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First-year experiences

with the

Interagency Guidelines

for Drug Donations

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World Health Organization

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Quotation from an individual health institution:

We see the Guidelines *as a help to us, to continue to provide essential services to as many patients as possible, and at reasonable cost. We also see the* Guidelines *as a necessary component in the development of a health care system that is sustainable, encouraging recipients and patients to take more responsibility in the management of health care delivery.*

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Executive summary

After extensive consultation the *Interagency Guidelines for Drug Donations* were issued in May 1996 on behalf of eight cosponsoring agencies active in humanitarian emergency relief. In the same month the World Health Organization (WHO) was requested by the World Health Assembly to review the experiences with the *Guidelines* after one year. In the autumn of 1997 WHO therefore initiated a global review of first year experiences with the *Guidelines*. The results of the review form the basis of this report.

The objective of the study was to make recommendations on any need for changes in the text and any other mechanisms to further increase the benefit of drug donations. The basis of the review was a postal survey with dedicated forms being sent to donors, consolidators (intermediaries) or recipients. Approximately half the questions were closed (yes/no answers). The following underlying research questions were asked. What have been the practical benefits of the *Guidelines*? What are the magnitude and the beneficial effects of drug donations? Which drug donations have been hampered, delayed or cancelled? What is the experience with Article 6 (12-month minimum shelf-life)? In what ways could the *Guidelines* be improved? In what ways could donation practices be further improved?

Four hundred questionnaires in English were sent out and fifty in French. All individuals and organizations on file in the WHO Action Programme on Essential Drugs (WHO/DAP)* who had expressed interest in drug donations were sent questionnaires. Special efforts were made to encourage those receiving questionnaires to request others, particularly recipients, involved in the donation process to fill in and return copies.

One hundred and seventy-two questionnaires were returned. Thirty-four were not included in the analysis. Those who had never seen or read the *Guidelines* and a number of pharmaceutical companies with their own donation policies who saw no point in filling in the questionnaire were excluded. One organization sent identical replies from different national offices; only one example was therefore entered into the analysis. The data from 138 respondents of whom 42 were donors, 17 consolidators and 79 recipients were entered in the database and analysed.

The survey found that in some 45 countries the *Guidelines* have been adopted or adapted by either the government or organizations involved with donations. This was undoubtedly linked to the fact that after their launch in 1996 the *Guidelines* were extensively disseminated. They were fully reproduced in the *Essential Drugs Monitor*, translated into French, Spanish and Russian, widely distributed by mail and discussed at conferences. Articles in the medical and general press highlighted the guidelines and problems related to donations of

* Since July 1998 incorporated in the Department of Essential Drugs and Medicines Policy (EDM).

drugs. Not all respondents who filled in questionnaires replied fully to every question. This made interpretation in some cases difficult. Of the responding donors less than 20% of their donations were made for acute emergencies. The total value of donations reported by donors was US$ 298 million of which US$ 228 million (76%) was from industry donors, US$ 68 from nongovernmental organizations and government agencies contributed US$ 3 million. Consolidators represented in the study reported donations totalling US$ 360 million. Bilateral drug donations by governments were not included in the overview but were estimated to be in the order of US$ 300 million a year.

Eighty-four percent of donors, 92% of consolidators and only 35% of recipients indicated that over half of their donations were based on specific requests. There is a difference in perception as to what forms a specific request with many recipients believing that they received many donations without specifically asking for them.

Open questions put to all respondents indicated general benefits brought about by the *Guidelines*. These included comments that the *Guidelines* were an excellent framework for improving drug donation practices, improved documentation of consignments and perception of the *Guidelines* as a useful tool for curtailing inappropriate donations.

Responses to closed questions showed 53% of replying recipients found it easier to refuse, return or destroy unwanted donations. Specific benefits for recipients included an improvement in donations meeting needs (45% of replying recipients), improvement in shelf-life (45% of replying recipients) and improvement in packaging and labelling (40% of replying recipients).

Hampered, delayed or cancelled drug donations troubled consolidators disproportionately compared to donors and recipients. This was mainly related to the 12-month shelf-life requirement in which some recipient governments had given insufficient consideration to the possible exceptions (Article 6) resulting in some valid donations being delayed or cancelled.

Recommendations based on questionnaire responses proposed that the interagency group should be reconvened to update the *Guidelines* incorporating the exceptions to direct donations into the main body of Article 6 to prevent the guideline from simply being copied and used without proper consideration of the exception. It was also recommended that the section on drug management be expanded and that a system be installed whereby recipients and consolidators could report examples of inappropriate donations. It was considered useful to have more partners involved in the cosponsorship of the *Guidelines*.

At a meeting on 5 March 1999 an update of the *Guidelines* introduction and modification and expansion to Article 6 were agreed. New paragraphs on managing drugs with less than one year expiry, rapid customs clearance, avoidance of donations of short-dated drugs and donor coordination were added. Seven additional organizations agreed to cosponsor the *Guidelines* bringing the total to fifteen.

In December 1999 the Department of Essential Drugs and Medicines Policy web site introduced a list for organizations wishing to underwrite and endorse the *Guidelines*. The site also contains an explanation of how complaints related to unhelpful donations may be registered with WHO.

1. Introduction

The *Interagency Guidelines for Drug Donations* were issued in May 1996 by the WHO Action Programme on Essential Drugs (WHO/DAP) on behalf of eight international agencies active in humanitarian emergency relief. That same month WHO was requested by the World Health Assembly to review the experiences with the *Guidelines* after one year. In autumn 1997 WHO therefore initiated a global review of first-year experiences with the *Guidelines.* The results of that review are presented in this report.

Short history of the concept of "good donation practice"

In the early 1990s an increasing number of examples of drug donations were reported which were unnecessary, inappropriate or even dangerous. There were detailed reports on the impact of drug donations after the large earthquake in Armenia in 1988[1] and the war in Bosnia-Herzegovina.[2] In 1994 WHO/DAP therefore started a global consultation process to develop international guidelines for drug donations.

The *Interagency Guidelines for Drug Donations* were built on the practical field experience of the Christian Medical Commission of the World Council of Churches and the International Committee of the Red Cross. They represent a consensus view of eight international relief organizations. Besides WHO, these are the Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross (ICRC), the International Federation of Red Cross and Red Crescent Societies (IFRC), Médecins Sans Frontières, the Office of the United Nations High Commissioner for Refugees (UNHCR), OXFAM, and the United Nations Children's Fund (UNICEF).

The *Guidelines* are presented as four core principles and twelve articles on selection, quality, supply and information regarding drug donations. The core principles of good donation practice are as follows:

maximum benefit for the recipient;
respect for the wishes and authority of the recipient;
no double standards in quality;
effective communication between donor and recipient.

The extensive consultation process which preceded the issue of the *Guidelines* included comments from over 100 individual experts, recipient countries, donor organizations, industry representatives and others on three successive drafts of the *Guidelines.* At a final meeting in Geneva on 30 April 1996 the *Guidelines* were adopted by the eight organizations, and were issued by WHO/DAP in May 1996 as an interagency document. In the months that followed WHO/DAP issued French, Spanish and Russian translations.

A truly global discussion took place after the *Guidelines* were issued. Newspapers and scientific journals published articles on drug donations. A large number of national organizations, donor countries, recipients, consumer organizations, pharmaceutical industries, nongovernmental organizations (NGOs) and individuals engaged in discussions on good donation practice in general and on the *Guidelines* in particular. In many cases the *Guidelines* were adopted and published. In addition, many adaptations and translations appeared, and large numbers of copies were disseminated for comments and for use. In the first year at least 15 countries, both developed and developing, issued national guidelines, largely based on the *Guidelines*. Donors started to change their practices, and recipients became more vocal in refusing certain types of donations.

