DRUG DONATION PRACTICES IN BOSNIA I HERZEGOVINA

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EXECUTIVE SUMMARY

Background: War in Bosnia and Herzegovina disorganized the health system. Many areas became totally dependent on foreign humanitarian assistance for the provision of medical supplies. In that context, large quantities of drugs and medical material were donated.

Methods: An investigation was carried out at the end of 1996 to evaluate the donation practices of drugs and disposable medical materials during the war in Bosnia and Herzegovina.

In the course of a survey in Central Bosnia (August 1996), interviews were conducted in Sarajevo, Mostar and Tuzla with representatives of the national and cantonal health authorities, international agencies, including the World Health Organization, the Office of the United Nations High Commissioner for Refugees and the European Commission Humanitarian Office, and the major non governmental organizations implementing drug supply and distribution programs in Bosnia and Herzegovina. We carried out research in the four main drug warehouses in Mostar and Tuzla, assessing contents and volumes, and collecting samples of medicines. Investigations were however limited due to restricted access to warehouses. When permitted, reports, documents and quantitative data were collected from local institutions and international relief organizations. Contacts were made in Europe with organizations active in research, policy and advocacy regarding pharmaceutical issues, as well as with the pharmaceutical industry and waste management companies. Finally, hard data and estimates were aggregated as to offer a global quantitative and qualitative assessment of the medical donations in Bosnia and Herzegovina between 1992 until mid-1996.

Inappropriate drugs comprised useless and unusable medicines. Useless drugs included medicines irrelevant to the epidemiological context or not within the scope of the National and WHO Essential Drug Lists (WHO, 1992). Unusable drugs comprised medicines already expired on arrival or expired after arrival (e.g. oversupply, too short expiry deadline), unidentifiable drugs (e.g. delivered unsorted, labeled in unknown foreign languages), drugs damaged during shelling of warehouses or spoilt by bad conditions of transport and storage.

Results: An estimated total of 27,800 to 34,800 tons of medical supplies was donated between 1992 and mid-1996, representing an overall value of 339 to 425 millions US$. Four large international agencies with health relief expertise, together with smaller organizations, contributed 40 to 50% of all donations. They delivered around 13,200 tons of medical supplies, out of which about 95% were considered appropriate for this type of situation. In contrast, up to 90% of other donations consisted of useless, unusable or expired drugs and disposable materials. In total, inappropriate medical supplies amounted to 17,000 tons, representing an opportunity cost of US$ 250 millions. Two thirds of inappropriate donations were unsorted unused medicines or samples returned by individuals and health professionals; one third resulted from dumping practices. Inappropriate donations may have resulted in a gain of US$ 25.5 millions for donors and a loss of US$ 34 millions for recipients.

In general, effective coordination of medical supplies was absent during the 4.5 years of relief efforts to Bosnia and Herzegovina. Had it been given priority, inappropriate drug donations as well as lack or excess of useful medicines could have been better identified.

Conclusions: Dumping practices and donations of mixed unused medicines, however well-intentioned, are neither acceptable, nor useful. Recommendations for improving the quality and efficiency of drug and medical material donations in emergency situations are detailed at three levels:

1. the policy level (international guidelines and regulations, national drug policies, regulations for drug donations and disposal of pharmaceutical waste in donor and recipient countries);

2. the advocacy and information level (awareness raising and campaigning activities, international monitoring of drug donations);

3. the operational level (coordination and management of medical donations, guideline for efficient drug donation programs).

