These *Guidelines for drug donations* have been developed by the World Health Organization (WHO) in cooperation with the major international agencies active in humanitarian relief.

The first version was issued in May 1996 and represented the consensus of WHO, Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, the Office of the United Nations High Commissioner for Refugees, OXFAM and the United Nations Children's Fund. In 1999 the number of co-sponsors expanded to include Caritas Internationalis, the International Pharmaceutical Federation, Pharmaciens Sans Frontières, UNAIDS, the United Nations Development Programme, the United Nations Population Fund and the World Bank.

The *Guidelines* aim to improve the quality of drug donations, not to hinder them. They are not an international regulation, but are intended to serve as a basis for national or institutional guidelines, to be reviewed, adapted and implemented by governments and organizations dealing with drug donations.

The original *Guidelines* were based on several rounds of consultation and comments by over 100 humanitarian organizations and individual experts. In 1996 WHO was requested by the World Health Assembly, in resolution WHA49.14, to review the experiences with the guidelines after one year. In autumn 1997 WHO's Action Programme on Essential Drugs therefore initiated a global review of first-year experiences. The results of the review are presented in the forthcoming document *First-year experiences with the interagency guidelines for drug donations*. The evaluation formed the basis for the changes in the text. In general, experiences with the *Guidelines* were very positive. But there were complaints that the authorities in some recipient countries strictly adhered to the *Guidelines*, without regard for the exceptions specifically included, and as a result useful donations were lost. For example, problems were reported with Guideline 6: *"donated drugs should have a remaining shelf-life of 12 months upon arrival in the recipient country"*. However, the problems arose from misunderstanding of or failure to refer to the stated exceptions to that guideline, rather than from the text of Guideline 6 itself. In this revised edition Guideline 6 has been modified. It now allows for direct donations of drugs with a remaining shelf-life of less than one year to specific health facilities, provided assurance can be given that the drugs can be used prior to expiration.

There are many different scenarios for drug donations. They may take place in acute emergencies or as part of development aid in non-emergency situations. They may be corporate donations (direct or through private voluntary organizations), aid by governments, or donations aimed directly at single health facilities. And although there are legitimate differences between these scenarios, there are many basic rules for an

appropriate donation that apply to all. The *Guidelines* aim to describe this common core of "Good Donation Practice".

This document starts with a discussion on the need for guidelines, followed by a presentation of the four core principles for drug donations. The guidelines for drug donations are presented in Chapter IV. When necessary for specific situations, possible exceptions to the general guidelines are indicated. Chapter V gives some suggestions on other ways that donors may help, and Chapter VI contains practical advice on how to implement a policy on drug donations.

These *Guidelines* are not international regulations; they are intended to serve as a basis for national or institutional guidelines, to be reviewed, adapted and implemented by governments and organizations dealing with drug donations.

II. The need for guidelines

In the face of disaster and suffering there is a natural human impulse to reach out and help those in need. Medicines are an essential element in alleviating suffering, and international humanitarian relief efforts can greatly benefit from donations of appropriate drugs.

Unfortunately, there are also many examples of drug donations which cause problems instead of being helpful. A sizeable disaster does not always lead to an objective assessment of emergency medical needs based on epidemiological data and past experience. Very often an emotional appeal for massive medical assistance is issued without guidance on what are the priority needs. Numerous examples of inappropriate drug donations have been reported (see Annex). The main problems can be summarized as follows:

- Donated drugs are often not relevant for the emergency situation, for the disease pattern or for the level of care that is available. They are often unknown to local health professionals and patients, and may not comply with locally agreed drug policies and standard treatment guidelines; they may even be dangerous.

- Many donated drugs arrive unsorted and labelled in a language which is not easily understood. Some donated drugs come under trade names which are not registered for use in the recipient country, and without an International Nonproprietary Name (INN) or generic name on the label.

- The quality of the drugs does not always comply with standards in the donor country. For example, donated drugs may have expired before they reach the patient, or they may be drugs or free samples returned to pharmacies by patients or health professionals.

- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the wishes of national authorities.