A number of problems emerged as well. Some recipient countries became very strict in implementing the *Guidelines*, and especially the requirement that donated drugs have a remaining shelf-life of 12 months upon arrival. Some pharmaceutical companies continued to offer donations of large quantities of drugs with 6–12 months' shelf-life, which nongovernmental organizations found difficult to refuse in view of the desperate needs of the poor in developing countries. A number of large consignments of valuable antibiotics with 11 months' remaining shelf-life were turned down. Some donations were kept in bond by the customs authorities while the 12-month mark passed, and were then refused entry.

Most drug donations are made with the best of intentions, and play a vital role in relieving human suffering. Yet some donations create more problems than they solve. The *Guidelines* are not intended to discourage drug donations, but only to improve their beneficial effect. It is in this spirit that the current review of first-year experiences was undertaken. Its ultimate objective is to further maximize the potential benefits of drug donations.

Objective of the study

The objective of the study conducted by WHO was to review the first-year experiences with the *Guidelines*, and to make recommendations on the need for changes in the text and any other mechanisms to further increase the benefit of drug donations.

The research questions were:

What have been the practical benefits of the *Guidelines*?
What are the magnitude and the beneficial effects of drug donations?
Which drug donations have been hampered, delayed or cancelled?
What is the experience with Article 6 (12-month minimum shelf-life)?
In what ways could the *Guidelines* be improved?
In what ways could donation practices be further improved?

Outline of the report

The information collected in the course of the review was so voluminous that it was not possible to publish it in its entirety in a reasonably accessible form. This short report therefore contains a summary of the results and conclusions of the study. The complete data tables and original questionnaires can be consulted in the Department of Essential Drugs and Medicines Policy (EDM) upon request.

2. Sources of information and study methodology

General overview of the method

The review conducted by WHO is a descriptive study for which the information was collected from standardized questionnaires sent to a large number of donors, consolidators and recipients of drug donations. The information obtained through these questionnaires includes self-reported data, experiences and opinions of the respondent organizations or individuals. These data were supplemented by information already available in WHO/DAP. If clarification was needed, additional information was obtained through direct interviews with respondents, and through reports and literature reviews. The observations and conclusions derived from the questionnaires were validated with key informants and experts. The data collected do not provide an independent and objective assessment of the impact of drug donations, but represent the opinions and experiences of a large number of organizations and experts dealing with drug donations.

Definition of respondents

The study distinguishes between three groups of organizations involved in drug donations: donors, consolidators and recipients.

Donors are organizations that provide pharmaceuticals or medical supplies on a non-commercial basis to recipient governments, national or international nongovernmental agencies, non-profit organizations, institutions or individuals for distribution to patients in recipient countries. Donors may be manufacturers (called "pharmaceutical industry donors" in the study) or donor purchaser organizations (called "government and nongovernmental organizations") that procure drugs for distribution to recipients. Donor purchasers may select what is donated, while manufacturers donate from the range of their manufactured products.

Consolidators ("intermediaries" would have been a better word) are private voluntary organizations (PVOs) that solicit medicines and medical supplies from donor organizations, with the intention of distributing them to health care organizations or health providers in recipient countries which provide services directly to patients. Most consolidators are based in the United States.

Recipients may be health ministries (called "government organizations"), national or international health relief organizations (called "nongovernmental organizations") or local health facilities (called "individual health care

institutions") that use donated drugs and medical supplies to care directly for patients.

Overlaps in functions occur. For example, in-country organizations may receive donations and then act as providers for other institutions or individuals directly looking after patients. Organizations such as UNICEF and Médecins Sans Frontières donate large quantities of drugs to their own field projects, and could be classified as donors and as recipients. In general, the questionnaires were classified in the category in which the organization or the individual respondent was most representative and, in cases of doubt, the category in which the respondents placed themselves.

Questionnaires

The questionnaires were prepared specifically for donors, consolidators and recipients. Definitions were placed at the beginning of each questionnaire to help organizations to identify themselves as a donor or a consolidator. The opinions of recipients were actively solicited, and donors and consolidators were encouraged to send copies of the questionnaire to their recipient partners, and to request their opinions.

The questions were divided into "closed questions" with a yes/no response and "open-ended questions" which allowed respondents freedom and space to formulate their replies and comments. The sequence followed as much as possible that of the *Guidelines* themselves and the overriding intention was to allow respondents sufficient space to express their opinions on any aspect of the *Guidelines.*

Copies of the draft questionnaires were first sent to 12 representative organizations, with a request for their comments and observations. Four were interagency co-sponsors of the *Guidelines.* The questionnaires were modified in the light of comments. French versions of the three questionnaires were also produced and distributed.

Distribution of questionnaires

The objective was to have as many responses as possible from the three types of organizations. Questionnaires were sent to all organizations known to be interested or involved as donors, recipients or consolidators of donated drugs. These included all individuals or organizations that had commented on the first edition of the *Guidelines* and those who had expressed interest by correspondence or e-mail. Mailing lists in WHO/EDM were scanned to find organizations or individuals likely to be interested in donations. A message for those interested was forwarded to the electronic pharmaceutical discussion group, E-Drug, which then made it available to its members (about 1,000 all over the world).

Questionnaires were sent out to approximately 400 addresses. Some organizations received donor, consolidator and recipient editions, while others, known or clearly fitting into one of the three categories, were sent the

appropriate questionnaire. Some 50 questionnaires were sent out in French to French-speaking correspondents. Mailing started in November–December 1997 and the official closing date was 17 March 1998. This date was later extended to August 1998. No more replies were received after that time.

Inclusion criteria

A total of 172 responses to questionnaires was returned, 34 of which are not included in the analysis for the following reasons. First, 18 respondents had never seen or read the *Guidelines*. For those who provided an address a copy of the *Guidelines* was sent with a further questionnaire requesting that it be filled in and returned; some complied with this request. Four pharmaceutical companies returned forms that were not filled in either because "The Company doesn't give donations" or because there was "No point in filling in the questionnaire as the company has its own donation policy". E-mail correspondence from a pharmaceutical company representative started with "We do not use your Guidelines" and continued with "We have our own guidelines". When asked gently if it was possible to see a copy, the representative replied "This guideline is an internal document, and therefore not subject to external distribution". Lastly, 14 largely identical replies from field offices of one organization were consolidated into one donor and one recipient reply. Data from the remaining 138 questionnaires were entered in the database and analysed.

Sample size

The sample sizes of the three types of respondents and the five subgroups are given in Table 1.

Table 1. Size of groups of respondents

Respondent category	n
DONOR	**42**
Pharmaceutical industry donor	24
Government / nongovernmental organization	18
CONSOLIDATOR	**17**
RECIPIENT	**79**
Government organization	19
Nongovernmental organization	42
Individual health care institution / health worker	18
TOTAL	**138**

Data analysis

All 138 replies to individual questions were collated in a table via a Microsoft Access query. The nature of the data determined the subsequent method of analysis.

For quantitative data from *closed questions*, responses were arranged by category. The counts were used to calculate percentage values and to generate a summary table and corresponding figure charts. As the sample of respondents was open-ended, values for the total group of respondents were of little relevance. Most results are therefore presented separately for the three groups. Where relevant, separate figures are also given for the two donor subgroups and the three recipient subgroups. Percentages relate to the number of responses received to a particular question; the denominator for a response may therefore be smaller than the total number of respondents.

Comments and replies to *open questions* were grouped and sorted by category, and summarized as much as possible. Some interesting and representative remarks are quoted separately. Where necessary and possible, the information was validated and supplemented with other materials available to the researchers.