Keywords: Disaster, Medical Supply, Humanitarian Aid, Public Health

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LIST OF ABBREVIATIONS

AEDES	Agence Européenne pour le Développement et la Santé
BMJ	British Medical Journal
BiH	Bosnia and Herzegovina
CHMP	Centrale Humanitaire Médico-Pharmaceutique
CMC	Christian Medical Commission
DEM	Deutsche Mark
ECTF	European Community Task Force
EDL	Essential Drugs List
HAI	Health Action International
ICRC	International Committee of the Red Cross
IDA	International Dispensary Association
IFPMA	International Federation of Pharmaceutical Manufacturers Association
IFRC	International Federation of the Red Cross and Red Crescent Societies
IPH	Institute of Public Health
JAMA	Journal of the American Medical Association
MDM	Médecins du Monde
MSF	Médecins sans Frontières (B=Belgium; F=France; H=The Netherlands)
MoH	Ministry of Health
ND	Not determinate
NGO	Non Governmental Agency
ODA	Overseas Development Administration
PAHO	Pan American Health Organisation
PIMED	Pour une Information Médicale Ethique et le Développement
PSF	Pharmaciens sans Frontières
ReMed	Réseau Médicaments & Développement
Tulipe	Transfert d'Urgence de l'Industrie Pharmaceutique
UNHCR	United Nations High Commissioner for Refugees
USD	US Dollar
Unicef	United Nations Children's Fund
Unprofor	United Nations Protection Force
WCC	World Council of Churches
WEMOS	Werkgroep Medische Ontwikkelingssamenwerking
WHO	World Health Organisation

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I. INTRODUCTION

I.1 TERMS OF REFERENCE

Following war and fierce fighting in Bosnia and Herzegovina since 1992, the health system has been totally disorganized and, in some places, was totally dependent on foreign humanitarian assistance. In that context, large quantities of drugs and medical material were donated to BiH and today, large amounts of inappropriate or expired medical supplies are reported to be stored in several locations in Central Bosnia or to have been destroyed throughout the years. Those inappropriate donated supplies raise important ethical, moral and medical questions. As for their disposal, no concerted and concrete measures have so far been taken.

MSF-B, involved in humanitarian assistance in BiH since 1993, expressed concern about this issue and wanted to get a clearer picture of the scale of the problem. Therefore, at the request of MSF-B medical and operational departments, two AEDES consultants carried out a general investigation to evaluate the donation practices of pharmaceuticals and medical material in BiH in terms of quantity, quality and appropriateness. More specifically, the investigation aimed at :

- assessing how far the donations responded to the specific needs of the country;
- assessing the scale of the inappropriate drug donations and their consequences in terms of costs, public health and environmental hazards, burden for the local authorities, etc.
- analysing the drug supply and distribution chain (donors, suppliers, selection of medical supplies, ordering, packaging, handling, transport, storage, distribution, etc.);
- identifying policies, mechanisms and legislation regarding drug donations;
- drawing up recommendations for action.

This report presents the results of AEDES investigations. It consists of five parts:

1. a review of relevant background information (Chapter II);
2. a description of the drug supply and distribution process in BiH throughout the war (Chapter III);
3. a detailed account of the facts and observations gathered from the field study (Chapter IV);
4. conclusions on the drug donation practices in BiH (Chapter V);
5. a set of strategic and operational recommendations and priorities for actions (Chapters VI and VII).

I.2 METHODOLOGY

In the course of a two-week visit in Central Bosnia (6-20 August 1996), the consultants met and discussed with representatives of the health authorities, international agencies and NGOs in Sarajevo, Mostar and Tuzla. They were able to visit and conduct some research in two of the three main warehouses of drugs and medical material in Mostar (Zalik central warehouse and stores of Bjieli Brijeg hospital). They were allowed to make a quick tour in the store of the Tuzla hospital and visited the Federal Drug Logistic Centre, recently set up in Tuzla, and the store of the Dom Zdravlja in Srebrenik.

To set the field study undertaken in Bosnia in a broader perspective, the consultants contacted various associations and experts involved in research, education, policy and advocacy in the field of pharmaceutical issues and particularly active in drug donations practices. In addition, they collected and reviewed documents and reports of local institutions, international agencies and NGOs, as well as relevant articles and publications in the medical and general press. They also investigated the regulations regarding the management and destruction of expired and unused drugs, mainly in Europe.