- Donated drugs may have a high declared value, e.g. the market value in the donor country rather than the world market price. In such cases import taxes and overheads for storage and distribution may be unnecessarily high, and the (inflated) value of the donation may be deducted from the government drug budget.

- Drugs may be donated in the wrong quantities, and some stocks may have to be destroyed. This is wasteful and creates problems of disposal at the receiving end.

There are several underlying reasons for these problems. Probably the most important factor is the common but mistaken belief that in an acute emergency any type of drug is better than none at all. Another important factor is a general lack of communication between the donor and the recipient, leading to many unnecessary donations. This is unfortunate because in disaster situations and war zones inappropriate drug donations create an extra workload in sorting, storage and distribution and can easily overstretch the capacity of precious human resources and scarce transport volume. Often, the total handling costs (duties, storage, transport) are higher than the value of the drugs. Stockpiling of unused drugs can encourage pilfering and black market sales.

Donating returned drugs (unused drugs returned to a pharmacy for safe disposal, or free samples given to health professionals) is an example of double standards because in most countries their use would not be permitted owing to quality control regulations. Apart from quality aspects, such donations also frustrate management efforts to administer drug stocks in a rational way. Prescribers are confronted with many different drugs and brands in ever-changing dosages; patients on long-term treatment suffer because the same drug may not be available the next time. For these reasons this type of donation is forbidden in an increasing number of countries and is generally discouraged.

In the early 1980s the first guidelines for drug donations were developed by international humanitarian organizations, such as the Christian Medical Commission of the World Council of Churches, later called Churches' Action for Health[1] and the International Committee of the Red Cross. In 1990 the WHO Action Programme on Essential Drugs, in close collaboration with the major international emergency aid agencies, issued a first set of WHO guidelines for donors,[2] later refined by the WHO Expert Committee on the Use of Essential Drugs.[3] In 1994 the WHO office in Zagreb issued specific guidelines for humanitarian assistance to former Yugoslavia.[4]

In view of the existence of these different drug donation guidelines, the need was felt for one comprehensive set of guidelines that would be endorsed and used by all major international agencies active in emergency relief. For this reason a first draft was prepared by the WHO Action Programme on Essential Drugs and further refined in close collaboration with the Division of Drug Management and Policies and the Division of Emergency and Humanitarian Action, major international relief organizations and a large number of international experts. The final text represented the consensus between WHO, Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, the Office of the United Nations High Commissioner for Refugees, OXFAM and the United Nations Children's Fund. In the process comments by over 100 humanitarian organizations and individual experts were taken into consideration.

The examples of inappropriate donations described here constitute ample reasons to develop international guidelines for drug donations. In summary, guidelines are needed because:

- Donors intend well, but often do not realize the possible inconveniences and unwanted consequences at the receiving end.

- Donor and recipient do not communicate on equal terms. Recipients may need support in specifying how they want to be helped.

- Drugs do not arrive in a vacuum. Drug needs may vary between countries and from situation to situation. Drug donations must be based on a sound analysis of the needs, and their selection and distribution must fit within existing drug policies and administrative systems. Unsolicited and unnecessary drug donations are wasteful and should not occur.

- The quality requirements of drugs are different from those for other donated items, such as food and clothing. Drugs can be harmful if misused; they need to be identified easily through labels and written information; they may expire; and they may have to be destroyed in a professional way.

III. Core principles

The twelve articles of the Guidelines for Drug Donations are based on four core principles. The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged. The second principle is that a donation should be made with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements. The third principle is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation. The fourth principle is that there should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced.

Core principles for a donation

1. Maximum benefit to the recipient
2. Respect for wishes and authority of the recipient
3. No double standards in quality
4. Effective communication between donor and recipient

IV. Guidelines for drug donations

Selection of drugs

1. All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.

Justification and explanation

This provision stresses the point that it is the prime responsibility of the recipients to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts.

Possible exceptions

In acute emergencies the need for prior consent by the recipient may be waived, provided the drugs are amongst those from the WHO Model List of Essential Drugs[5] that are included in the UN list of emergency relief items recommended for use in acute emergencies.[6]

2. All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.

Justification and explanation

This provision is intended to ensure that drug donations comply with national drug policies and essential drugs programmes. It aims at maximizing the positive impact of the donation, and prevents the donation of drugs which are unnecessary and/or unknown in the recipient country.