3. Dissemination and uptake of the *Guidelines*

In this chapter an overview is given of the different ways in which donors, consolidators and recipients have reacted to the issuing of the *Guidelines* in May 1996. Apart from being valuable in the discussion on the impact of the *Guidelines* in improving donation practices, this part of the review constitutes an interesting case study of the impact of a portion of WHO's work.

The development stage: September 1994 – May 1996

In September 1994 the WHO Action Programme on Essential Drugs (WHO/DAP) started collecting information on drug donations and reviewed copies of existing drug donations guidelines. The guidelines for drug donations of the Christian Medical Commission of the World Council of Churches in particular served as a starting point. By the end of 1994 a first working draft of international guidelines had been prepared and discussed within WHO.

In February 1995 the second working draft was sent out to an interagency group which had previously been collaborating in the development of the New Emergency Health Kit. At the same time it was also sent to WHO/DAP's working partners, such as regional offices, country offices, essential drugs programmes, consumer organizations, pharmaceutical industry representatives and others.

Comments were received and incorporated into the third draft, dated November 1995, which was sent out again to all persons who had responded to the second draft, and to any other person or organization that had expressed an interest. Their comments were incorporated into the final text, which was finalized and adopted by the interagency group on 30 April 1996, and issued by WHO/DAP on 9 May 1996.

Discussion
In the course of the development process an unknown number of individual experts and organizations received the draft *Guidelines*; over 100 individuals and groups sent their comments to WHO. Although the *Guidelines* were presented as drafts, many groups and individuals immediately started using them for internal discussions, reviews, local adaptations, and so forth. In fact, the process of development of the *Guidelines* was an important component of their final dissemination, as most experts and organizations active in the field were already involved and had been informed before the final *Guidelines* were issued.

Perhaps the only exception to this were some private voluntary organizations and pharmaceutical industry donors in the United States, which entered the picture only early in 1996 after the third draft was circulated to them. Through a

special meeting with industry representatives in March 1996 their comments and concerns were heard and most of them were incorporated into the final text.

The launch: May 1996

On 30 April 1996, after the interagency meeting had approved the final text, WHO issued a press release to announce the new interagency *Guidelines*. The problem of donations and the new guidelines attracted considerable media attention, resulting in a stream of newspaper articles and radio interviews with WHO staff and external experts. This coincided with a story in *TIME* of 27 April 1996, which was very critical of certain types of drug donations and raised awareness among the general public, especially in the United States. Partly because of the United States interest the topic was also discussed at the World Health Assembly later in May 1996, and this resulted in a paragraph in resolution WHA 49.14 in which the need for donation guidelines was reconfirmed. In this resolution WHO was also requested to disseminate the *Guidelines*, to encourage their use and to review experiences with the *Guidelines* after one year.

Discussion
The *TIME* article, the WHO press release, the issuing of the *Guidelines* and the subsequent discussion at the Assembly, all within one month, resulted in a sudden awareness among the general public that not all drug donations were equally helpful, and that guidelines were needed to maximize their impact. Three types of donations became the focus of attention: the donation of returned drugs and samples, large donations of drugs not really relevant for the recipients, and donations of drugs close to their expiry date. This awareness then contributed to the general interest in disseminating, adapting and using the *Guidelines* which followed.

After May 1996: dissemination of the *Guidelines*

The English version of the *Guidelines* was issued in May 1996. Hundreds of copies were disseminated through the WHO mailing lists. Each of the organizations in the interagency group received about 500 copies for dissemination through their regional and field offices. OXFAM received 1,000 copies for distribution to nongovernmental organizations, especially those dealing with Romania. The *Guidelines* were also made available through the DAP web site. In total, about 8,000 copies were printed and distributed in English in the first year. In March 1997 WHO published an article on the *Guidelines* in the *British Medical Journal*. In addition, the *Guidelines* were included in a chapter on drug donations in the second edition of the standard textbook, *Managing drug supply*,[3] which appeared in April 1997.

Translations into other languages followed. In August 1996 the French edition was issued and in September the Spanish translation. In total, over 6,000 copies were printed and distributed in these two languages. In December 1996 the *Guidelines* were reproduced in their entirety in the *Essential Drugs Monitor* (No. 21) in English, later followed by editions in French, Spanish and Russian; a

total of about 35,000 copies were printed. In the subsequent issue of the *Monitor* national adaptations of the *Guidelines* were reported.

Other publications about drug donations

Many articles on drug donations appeared in the lay and scientific press. The following, several of which have already been mentioned, are the most important examples, but the list is not exhaustive.

A. Purvis. The goodwill pill mess. *TIME,* 29 April 1996: 39.
Mentioned for the first time to the general public that not all drug donations were appropriate, quoting one example from Africa in detail; announced the new *Guidelines.*

H. V. Hogerzeil, M. R. Couper & R. Gray. Guidelines for drug donations. *British Medical Journal* 1997; 314: 737–740.
Presented the need for drug donation guidelines, and the *Guidelines* themselves.

P. Berckmans et al. Inappropriate drug-donation practices in Bosnia and Herzegovina, 1992 to 1996. *New England Journal of Medicine* 1997; 337(25): 1842–1845.
Reported an estimated 17,000 metric tons of accumulated unusable and/or expired donated drugs and medical supplies (the figure was later challenged).

J. Rovner. Substandard Bosnia drug donations challenged in US Congress. *Lancet* 1998; 351: 275.
Reported on a discussion in the United States Congress on tax reductions for drug donations, in reaction to the article in the *New England Journal of Medicine.*

S. Nemecek. Not what the doctor ordered. *Scientific American,* April 1998: 31–32.
Mentioned examples of inappropriate donations and the need for the *Guidelines.*

N. Rehlis. "Yes" to help, "no" to waste. *Bulletin Medicus Mundi* 1998; 68: 11–12.
Reported on experiences with donations in India.

G. Crooks. Drug donation: protecting industry philanthropy. *Pharmaceutical Executive,* August 1998: 66–76.
Analysed the background of how some large industry drug donations turned into negative publicity. Largely represented thinking in the United States but failed to correct misconceptions.

Conferences at which the *Guidelines* were discussed

Drug Policy Issues for Senior Managers, Boston, March 1996
At this international training course, jointly organized by the School of Public Health of Boston University and WHO/DAP, the *Guidelines* were presented to 38 senior pharmaceutical managers from 28 developing countries. In an official letter to WHO they later proposed that the minimum expiry dating be extended

to 18 months. The *Guidelines* were presented and discussed at each subsequent annual international training course on drug policy issues.

UK–Romania Drugs Advisory Group meeting, London, April 1996
This nongovernmental organization was formed following reports of poor-quality drug donations to Romania. Problems with drug donations were discussed, and the *Guidelines* were distributed. Organizations in attendance were: Agents for Change, Christ Church Aid for Romania, Clinical Sciences Foundation, ECHO International Health Services, Express Aid International, Health Action International, Jolinda International, Jubilee Outreach Yorkshire, Kings Church Romania Fund, Linx SRL, Medical Support for Romania, Mission Romania (St Albans), Relief Fund for Romania, Romania at Heart, Romania Information Centre, Royal College of General Practitioners and SOS Romania.

Effective Drug Management and Rational Drug Use training course, Aberdeen, June 1996
The *Guidelines* were presented and discussed at this training course run by the Robert Gordon University in Aberdeen in June–July 1996. This topic then became part of the curriculum of this annual course for senior pharmacists from developing countries.

8th International Conference of Drug Regulatory Authorities, Bahrain, November 1996
The *Guidelines* were presented to about 135 national regulatory authorities. In the discussion it was suggested that the following wording be added: "The donor may be asked to pay the cost of quality control testing and the cost of destroying expired or unusable drugs".