I.3 LIMITS OF THE INVESTIGATION

The field study and the results of the investigation had to be narrowed to a general qualitative assessment of the drug donations situation and practices in BiH, as the consultants found themselves confronted to two major limitations in addition to limited time :

1. unavailability of reliable quantitative information, aggregate data, statistics and systematic and comprehensive analysis of the drug supply programmes;
2. restricted access to the warehouses where inappropriate or expired drugs are stored.

I.3.1 Lack of coordination and monitoring

Probably the most important underlying factor for the unavailability of data was the ***poor coordination and absence of central monitoring*** at field level of the humanitarian assistance in general, and medical aid in particular, throughout the conflict.

It is recognised that in large-scale relief operations, and all the more under war context, coordination, exchange of information and control of the flow of incoming supplies are challenging tasks; but they nevertheless remain an issue of prime importance in ensuring the best relief response. In BiH, in spite of UNHCR, WHO and the health authorities attempts to coordinate actions and monitor relief efforts, no effective drug supply management, reporting and monitoring systems have been established to formally register needs, requests, deliveries and distribution of drugs, screen the conditions of the donated medical supplies (volume, quality, relevance) and evaluate the impact and efficiency of the drug supply programmes. This is surprising in regard to the large amount of funds and resources granted for drug supply programmes in BiH (see chapter III) and the experience intergovernmental agencies and international NGOs should have gained through past relief activities as well as numerous recommendations, advises and lessons drawn from past disasters.

Many reasons may be given to explain the lack of coordination and monitoring although none of them can justify it. On one side, the coordination and monitoring process was hampered by the resources constraints encountered by UN agencies, particularly WHO whose mandate was to lead and centralise the coordination of the health care relief activities [33, 34].

On the other side, in addition to the chaos inherent to the war environment in BiH and the fact that aid agencies had to face and adapt their operations to a new emergency context (a war in Europe while their expertise in dealing with conflicts was limited to relief operations in the Third-World), other significant difficulties which should be emphasised are:

- the diversity and large number of intergovernmental agencies, non governmental organisations and individuals involved in medical supplies distribution;
- the rapid and unforeseen changes and disruptions in the supplying roads, the security situation and the communication between central and field areas (enclaves, fast-changing front lines, lack of access to key interlocutors, etc.);
- the non-comparability of data compiled by implementing agencies and often, their unwillingness to give details on their activities;
- the differing policies and procedures for drug procurement, supply and distribution set up by implementing agencies and donors;
- the rapid turnover of expatriate field staff in most organisations;
- the reluctance of some local authorities to cooperate with the central health authorities and the international coordinating agencies;
- the off-centring in bordering countries of the coordination centres of the main implementing agencies during the war (Zagreb, Split, Belgrade).

Some agencies (WHO, ICRC, MSF) have conducted internal and/or external evaluations of their activities and relief programmes, but on a qualitative rather than a systematic and analytical approach, and limited to their own operations rather than on a comprehensive level [1, 35, 36 & 37].

I.3.2 Lack of cooperation from the health authorities

Another factor impeding the collection of data and information was the ***reluctance of the health authorities*** to provide any details and most of the time their unwillingness to discuss the problems of inappropriate medical donations. The main reasons for this attitude are:

- political sensitivity;
- tensions and lack of coordination between the federal and cantonal health authorities (enclaves, disruption in communication facilities, desire for independence leading cantonal health authorities to overrule or disregard federal actions and policies, etc.);
- bureaucratic and uncommunicative attitude, remnant of a pre-war centralised socialist system;
- difficulties to admit that data and information requested are simply not available due to the breakdown of the health services management capacities, hampered by difficult working conditions, drastic reduction of health staff (particularly pharmacists and handling workers), overwhelmed by the scale of the medical supplies donations (mainly unsolicited and unsorted consignments) and confronted to fluctuating demands and variable accessibility to the health care structures.