Possible exceptions

An exception can be made for drugs needed in sudden outbreaks of uncommon or newly emerging diseases, since such drugs may not be approved for use in the recipient country.

3. The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.

Justification and explanation

Most staff working at different health care levels in the recipient country have been trained to use a certain formulation and dosage schedule and cannot constantly change their treatment practices. Moreover, they often have insufficient training in performing the necessary dosage calculations required for such changes.

Quality assurance and shelf-life

4. All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[7] should be used.

Justification and explanation

This provision prevents double standards: drugs of unacceptable quality in the donor country should not be donated to other countries. Donated drugs should be authorized for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP).

Possible exceptions

In acute emergencies the use of the WHO Certification Scheme may not be practical. However, if it is not used, a justification should be given by the donor. When donors provide funds to purchase drugs from local producers, those which comply with national standards should not be excluded on the sole grounds that they do not meet quality standards of the donor country.

5. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

Justification and explanation

Patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality issues, returned drugs are very difficult to manage at the receiving end because of broken packages and the small quantities involved.

6. After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year. An exception may be made for direct donations to specific health facilities, provided that: the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf-life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases it is important that the date of arrival and the expiry dates of the drugs be communicated to the recipient well in advance.

Justification and explanation

In many recipient countries, and especially under emergency situations, there are logistical problems. Very often the regular drug distribution system has limited possibilities for immediate distribution. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of drugs just before their expiry, as in most cases such drugs would only reach the patient after expiry**.** It is important that the recipient official responsible for acceptance of the donation is fully aware of the quantities of drugs being

donated, as overstocking may lead to wastage. The argument that short-dated products can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect. In emergency situations the systems for reception, storage and distribution of drugs are very often disrupted and overloaded, and many donated drugs tend to accumulate.

Additional exception
Besides the possible exception for direct donations mentioned above, an exception should be made for drugs with a total shelf-life of less than two years, in which case at least one-third of the shelf-life should remain.

Presentation, packing and labelling

7. All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.

Justification and explanation
All donated drugs, including those under brand name, should be labelled also with their INN or the official generic name. Most training programmes are based on the use of generic names. Receiving drugs under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients. In the case of injections, the route of administration should be indicated.

8. As much as possible, donated drugs should be presented in larger quantity units and hospital packs.

Justification and explanation
Large quantity packs are cheaper, less bulky to transport and conform better with public sector supply systems in most developing countries. This provision also prevents the donation of drugs in sample packages, which are impractical to manage. In precarious situations, the donations of paediatric syrups and mixtures may be inappropriate because of logistical problems and their potential misuse.

9. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.

Justification and explanation
This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed drugs is very time- and labour-intensive. This

provision specifically discourages donations of small quantities of mixed drugs. The maximum weight of 50 kilograms ensures that each carton can be handled without special equipment.

Information and management

10. Recipients should be informed of all drug donations that are being considered, prepared or actually under way.

Justification and explanation

Many drug donations arrive unannounced. Detailed advance information on all drug donations is essential to enable the recipient to plan for the receipt of the donation and to coordinate the donation with other sources of supply. The information should at least include: the type and quantities of donated drugs including their International Nonproprietary Name (INN) or generic name, strength, dosage form, manufacturer and expiry date; reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor.

11. In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.

Justification and explanation

This provision is needed solely to prevent drug donations being valued in the recipient country according to the retail price of the product in the donor country. This may lead to elevated overhead costs for import tax, port clearance and handling in the recipient country. It may also result in a corresponding decrease in the public sector drug budget in the recipient country.

Possible exception

In the case of patented drugs (for which there is no generic equivalent) the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

12. Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

Justification and explanation

This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items, and also enables the recipient to review the list of donated items at an early stage.