Corporate Partnerships for Development, Washington DC, December 1996
This was a meeting on collaboration with the private sector organized jointly by the World Bank and International Medical Services for Health. One afternoon session was devoted to a forum discussion on drug donations. WHO participated and the *Guidelines* were presented and discussed. About 50–60 United States private voluntary organizations and pharmaceutical industries took part.

Conference on the WHO Guidelines for Drug Donations – Notre Dame Center for Ethics and Religious Values in Business, Notre Dame, USA, April 1997
The *Guidelines* were presented by WHO staff and discussed at this national conference, which was attended by over 100 participants from the United States pharmaceutical industry, private voluntary organizations and other groups, and three representatives from developing countries.

Drug Donation Round Table, New York, September 1998
WHO presented the first outcome of the review of experiences with the *Guidelines* at a meeting organized by the UN/NGO Health Committee, and supported by Pfizer. It was attended by about 40 representatives from the United States Government, pharmaceutical industry and private voluntary organizations.

Towards Appropriate Drug Donations from the European Union, Leiden, Netherlands, June 1999
Meeting organized by the Dutch Wemos Foundation.

International organizations subscribing to the *Guidelines*

The United Nations Population Fund (UNFPA), which became involved in other activities of the interagency group, expressed an interest in becoming a sponsor of the *Guidelines.*

The International Pharmaceutical Federation (FIP) discussed the *Guidelines* at its annual meeting in 1997 and issued "Good Practice in Donations of Medicines", largely based on the interagency guidelines. It distributed 6,000 copies.

After August 1998 Caritas Internationalis (the international Catholic relief agency), FIP, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP), and the World Bank decided to officially sponsor the *Guidelines.*

Countries and national organizations that have adapted or adopted the *Guidelines*

Since the launch many organizations and governments have discussed, adopted and/or adapted the *Guidelines.* This is an ongoing process and quantitative data and percentages are of very little value. The summary below has been prepared through the questionnaire and through other information available to WHO. It is updated to August 1998.

National guidelines were issued or endorsed by the Governments of the following six developed (donor) countries: Australia, Canada, Italy, Netherlands, New Zealand and Norway. In the following 14 recipient countries the Government issued or endorsed national guidelines for drug donations: Armenia, Bolivia, Estonia, Indonesia, Jamaica, Madagascar, Mali, Mongolia, Namibia, Niger, Peru, Sri Lanka, United Republic of Tanzania and Zimbabwe. In all other countries mentioned below, national organizations or groups of organizations discussed, adapted and/or adopted the *Guidelines.* In all, copies of the interagency guidelines were distributed or local adaptations developed and/or issued in over 40 countries, and the number is still increasing.

Armenia: The Ministry of Health consulted with donors and issued national guidelines, partly based on the interagency guidelines.

Australia: The Pharmaceutical Society of Australia issued national guidelines for drug donations, largely based on the interagency guidelines. Rotary Australia, World Vision, the St Vincent de Paul Society, Asian Outreach of Australia and

	the Macfarlane Burnet Centre started a process to adopt the *Guidelines.*
Bolivia:	The Unidad de Medicamentos y Laboratorios of the Ministry of Health adopted and translated the *Guidelines.*
Cameroon:	Sadebay and Horizons Santé (nongovernmental organizations) started a process to adapt the *Guidelines.* The Presbyterian Medical Institute adopted the *Guidelines* unchanged.
Canada:	The Government of Canada considers the *Guidelines* useful and appropriate but did not endorse or approve them since it was not invited to do either. The International Affairs Directorate of Health Canada has brought the *Guidelines* to the attention of Canadian organizations that are involved with drug donations. Canada does not require an export licence for donated drugs, but will issue one if it is requested by the receiving country. MAP (Canada) started a process to adapt the *Guidelines.*
Chile:	The Order of Malta (Chile) started a process to adapt the *Guidelines.*
Croatia:	The Hrvatska Malteska Sluzba (Croatia) adopted the *Guidelines* unchanged.
Dominican Republic:	The Order of Malta (Dominican Republic) adapted the *Guidelines.*
El Salvador:	The Order of Malta (El Salvador) started a process to adapt the *Guidelines.*
Estonia:	The State Agency for Medicines distributed 5,000 copies of the *Guidelines.*
Ethiopia:	The Medical Mission Sisters adapted the *Guidelines.*
France:	Tulipe adopted the *Guidelines.* Médecins Sans Frontières (MSF) France disseminated the *Guidelines* and started a process to adapt them. The Order of Malta (France) also started a review process.
Georgia:	UMCOR (a nongovernmental organization) adopted the *Guidelines.*
Germany:	DIFÄM adapted and translated the *Guidelines* into German for use in Germany, Austria and Switzerland, and distributed 6,200 copies. It also wrote reports in about 30 German newsletters, and organized meetings and seminars on the subject. Action Medeor, a non-profit drug supply organization, distributed the *Guidelines* in German. It also

developed a poster presentation for conferences and teaching.

Guinea: The Order of Malta (Guinea) adopted the *Guidelines* unchanged.

Haiti: The Center for Development and Health adopted the *Guidelines* unchanged.

India: The Community Development Medical Unit in Calcutta disseminated the *Guidelines*. The Ramakrishna Mission Ashrama and Alleppey Diocesan Charitable and Social Welfare Society started the process to adopt the *Guidelines*.

Indonesia: The Ministry of Health has started to translate the *Guidelines* into Bahasa with the intention of disseminating them widely within the country. Together with WHO it also submitted the *Guidelines* to all foreign embassies in Jakarta, urging them to respect the guidelines for any drug donations.

Ireland: TRÓCAIRE adopted the *Guidelines* unchanged.

Italy: The Mario Negri Institute and the Ministry of Health translated the *Guidelines* into Italian and disseminated them widely within the country.

Jamaica: The Ministry of Health summarized the *Guidelines*, which were published as guidelines for donations of pharmaceuticals.

Kenya: The Ministry of Health and the Kenya National Drug Policy Implementation Programme started a process to adopt and translate the *Guidelines*.

Lithuania: The Humanitarian Commission of the Ministry of Health started a process to adopt the *Guidelines*, and changed the national drug policy accordingly. Maltos Ordino Pagalbos (Lithuania) adapted the *Guidelines*.

Madagascar: The Ministry of Health adopted the guidelines.

Malawi: The Christian Health Association of Malawi originally used the guidelines of the Christian Medical Commission. It distributed 200 copies of the interagency guidelines to hospitals and clinics and started a process of adaptation to the new guidelines.

Mali: The Direction Nationale de Santé Publique adapted the *Guidelines*.

Mongolia:	The Agency for Quality Assurance of Biological Preparations and Medical Care has started a process to prepare national donation guidelines.
Namibia:	The Ministry of Health and Social Services developed national guidelines but often refers to the *Guidelines* as well.
Netherlands:	The Wemos Foundation, supported by the Ministry for Development Cooperation and the Ministry of Health, Welfare and Sport, coordinated the Dutch Working Group on Donations with 18 organizations subscribing to the *Guidelines*, including Nefarma, the Dutch pharmaceutical manufacturers' association. Additions were made, but the basis of the WHO *Guidelines* remains unchanged. A poster presentation was developed for conferences entitled "A Call for Good Donation Practices". Memisa Medicus Mundi started a process to adopt the *Guidelines*.
New Zealand:	The Pharmaceutical Society developed its own guidelines, and advised all pharmacists about their responsibilities for donating drugs overseas.
Niger:	The Ministry of Health issued guidelines for drug donations, based on the *Guidelines*, and informed donors about these guidelines in an official letter.
Norway:	The Government issued national guidelines for drug donations.
Panama:	The Order of Malta (Panama) adopted the *Guidelines* unchanged.
Peru:	The Centro de Obras Sociales translated and distributed the *Guidelines*.
Philippines:	The Order of Malta (Philippines) and Sisters of the Poor adopted the *Guidelines* unchanged.
Poland:	The Ministry of Health and Social Welfare started a process to adapt the *Guidelines*. The Institute of Haematology and Blood Transfusion translated the *Guidelines* into Polish.
Republic of Moldova:	The Association for Drug Information translated and distributed the *Guidelines*. It also carried out a questionnaire survey.
Romania:	In the United Kingdom about 700 nongovernmental organizations dealing with Romania received copies of the *Guidelines*.
Spain:	The nongovernmental organization Prosalus adapted and printed the *Guidelines* for Spanish-speaking countries.