II. BACKGROUND INFORMATION ON INAPPROPRIATE DRUG DONATIONS IN EMERGENCY SITUATION

Medical supplies are a critical element in health operations in emergency situations. Effective supply and distribution of appropriate drugs and medical material are essential in alleviating suffering and saving lives. Since the seventies, a diverse range of actions, guidelines, regulations, publications and campaigns have been developed to improve the quality and efficiency of drug donations in emergency situations.

Yet, in spite of experience gained, repeated pleas and recommendations made by assisted countries, intergovernmental agencies (WHO, UNHCR, PAHO, UNICEF, etc.), international relief agencies and Western governments, current donation practices show that lessons are not being learned. Indeed, cases of drug supply mismanagement continue to occur on a large scale. Huge quantities of unrequested and unnecessary drugs and medical supplies continue to be sent to affected countries as soon as a disaster strikes.

It is therefore of prime importance to continuously:

- increase awareness that unsolicited donations can be more harmful than useful (and even create a "second disaster");
- foster changes of attitude;
- increase the central coordination and monitoring of relief operations;
- encourage the use by donors, suppliers and recipients of a systematic and rational framework for the supply and management of drug donations.

II.1 REVIEW OF INAPPROPRIATE DRUG DONATIONS

Numerous examples have demonstrated that unsolicited and inappropriate donations of medical supplies, generally not based on precise assessment of actual medical needs and proper requests for external assistance by the authorities of the stricken country, are impeding the relief efforts and doing more harm than good. Such donations overwhelm the already fully stretched health facilities and management capacities of the affected area, cause various health and environmental hazards, use critical and often limited resources and create logistical nightmares with high handling, sorting, transport, storage and disposal costs, very often at the expenses of the recipient country.

The prevailing crisis in Bosnia and Rwanda have not been exempt of such problems and can be added to the already numerous cases reported over the last twenty years.

A list of such cases is compiled in Annex 3. Those examples illustrate the scale and the variety of inadequate responses to emergency situations. They are drawn from a comprehensive review of the medical and general press.

Most reports on inappropriate drug donations are stories based on actual experience and visual observations of facts. Drug donation practices have very seldom been evaluated in a comprehensive, analytical and systematic way. It is therefore very difficult to quantitatively assess and compare the impact, quality and appropriateness of medical supply donations to the recipient countries. Some specific and general analysis have been carried out in the aftermath of the earthquake in Guatemala [2 & 3], Mexico [4], Armenia [5], as well as in Guinea Bissau [6].

The following table puts in parallel the results of these analysis as well as estimations gathered from other sources ; ***it shows that inappropriate medicines represented between 30 to 70% of the donated drugs or, on average, 55-60% of all donations.***

Table 1 - Comparative data on the quality of drug donations

Source	Ref.	Unusable	Not needed / Irrelevant	Relevant but unsorted or not easy to identify	Immediately useful
MSF-AEDES (Armenia) in the aftermath of the earthquake 1988	5	12% (8% expired and 4% frozen on arrival)	32% (11% total useless, 21% not for emergency)	26% (12% difficult to identify, 14% unsorted)	30%
		44%		56%	
Essential Drugs Programme, Armenia, 1994	38	**30 to 40%** of the donated drugs is discarded due to expiration, bad quality or unusefulness			
PAHO (Guatemala)	2 & 3	**90%** of aid was unsorted and unsolicited		< **10%** of unsolicited aid was useful	
WHO Zagreb	7, 8, 39	**45%**		**55%**	
		15%	30%		
Essential Drugs Programme, Georgia, 94	H	**70%** of all donated drugs are useless			

II.2 THE ISSUE OF UNUSED DRUGS IN THE WESTERN WORLD

II.2.1 Scale of the problem and regulations

Referring to the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal [41] to which former Yugoslavia participated, unused drugs are considered as wastes to be controlled (category Y3). It is also clearly stated that:

- "a party shall not permit hazardous wastes or other wastes to be exported to a non-party or to be imported from a non-party" (art.4, §5)
- "any transboundary movement of hazardous wastes or other wastes that results in deliberate disposal (e.g. dumping) of hazardous wastes in contravention of this Convention and of general principles of international law, shall be deemed to be illegal traffic" (art.9, §1e)

In France, unused medicines represent 22,500 tons per year, that is to say around 40% of the amount of drugs marketed annually [42].