V. Other ways donors can help

The new emergency health kit

In the acute phase of an emergency, or in the case of displacements of refugee populations without any medical care, it is better to send a standardized kit of drugs and medical supplies that is specifically designed for this purpose. For example, the new emergency health kit,[8] which has been widely used since 1990 and was updated in 1998, contains drugs, disposable supplies and basic equipment needed for general medical care for a population of 10,000 for three months. Its contents are based on a consensus among major international aid agencies. It is permanently stocked by several major international suppliers (for example, the International Dispensary Association, Médecins Sans Frontières and the United Nations Children's Fund) and can be available within 48 hours. It is especially relevant in the absence of specific requests.

Donations in cash

After the acute phase of the emergency is over, a donation in cash for local or regional purchase of essential drugs is usually much more welcome than further drug donations in kind. Such a cash contribution is very supportive to the activities of the local government or coordinating committee, it is supportive to the local and regional pharmaceutical industry, and it may also be more cost-effective. In addition, prescribers and patients are usually more familiar with locally produced drugs.

Additional guidelines for drug donations as part ofdevelopment aid

When drug donations are made between governments as humanitarian support in long-lasting complex emergencies and as regular development (commodity) aid there is usually more time to consider specific demands from the recipient's side. On the other hand, there is also time to link more restrictions to the donation, e.g. to products from manufacturers in the donor country, and to drugs registered for use in the recipient country.

It should be recognized that drugs do not arrive in an administrative vacuum. Drug donations should not create an abnormal situation which may obstruct or delay national capacity building in selection, procurement, storage, distribution and rational use of drugs. Special care should therefore be taken that the donated drugs respond to an expressed need, comply with the national drug policy, and are in accordance with national treatment guidelines in the recipient country. Administratively, the drugs should be treated as if they were procured. This means that they should be registered or authorized for use in the country through the same procedure that is used for government tenders. They should be entered into the inventory, distributed through the existing distribution channels and be subject to the same quality assurance procedures. If cost-sharing procedures are operational in the recipient country, the donated drugs should not automatically be distributed free of charge.

VI. How to implement a policy on drug donations

Management of drug donations by the recipient

Define national guidelines for drug donations

It is difficult for a recipient to refuse a donation that has already arrived. Prevention is therefore better than cure. Recipients should indicate to their prospective donors what kind of assistance they need, and how they would like to receive it. If this information is provided in a professional way, most donors will appreciate it and will comply.

Therefore, recipients should first formulate their own national guidelines for drug donations on the basis of the international guidelines. They can also be included in the national drug policy. These national guidelines should then be officially presented and explained to the donor community. Only after they have been presented and officially published can they be enforced.

Define administrative procedures for receiving drug donations

It is not enough for the recipient to adopt and publish the general guidelines on the selection, quality, presentation and management of drug donations. Administrative procedures need to be developed by the recipient to maximize the potential benefit of drug donations. As much as possible such arrangements should be linked with existing drug supply systems, but there are several decisions to be made which apply to donations only. Examples of such important issues, which have to be addressed in each country, are:

- Decide who is responsible for defining the needs, and who will prioritize them.
- Decide who coordinates all drug donations.
- Which documents are needed when a donation is planned; who should receive them?
- Which procedure is used when donations do not follow the guidelines?
- What are the criteria for accepting/rejecting a donation, and who makes the final decision?
- Decide who coordinates reception, storage and distribution of the donated drugs.
- How are donations valued and entered into the budget/expenditure records?
- How will inappropriate donations be disposed of?

Specify the needs for donated drugs

The third important action by the recipient is to specify the needs for donated drugs as much as possible. This puts the onus on the recipient to carefully prepare requests, indicating the required quantities and prioritizing the items. The more information given, the better. Information on donations that are already in the pipeline, or anticipated, is very helpful to other potential donors. Full information from the side of the recipient is greatly appreciated by donors and pays off in the long run.

Manage drugs with less than one-year expiry

Drugs do not become toxic or ineffective on their date of expiry but may slowly deteriorate depending on the product, formulation and storage conditions. Some become toxic but most simply lose their efficacy. An expiry date is the date given on the individual container (usually on the label) of a drug product, up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life period to the date of manufacture. The recommendation that all drugs should have a remaining shelf-life of at least one year upon arrival in a recipient country is to allow for the all too frequent in-country distribution delays. It gives a measure of security that patients will receive drugs of good quality.