Sri Lanka: All potential donors received a copy of the *Guidelines*.

United Kingdom: At least one meeting was held by OXFAM to disseminate the *Guidelines* to nongovernmental organizations active in emergency relief operations in Romania.

United Republic of Tanzania: The Ministry of Health summarized the *Guidelines* in a small booklet and disseminated them to all hospitals.

United States: The United States Department of Defense and the United States Agency for International Development (USAID), even before the issue of the *Guidelines*, took up the draft. As a result, all product shipments to locations abroad must have a minimum 12-month product dating. Large numbers of copies of the *Guidelines* were distributed among donors and consolidators during three national meetings on the subject (see under "Conferences"). The United States Pharmacopoeia has also adopted the *Guidelines*. In April 1998 the US/NGO Pharmaceutical Product Donation Steering Committee, composed of eight pharmaceutical companies and seven private voluntary organizations, issued a *Statement of Principles on the Provision and Distribution of Donated Medicines and Medical Supplies for Disaster and Humanitarian Relief*. The Catholic Medical Mission Board started a process to adapt the *Guidelines*. The United Armenian Fund adapted and translated the *Guidelines*.

Yugoslavia: The Order of Malta (Yugoslavia) translated the *Guidelines*.

Zimbabwe: The Ministry of Health and Welfare issued national guidelines for drug donations, largely based on the *Guidelines*. The Commonwealth Pharmaceutical Association (Zimbabwe) adopted the *Guidelines*.

Other country studies on drug donations

The Association for Drug Information in the Republic of Moldova issued a questionnaire about the use of donated drugs among 600 health care professionals. Of the respondents, 21% reported that all drugs were used completely, 35% noted that drugs went into the illegal market, and 47% said that drugs were not used owing to unskilled distribution.

The Harvard School of Public Health in Boston initiated and completed a three-country study (Armenia, Haiti and the United Republic of Tanzania) on drug donations.[4]

In the Netherlands an evaluation study revealed that the number of pharmacists giving returned drugs to small-scale charity organizations for donation purposes dropped from approximately 70% in 1995 to 25% in 1998. A qualitative study among such organizations showed more awareness about the possible negative implications of using returned drugs for donations.

DIFÄM in Germany distributed an abbreviated questionnaire on drug donations to the 500 members on its mailing list. Results are awaited.

4. Basic characteristics of drug donations

Magnitude of donations made in the past 12 months

The total value of donations reported by the donors in this study was US$ 298 million – 14 industry donors contributed US$ 228 million (76%), 11 non-governmental organizations contributed US$ 68 million (23%) and governmental agencies contributed US$ 3 million (1%). Consolidators represented in this study reported donations totalling US$ 360 million.

There were huge differences in size between amounts donated by the various donors. For example, one pharmaceutical industry donor reported annual donations of US$ 170 million, which is 74% of all industry donors. The four largest donors (with US$ 170, 18, 15 and 11 million) constitute 94% of industry donations. The situation is similar with regard to consolidators. With a reported annual turnover of US$ 148 and 141 million, the two largest consolidators constitute 80% of all consolidators.

Soft loans by the World Bank as well as the many ongoing bilateral drug donations by the Governments of Denmark, the Netherlands, Sweden and other countries are not included in this overview. The former are estimated at about US$ 300 million a year, while the latter are not really known but can be estimated at several tens of millions of dollars per government per year. These are all donations of procured drugs (usually through tender).

Cost basis of donation value

There was no consistency of method for calculating the value of donations. Some respondents cited more than one method, depending on the nature of the donation. Overall, wholesale cost basis calculation appears to be the commonest (28%), followed by generic cost basis (20%), retail cost basis (9%) and other methods (3%).

Percentage of donations made for emergencies

Twenty-nine of the 41 responding donors (71%) indicated that less than 20% of their donations were made for acute emergencies. This implies that most drug donations reported in this study were made as part of development aid.

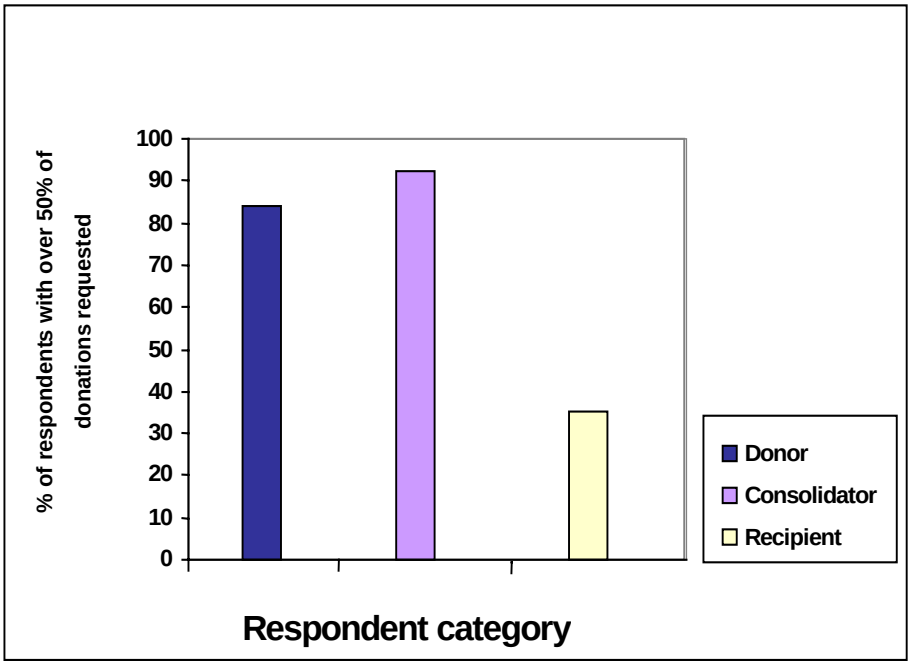
Discussion
Assuming that this is a representative sample of all donations, over three-quarters of drug donations are made on an ongoing basis and as part of

development aid. This implies that for such donations "lack of time" or "urgency of the request" cannot be an excuse for not following the core principles and articles of the *Guidelines*, such as carefully indicating which drugs are needed, and informing the recipient about what is coming, and when. It also supports the general impression that most donations are used to replace or complement the usual supply system, and end up in the normal distribution pipeline. The latter underscores the need for sufficient shelf-life upon arrival in the country.

Percentage of donations based on specific requests

Eight-four per cent of donors, 92% of consolidators and 35% of recipients indicated that over half of their donations are based on a specific request (Figure 1).

Figure 1. Percentage of respondents that replied that over 50% of their donations are based on a specific request (n = 96)



Discussion

The difference of opinion between donors and consolidators on the one hand and recipients on the other probably indicates a real difference in perception as to what constitutes a "specific request", with many recipients believing that they received many donations without specifically having asked for them. The review of the experiences with the *Guidelines* was undertaken relatively shortly after their launch. It is possible that donation practice has changed at the level of the donors and consolidators (resulting in more new donations based on requests), while older donations (without specific requests) are still arriving in the field. If this is so, it would indicate that donations are improving. If not, there is a serious misunderstanding between donors and recipients. A follow-up study will be needed to see whether recipient opinion is changing over the next year.