Regulations on unused drugs differ and are subject to country rules, e.g. the decision to consider a drug as a waste product.According to countries, collected medicines may be considered either as household wastes or as dangerous wastes. Surprisingly, there are no established international regulations concerning the collection and destruction of unused medicines and their re-use for humanitarian purposes. On the other hand, there is a vast array of national, regional, and local directives, sometimes conflicting or ambiguous (cf. § II.3.2) [42].

Lack of *ad hoc* incinerators is rife in most developing countries, and their use is expensive (in the order of 3,000 DM per ton in the European market). Many health associations emphasised that donations of unused drugs are a hazard not only to public health, but also to the implementation of essential drugs programmes and costs recovery. Recently, unused drugs donations were subject to specific criticisms from international bodies and NGOs [7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 39, 43]. Several guidelines for drug donors and donations were issued over the past few years, e.g. the recent *WHO Guidelines for Drug Donation* in May 1996. These guidelines are the most extensive ones issued so far, and are based on a consensus reached between the main agencies involved in humanitarian actions or development, the pharmaceutical companies, various universities and even countries.

II.2.2 Review of previous attempts at sorting unused drugs

Table 2 : Comparative data on the quality of unused drugs

Sources	ref	weight (Kg)	nb of brands	to dispose of		comments
				expired	useless	
1980 Operation Marjolaine	42	7,230	ND	82%	11 to 13%	
				93 to 95%		
1983 Hérion	42	216	3,025	54%	ND	
1983-84 Bissau Guinea Maritoux	6	8,000	1,714	ND		funding to local health facilities equivalent to the transport and packaging costs would have been more valuable
1987 PSF Hérault	42	433	5,226	86%		51% of total weight was accounted for by packaging
1991 PSF	42	4,000,000	ND	80%		
PIMED report on unused drugs	42	ND	ND	80%		
1992 Ordre de Malte France	42	1,200,000	ND	41%		54% was sent to Third-World countries
MSF-F warehouse (unused drugs or surpluses from health structures)	44	ND	ND	30 to 40%		

The following main points can be drawn out of the table and the reports referred to:

- ⇒ high diversity of brands making the sorting operation arduous;
- ⇒ high proportion of medicines to be destroyed after sorting (from 30 to 95%) ;
- ⇒ high proportion of expired medicines;
- ⇒ around 50% of total weight represented by packaging;
- ⇒ very low proportion of appropriate medicines i.e. belonging to WHO essential drugs list and corresponding to population needs in developing countries or during emergency crisis;
- ⇒ although it is difficult to quantify the costs of a systematic drug sorting process, it is recognised that the benefits of such a process are very marginal in regards the investment needed.

II.3 DEVELOPMENT OF GUIDELINES, POLICIES AND LEGISLATIONS REGARDING DRUG DONATIONS AT THE INTERNATIONAL, NATIONAL AND LOCAL LEVELS

II.3.1 International actions

WHO is continuously developing systems and guidelines for assisting both developed and developing countries in regulating international drug trade and improving drug policies, such as:

- WHO essential drugs principles [45];
- WHO certification scheme adopted in 1975 providing recommendations for improving the quality of pharmaceuticals entering international trade [46];
- WHO emergency health kit ;
- WHO's resolution (EB97.R14) to the World Health Assembly in May 1996 regarding drug donations. It urges the member-states to eliminate inappropriate donations of drugs and requests the Director-General to disseminate the interagency guidelines for drug donations and encourage its use and review after one year [18, 19].
- WHO inter-agency guidelines for drug donations released in May 1996.