A specific exception to the one-year shelf-life requirement can be made for donated drugs provided that: they are direct donations to specific health facilities; the responsible professional acknowledges that (s)he is aware they are short-dated; and the quantity and the remaining shelf-life allow for proper administration, distribution and prescription prior to expiry. Experience has shown that some recipient governments have applied the *Guidelines* very strictly, without due consideration of the possible exceptions to the general rule. This has resulted in unnecessary impounding and disposal of valuable donations.

Ensure rapid customs clearance of donated drugs

Rapid customs clearance is required for all donated drugs. Customs and health ministry officials managing drug donations covered by the *Guidelines* have the responsible task of allowing entry for useful donations, while rejecting short-dated donations for which satisfactory distribution provisions have not been made.

Manage donated drugs carefully

The value of donated drugs can be considerable, and the gift should be treated with due expedition and care. On arrival the drugs should be inspected and their receipt confirmed to the donor agency. They should then be stored and distributed in accordance with normal principles of good pharmacy practice, and under the responsibility of adequately trained professionals. There must be due vigilance to ensure that donated products are not diverted for export, commercial sale, or into illicit channels. Good donation management also includes agreed systems of accountability.

Action required from donor agencies

Donors should always respect the four core principles for drug donations presented above. Donors should also respect the national guidelines for drug donations and respond to the priority needs indicated by the recipient. Unannounced donations should be prevented as much as possible.

Avoid donations of drugs with short expiry dates

The fundamental problem of donated drugs with short expiry dates has troubled recipients for many years. On the other hand, global experiences indicate that well-managed donor organizations and pharmaceutical companies are generally able to avoid donating products with short expiry dates. Some large companies have product outreach programmes under which products are specifically donated from

normal inventories, on the basis of an agreed-upon schedule, to meet recipients' needs.

One objective of the *Guidelines* is to reduce donations of drugs with short expiry dates through better inventory control on the part of donor companies and intermediaries, and through better communications. Donors and intermediaries should avoid donations of drugs with short expiry dates as much as possible.

Inform the public

The general public in the donor country is not always aware of the common problems with drug donations. It is therefore important that governments in donor countries make some effort to create more public awareness on "good donor practice". The best moment for this is probably at the time of the public appeal through the media.

Establish donor coordination

It is recommended that within the recipient country the different donors collaborate in the establishment of a coordinating body. In emergency situations this is essential. This body should determine the needs, priorities, storage, logistics and distribution, and act as the central contact point in discussion with the recipient government authorities.

The responsible government department should supply relief agencies with as much information as possible about requested and approved donations. Conversely, relief agencies should keep the donor coordinating body and the responsible government department fully informed of the specific identity, arrival dates, quantities, and expiry dates of donations. This will greatly assist the co-ordinating body in the recipient country to plan for the proper reception of the donations, and to identify the need for additional supplies.

Within donor countries all organizations should likewise establish a coordinating body at headquarters level, to ensure that appropriate donation policies and processes are followed.

The argument that products with short expiry dates can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect. In emergency situations the systems for reception, storage and distribution of drugs are very often disrupted and overloaded, and many donated drugs tend to accumulate.

Annex: Examples of problems with drug donations

Armenia, 1988

After the earthquake, 5,000 tons of drugs and medical supplies worth US$ 55 million were sent. This quantity far exceeded needs. It took 50 people six months to gain a clear picture of the drugs that had been received. Eight per cent of the drugs had expired on arrival, and 4% were destroyed by frost. Of the remaining 88%, only 30% were easy to identify and only 42% were relevant for an emergency situation. The majority of the drugs were only labelled with brand names.[9]

Eritrea, 1989

During the war for independence, despite careful wording of appeals, many inappropriate donations were received. Examples were: seven truckloads of expired aspirin tablets that took six months to burn; a whole container of unsolicited cardiovascular drugs with two months to expiry; and 30,000 half-litre bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the smell.[10]