5. Practical benefits as a result of the *Guidelines*

General benefits

In open questions put to all respondent categories, many respondents indicated various benefits they had derived from the *Guidelines*. The most frequently quoted benefits are summarized below.

About one-third of all respondents indicated that the *Guidelines* provided a beneficial framework for improved drug donation practices and procedures. Many respondents noted the link between the *Guidelines* and a national drug policy: the *Guidelines* are needed to support a national drug policy, or may lead to its development.

More than 20 respondents reported better documentation of consignments as well as improved communication between donors, consolidators and recipients. Fifteen mentioned that requests for donations are now more carefully solicited and formulated in keeping with the *Guidelines*.

Many respondents believe that the *Guidelines* are useful tools for curtailing inappropriate donations. Sixteen reported enhanced awareness and understanding of drug donation issues. Twelve felt that the *Guidelines* help to ensure the quality of donations.

Specific benefits for recipients

The figures and results reported below are based on replies to questions which were put only to recipients. All but the last were closed questions.

Improvement in donations meeting needs
Twenty-three of the 51 responding recipients (45%) reported that donations now better meet their needs, while only 2 out of 51 (4%) reported a deterioration. Eight out of 14 government organizations (57%) reported an improvement, followed by 10 out of 25 nongovernmental organizations (40%) and 5 out of 12 individual health care institutions / health workers / prescribers (42%).

Improvement in shelf-life
Twenty-two out of 51 recipients (43%) reported that the remaining shelf-life of donations had improved, and 3 out of 51 (6%) reported a deterioration. There were differences between recipient categories, with 8 out of 14 government organizations (57%), 11 out of 25 nongovernmental organizations (44%) and 3 out

of 12 individual health care institutions or health workers (25%) reporting an improvement.

Improvement in packaging and labelling
Twenty-one out of 53 recipients (40%) reported that the packaging and labelling of donated drugs had improved, while 1 out of 53 (2%) reported a deterioration. There was a difference between recipient categories, with 8 out of 15 government organizations (53%), 9 out of 25 nongovernmental organizations (36%) and only 4 out of 13 individual health care institutions or health workers (31%) reporting an improvement.

Easier to refuse, return or destroy unwanted donations
Twenty-eight out of 53 recipients (53%) felt that the *Guidelines* had made it easier to refuse unwanted donations. Government organizations (62%) were slightly more in agreement than nongovernmental organizations (50%) and individual health care institutions / health workers / prescribers (50%).

Shorter distribution time
Three recipients reported an improvement in distribution time and a reduction in the period between drugs' reception, selection and distribution to final users.

Discussion
The questionnaires specifically inquired about the link between the introduction of the *Guidelines* and any change in donation practice. The replies therefore represent the respondents' perception of this link, but do not constitute a proof of causality.

In the open questions, about one-third of respondents reported non-specific benefits from the *Guidelines*. Approval of a practical and ethical framework for donations, improved communication and awareness, and the establishment of donation standards were most frequently quoted as benefits.

In closed questions, approximately 40% of recipients reported an improvement in particular aspects, such as donations meeting expressed needs, duration of shelf-life and packaging and labelling. However, significantly fewer individual health institutions and health workers reported an improvement compared with government and nongovernmental organizations. The different rating among recipients is interesting. It could be the result of a pipe-line effect (the time it takes for the "better donations" to reach the end-users, with older donations still being received by more peripheral recipients). It could also be related to better appreciation of the importance of the shelf-life issue by the national planners, compared with the end-users.

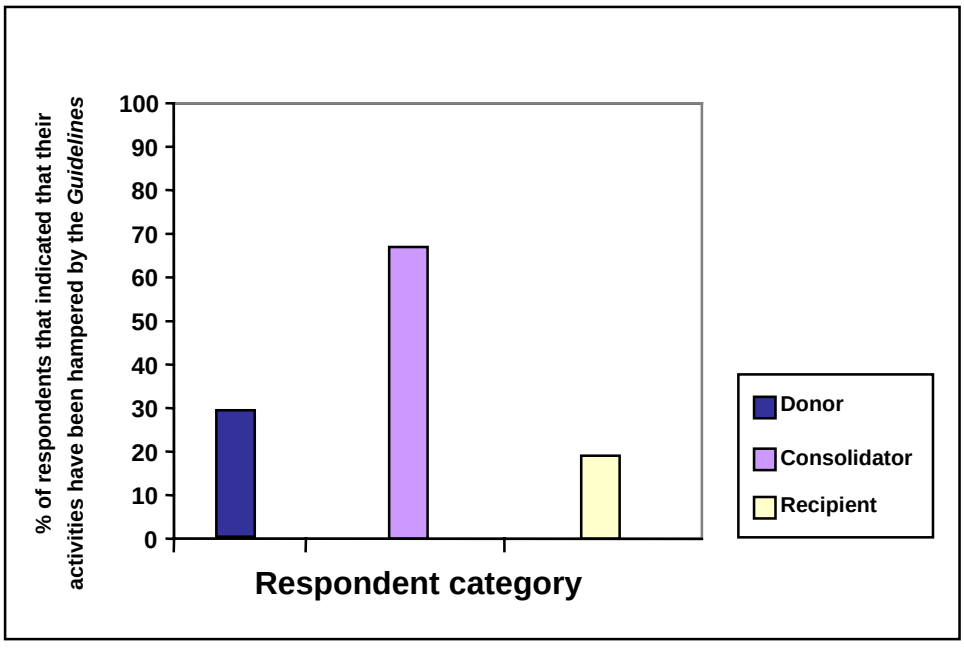
6. Drug donations which were hampered, delayed or cancelled

Nineteen out of 68 respondents (28%) felt that their organization's activities had been hampered by the *Guidelines*. This figure comprised mostly consolidators (67%), as contrasted with donors (29%) or recipients (19%). This outcome is visualized in Figure 2. Thirty-four out of 117 respondents (29%) had experienced a delay or cancellation of donations as a result of the *Guidelines*. Again, 63% of consolidators reported this problem, as compared with only 24% of donors and 29% of recipients.

Thirty-nine out of 111 respondents (35%) reported that the requirement of Article 6 (a minimum one-year shelf-life upon arrival in the recipient country) had caused problems for their organization. This figure comprised significantly more consolidators (75%) than donors (31%) or recipients (23%).

The following were mentioned as the main causes of the delaying and hampering of drug donations: the restrictive and arbitrary nature of the one-year dating limit (Article 6 requires a minimum remaining shelf-life of 12 months after arrival in the recipient country), the recipient's rigidity in applying this article, and problems with customs clearance. These are seen to lead to cessation, reduction or loss of donations, a negative impact on health care provision, limitation of donations of drugs with an intrinsic short shelf-life, and hampering of emergency aid.

Figure 2. Percentage of respondents that indicated that their activities have been hampered by the *Guidelines* (n = 68)



Discussion

About one-third of respondents found that (some of) their activities had been hampered by the *Guidelines*. This usually related to a delay in or cancellation of drug donations, and was usually because of the one-year minimum shelf-life requirement.

It is interesting to note that consolidators in particular indicated problems (63–75%), with much lower percentages for donors and recipients (19–35%). It is clear that consolidators in particular have a problem with this part of the *Guidelines*.

We conclude that Article 6 is the only article in the *Guidelines* that has resulted in delaying or hampering drug donations. However, this problem is reported particularly by consolidators. In the next chapter a more detailed analysis of the practical experiences with Article 6 is presented.

7. Experiences and opinions regarding the 12-month shelf-life requirement

Impact of the *Guidelines*

Twenty-two out of 51 recipients (43%) reported an improvement in the shelf-life of donations, thanks to the *Guidelines*. As advantages they mentioned the following: the *Guidelines* provided a solid policy framework; there were fewer short-dated donations; it was easier to refuse short-dated products; there was reduced waste; and longer-dated donations improved the quality of their services.