Sudan, 1990

A large consignment of drugs was sent to war-devastated southern Sudan. Each box contained a collection of small packets of drugs, some partly used. All were labelled in French, a language not spoken in Sudan. Most drugs were inappropriate, some could be dangerous. These included: contact lens solution, appetite stimulants, mono-amine oxidase inhibitors (dangerous in Sudan), X-ray solutions, drugs against hypercholesterolaemia, and expired antibiotics. Of 50 boxes, 12 contained drugs of some use.[11]

France, 1991

Pharmaciens Sans Frontières collected 4 million kilograms of unused drugs from 4,000 pharmacies in France. These were sorted out in 88 centres in the country. Only about 20% could be used for international aid programmes, and 80% were burnt.[12]

Russian Federation, 1992

Russian pharmaceutical production has fallen far below its 1990 level, and donations of drugs have been welcomed. However, initial enthusiasm soured when the nature of some donations was discovered. Examples of donations include: 189,000 bottles of dextromethorfan cough syrup; pentoxifylline and clonidine as the only antihypertensive items; triamterene and spironolactone as diuretics; pancreatic enzyme and bismuth preparations as the only gastrointestinal drugs.[13]

Guinea-Bissau, 1993

In September 1993 eight tons of donated drugs were sent; all were collected from pharmacies in quantities of between 1 and 100 tablets. The donation contained 22,123 packages of 1,714 different drugs which were very difficult to manage and greatly interfered with government efforts to rationalize drug supply and drug use.[14]

Lithuania, 1993

Eleven women in Lithuania temporarily lost their eyesight after using a donated drug. The drug, closantel, was a veterinary anthelmintic but was mistakenly given to treat endometritis. The drug had been received without product information or package insert, and doctors had tried to identify the product by matching its name with those on leaflets of other products.[15]

Former Yugoslavia, 1994, 1995

Of all drug donations received by the WHO field office in Zagreb in 1994, 15% were completely unusable and 30% were not needed.[16] By the end of 1995, 340 tons of expired drugs were stored in Mostar. Most of these were donated by different European nations.[17]

Rwanda, 1994

Large quantities of a sophisticated antibiotic were donated to refugee camps in Rwanda. Drugs were donated in bulk through private voluntary organizations. Refugee workers were not used to using the drug; most of it was recalled; the remainder posed disposal problems.[18,19]

Bosnia and Herzegovina, 1992-1996

Between 1992 and mid-1996 an estimated 17,000 metric tons of inappropriate donations were received with an estimated disposal cost of US$34 million.[20]

Albania, 1999

A WHO audit of humanitarian drug donations received in Albania during May 1999 revealed serious quality problems. It was estimated that 50% of the drugs coming into Albania during the Kosovo refugee crisis were inappropriate or useless and would have to be destroyed. Sixty-five per cent of drugs had an inadequate expiry date (either missing or expiring less than one year from the date of donation); and 32% were identified only by brand names, which were unfamiliar to Albanian health professionals. None of the short shelf-life donations were requested, and according to aid workers they could not be distributed and used before the end of the year.[21]

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BACK COVER PAGE

There are many types of drug donation. Some are a rapid response to an acute emergency or form a component of development aid. Others represent the philanthropic aims of large corporations. Yet others are small and targeted for use by individual health facilities. But all too often, drug donations are inappropriate and cause disposal problems for their recipients.

By describing "good donation practice", these guidelines aim to improve the quality of drug donations. As a basis for national or institutional guidelines, they can be adapted and implemented by governments and organizations dealing with this type of assistance.

First issued in 1996, the guidelines have since been revised, following an extensive review of experiences with their use. This second edition begins with a discussion of the need for guidelines and goes on to present four core principles and 12 guidelines for drug donations, covering such issues as selection of drugs, quality assurance, and presentation and packaging. Exceptions to the general guidelines are also given, to take account of specific drug donation situations. The guidelines conclude with suggestions on other ways in which donors can provide assistance, and advice on how recipients can implement a drug donations policy.

This is an intergagency consensus document published by the WHO *Department of Essential Drugs and Other Medicines* on behalf of the organizations listed.