Guidelines by other organizations

All governments and organizations that developed national or institutional guidelines on the basis of the *Guidelines* maintained the 12-month minimum shelf-life requirement, sometimes with exceptions (see Table 2).

Table 2. Minimum shelf-life upon arrival, as formulated in other guidelines

Italy, Netherlands, Norway, United Republic of Tanzania	12 months, same exceptions as *Guidelines*
Australia, Zimbabwe	12 months, no exceptions
International Pharmaceutical Federation	Should normally be 12 months; when a shorter shelf-life is appropriate, the donor is responsible for informing the recipient and for ensuring that the remaining shelf-life allows for proper administration

Agreement with the current provision

Seventy out of 128 respondents (55%) agreed with the current provision that, after arrival, all donated drugs should have a remaining shelf-life of one year. Over 50% of the donors and 61% of recipients were in agreement, but only 25% of the consolidators. Within the group of recipients there was, however, a difference in agreement between government organizations (79%), nongovernmental organizations (59%) and individual health care institutions and health workers (44%).

A hundred and two out of 120 respondents (85%) agreed with the current exception clause to the minimum shelf-life provision, as already included in the

Guidelines. There was little difference between respondent categories. Several respondents confirmed that the exception clause was a valid and useful principle on which to base donations.

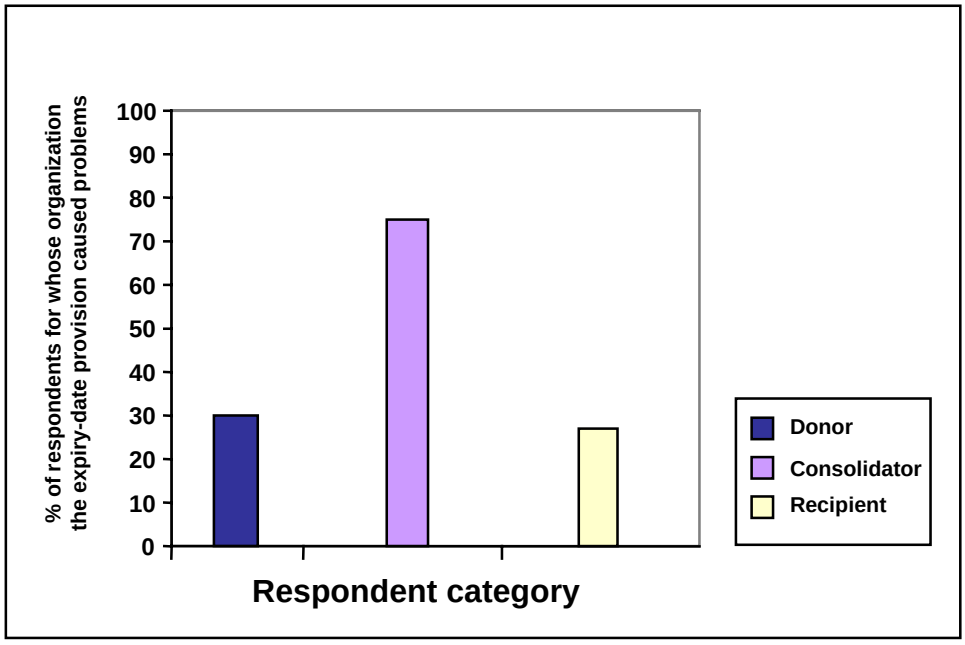
Discussion

Lower levels of agreement by rural health workers, when compared with recipient governments, may point to two factors. First, there may be a general lack of interest in regulatory issues such as shelf-life, and a more "hands-on" attitude. Secondly, there may be a misunderstanding of the question: rural respondents may have understood shelf-life in terms of "upon arrival in the facility" rather than "arrival in the country"; and for them a one-year shelf-life upon arrival in the facility may not have been a top priority.

Problems with the *Guidelines*

Twelve out of 16 consolidators (75%) have experienced problems with the 12-month minimum shelf-life guideline, as compared with only 30% of donors and 27% of recipients (see Figure 3). Within the donor group 21% of the pharmaceutical industry had experienced problems with the provision. Comments mentioned the restrictive and arbitrary nature of the guideline, and rigidity in its use. Some recipient governments have given insufficient consideration to the possible exceptions, resulting in some valid donations being delayed or cancelled.

Figure 3. Percentage of respondents for whose organization the expiry date provision (Article 6) caused problems (n = 111)



Arguments for and against the 12-month shelf-life provision

Several respondents suggested that the minimum shelf-life required be extended to 18, 24 or even 36 months. Their main arguments were the following: the distribution channels are so slow that more time is needed; and irregular donations and drug needs are so difficult to predict that donations need to last for a long time and therefore need a long remaining shelf-life.

Several respondents advanced arguments for reducing the minimum shelf-life. The main arguments were as follows: supplies are quickly used and do not need such a long shelf-life, especially in emergency situations; expired medicines can still be used; pharmaceutical companies mainly donate drugs with a shelf-life of less than one year; and national guidelines in the donor country also allow for supplies with a minimum shelf-life of six months.

Several donors felt that the circumstances should dictate the dating – shelf-life should be determined by nature of need, distribution system, turnover, governmental restrictions, patient load, level of planning, speed of customs clearance, and other unique features. The recipient should specify the dating requirements and be held accountable.

Discussion

It is clear that Article 6 is the most contentious issue of the *Guidelines*. From the responses and many comments received the following observations can be made.

A majority of the respondents agree with the requirement that donated drugs have a minimum shelf-life of 12 months upon arrival, and all national governments that developed their own guidelines have copied that provision. It is mainly the consolidators that have experienced problems in practice and that foresee reduced drug donations in the future.

In some cases, recipient governments have specifically decided not to allow for exceptions to the minimum shelf-life of donations. Some examples have been reported of delays in or cancellations of valuable donations which could have been used before expiry if recipient authorities had applied the exception clauses in a flexible way.

However, we should be careful not to blame the victim. Recipient governments are fully entitled to refuse certain donations on their territory if admitting them could lead to substandard therapy or double standards in quality. Relief agencies may or may not agree with a decision to refuse entry of an important drug with (sometimes slightly) less than a one-year expiry. But accepting the rule of law and the power of regulation implies accepting a government decision. And if an exception is not granted, it should perhaps be asked why it was asked for in the first place.

In this regard it would be interesting to know why some private voluntary organizations seem to continue to receive such large offers of drug donations with a shelf-life of less than one year. Have they failed to inform their donor partners, or do companies continue to donate short-dated products despite

growing international resistance? However, only 21% of companies indicated that they had experienced problems with the minimum shelf-life provision.

If it is agreed that donations are a useful means of supporting health care delivery when there are chronic shortages of essential drugs, any delay in or cancellation of such donations has a negative impact on health. On the other hand, the *Guidelines* were specifically intended to reduce the number of donations of (nearly) expired drugs. Any report on cancellations of donations of short-dated products shows that the *Guidelines* have had an impact in reducing such practices. The questions remains whether short-dated donations have now been replaced with longer-dated ones.

Most of the special circumstances mentioned above are already part of the exception clause of the *Guidelines*. Small quantities of drugs, donated directly to health facilities where the recipient knows and agrees with the short-dated donation and can guarantee that the drugs will be used before expiry, were already foreseen in the 1996 version. The fact that there is a technical justification for an exception to a general rule, or the possibility that an unfavourable decision is taken by an uninformed civil servant or customs officer who simply follows instructions and refuses to make an exception, does not imply that the rule should be changed or scrapped. Instead, the capacity of the government to deal with such situations should be increased through information and training.

Recommendations

- A special education effort should be made with regard to all donors and consolidators, in order to reduce the number and quantities of short-dated drugs offered for donation.

- A special education effort should be made with regard to all recipient governments, informing them about the *Guidelines*, with emphasis on the guideline for the minimum shelf-life of donations upon arrival, the exceptions provided for, and the need for rapid customs clearance of donated drugs.

- WHO should convene the interagency group and propose to it that the interagency guidelines be updated, including the incorporation of the current text of the exception for direct donations into the main body of the text of Article 6 in order to prevent the guidelines from being copied and used without proper consideration of the exception. In addition, the current text of the section on how to manage drug donations should be expanded with explanatory notes on the issue.

- WHO should establish a system whereby recipients and consolidators can report examples of inappropriate donations or unacceptable donation practices.

- WHO should establish a system, probably in the Department of Essential Drugs and Medicines Policy, where donors and consolidators can report drug donations that are unnecessarily hampered or delayed by customs formalities. If WHO agrees that the delay is technically unjustified, it should approach the recipient authorities in order to assist in the rapid clearance of the goods. Subsequent action taken on this proposal is to be found on page 33.

8. Other suggestions to improve the *Guidelines*

Suggestions about changing Article 6 were discussed in the previous chapter. Respondents also made a large number of suggestions regarding further fine-tuning of the interagency guidelines.

Most of these observations had already been made during the three rounds of consultation which preceded the issuing of the interagency guidelines, and had been discussed and rejected by the interagency group. They do not contain any new suggestion that could improve the content and clarity of the *Guidelines*.

Recommendation

- The text of the other articles of the interagency guidelines should remain unchanged.

9. How could donation practice be further improved?

From the review undertaken it has become clear that governments and organizations in a large number of countries (46 by August 1998) have adopted or adapted the interagency guidelines, with the intention of improving drug donation practices. There are many indications that actual donation practice has improved because of the *Guidelines*. For example, about one-third of respondents mentioned in their replies to open questions that the *Guidelines* provided a beneficial framework for improved drug donation practices; 45% of recipients reported that donations now better meet their needs; 41% of recipients reported that the packaging and labelling of donated drugs has improved; and 53% of recipients felt that the *Guidelines* had made it easier to refuse unwanted donations.

Taking into account the short time (less than 16 months) between the issuing of the *Guidelines* in the summer of 1996 and this review at the end of 1997 and early 1998, the impact of the interagency guidelines can only be described as impressive. If we assume that "improved donations" need a certain time to travel through the donation pipeline, reports on positive effects can only increase in number.

Discussing the *Guidelines* improves donation practice

The *Guidelines* were never intended to serve as an international regulation; and they would never be accepted as such. However, they have certainly raised awareness of the potential benefits and problems of drug donations, and have often served as a starting point for intensive discussions within donor groups and between donor and recipient organizations. It was particularly these discussions, and a better exchange of information between donor and recipient, that have helped to rectify the imbalance between the two sides. Several recipients have confirmed that the *Guidelines* have enabled them to express openly how they would like to be helped, and have made it possible for them to refuse certain types of donations.

Thus it is the awareness and the discussion that have actually led to better donation practice, not the *Guidelines* themselves. This implies that further dissemination of the *Guidelines* is useful, and that governments and organizations should continue to be encouraged to discuss the issue of drug donations, and to develop their own guidelines.

Give more practical advice on good donation practice

The review has also shown that some governments or regulatory agencies have sometimes applied the interagency guidelines, or their own, in a rather inflexible manner, for example by refusing to make exceptions to the minimum shelf-life when an exception would have been justified. Also, it has become clear that in some countries the process of customs clearance of donated drugs is unacceptably long, leading to unnecessary delays and loss of effective shelf-life.

The quality of supply management of donated drugs is likely to be linked to the quality of drug supply management in general. In this regard, WHO is giving technical assistance to a large number of developing countries. An extra effort could be made to specifically focus on the management of donations; and more specific technical advice on good donation practice could be included in the next version of the interagency guidelines (although the main principles are already present). WHO may need to give special attention to nongovernmental organizations' drug management practices.

It is not clear what can be done with central governments that do not request technical advice or management assistance, or that even actively discourage a rapid handling of drug donations intended for sections of their population with which they consider themselves at war (for example, Chechnya and Southern Sudan). In these cases the obstruction is probably political rather than technical, and is likely to continue with or without guidelines.

Recommendations

- WHO and all partner organizations should continue to actively disseminate the *Guidelines*, and should encourage all governments and organizations involved in drug donations to formulate their own guidelines.

- WHO should involve as many partners as possible in the next version of the *Guidelines*. International organizations which have expressed an interest should be invited to become co-sponsors of the second version. Examples of such organizations are Caritas Internationalis, the International Pharmaceutical Federation, Pharmaciens Sans Frontières, UNAIDS, the United Nations Development Programme, the United Nations Population Fund, and the World Bank.

- WHO should expand the section in the *Guidelines* on the management of drug donations, stressing the need for rapid clearance of drug donations and reconfirming the justification of certain exceptions to the minimum shelf-life provision.

10. Summary of recommendations

The chapters of this report contain a number of recommendations made by those who replied to the questionnaires. They are reproduced below and are followed in the postscript by a brief account of the subsequent outcome and action taken.

- WHO and all partner organizations should continue to actively disseminate the *Interagency Guidelines for Drug Donations*, and should encourage all governments and organizations involved in drug donations to formulate their own guidelines.

- A special education effort should be made with regard to all recipient governments, informing them about the *Guidelines*, with emphasis on the guideline for the minimum shelf-life of donations upon arrival, the exceptions provided for, and the need for rapid customs clearance of donated drugs.

- A special education effort should be made with regard to all donors and consolidators, in order to reduce the number and quantities of short-dated drugs offered for donation.

- WHO should establish a system whereby recipients and consolidators can report examples of inappropriate donations or unacceptable donation practices.

- WHO should convene the interagency group and propose to it an update of the *Guidelines*, including the incorporation of the current text of the exception for direct donations into the main body of the text of Article 6, in order to prevent that guideline from being copied and used without proper consideration of the exception.

- WHO should expand the section on the management of drug donations in the next version of the *Guidelines*, stressing the need for rapid clearance of drug donations and reconfirming the justification of certain exceptions to the minimum shelf-life provision.

- WHO should involve as many partners as possible in the next version of the *Guidelines*. International organizations which have expressed an interest should be invited to become co-sponsors of the second version. Examples of such organizations are Caritas Internationalis, the United Nations Population Fund and the World Bank.

11. Postscript

An interagency meeting was held on 5 March 1999 to discuss the questionnaire recommendations. Changes to the *Guidelines* were agreed and additions and modifications incorporated into the revised 1999 edition which was issued later that year. Changes include the following:

The introduction was updated and the justification and explanation to Article 6 were modified and expanded. Four new paragraphs entitled "Manage drugs with less than one year expiry", "Ensure rapid customs clearance of donated drugs", "Avoid donations of drugs with short expiry dates" and "Establish donor coordination" were added.

Interagency partners cosponsoring the final version of the revised *Guidelines* are Caritas Internationalis, Churches' Action for Health of the World Council of Churches, International Committee of the Red Cross, International Red Cross and Red Crescent Societies, International Pharmaceutical Federation, Joint United Nations Programme on HIV/AIDS, Médécins 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 and the World Bank.

In December 1999 the Department of Essential Drugs and Medicines Policy web site (http://www.who.int/medicines) introduced a list for organizations wishing to underwrite and endorse the *Guidelines*. The site also contains an explanation of how complaints related to unhelpful donations may be registered with WHO. Donations delayed or hampered by customs formalities may also be reported.

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