The key limitation is that WHO recommendations are not compelling and cannot therefore be enforced. Some countries are still not adhering to the WHO systems and principles and those which did adhere to, do not always apply them. Therefore they have limited effectiveness and there is a great deal to be done at the international level to turn them into regulations and laws [46, 47, 48, 15, 20].

II.3.2 Actions in donor countries

Although international and national pharmaceutical legislation are very strict regarding the production, selling and distribution of medicines, they very seldom include measures regulating the management of unused medicines resulting from households and professional surpluses. None of them include policies regarding the collection and export of such medicines for humanitarian purposes [42, 46, 47, 48].

In the European Union, the legal framework prohibits the collection and export of drugs that have been issued to patients and returned to pharmacies. Nevertheless in most European countries, the legal status of those medicines remains ambiguous: pharmaceuticals are legally considered as dangerous waste but unused drugs are usually considered as household waste and therefore are not regulated by the legislation on dangerous waste. Although various systems for collecting and destroying unused medicines have been set up in European countries, several relief agencies are still promoting the collection of unused medicines for humanitarian purposes and households are very often disposing of their unused drugs through unofficial channels, such as throwing them away in the dustbin or in the toilets or else giving them to charities [15, 42].

Some European countries are taking positive initiatives to tackle the issue of unused medicines. UK and the Netherlands have adopted measures regulating the prescription of pharmaceuticals with the aim of reducing the amount of wasted medicines. Professional pharmaceutical organisations in Norway and UK have set up measures for a proper management of unused medicines (collection and destruction) and conducted awareness campaigns among the public. In addition, British and Dutch organisations have taken position against the delivery of unused medicines for charitable purposes [42].

The Dutch government also took a strong stance against such drug donation practices stating that „the collection of unused drugs is not acceptable according to the WHO's guidelines, to which the Dutch government subscribes." [15,46].

In France, a specific organisation, named Cyclamed, created and funded by the pharmaceutical industry, is coordinating the collection of unused drugs from households through a specific channel; some of the collected medicines are used for charitable purposes.

II.3.3 Actions in recipient countries

More and more recipient countries are reinforcing their national drug policies and some are in the process of establishing specific systems and procedures regulating import and quality control for in-kind donations of medicines and medical supplies as part of emergency as well as development aid. A few examples are listed herewith:

- In the Yugoslav Republic (Belgrade) and Azerbaidjan, the authorities request to be advised in advance of the details of the donations and to receive the packing lists including batch n° and expiry dates. The donations are then granted a shipment authorisation and screened through the national customs clearance procedures.

- In Mozambique and Guinea-Conakry, the authorities have assigned an international quality control institute (e.g. FGS for Guinea) and request drug donations to be screened by this institute who is responsible for delivering conformity certificates before shipment.
- Eritrea has established a strict policy on drug donations [21, 22].
- Tanzania drew up guidelines for drug donations.
- Georgia and Armenia too has set up measures regulating drug donations [20, 38, 40].

But in many countries, there are still no effective controls on drug donations and legislation regulating donations is still non-existent (e.g. in Lithuania) [23].

II.4 HEALTH AGENCIES AND NETWORKS INVOLVED IN THE ISSUE OF INAPPROPRIATE DRUG DONATIONS

Various international relief agencies and health networks are involved in research, advocacy, campaigning and development of regulations regarding the issue of drug donations. Several key organisations have been identified during this investigation. The current status of their positions as well as the actions undertaken at national and international levels are briefly detailed here below.
This list is far from being exhaustive; it gives a broad picture as an attempt to gather information and facilitate the coordination of efforts, the sharing of experiences and the exchange of information.

Christian Medical Commission (CMC) of the World Council of Churches (WCC)

The World Council of Churches is a fellowship of over 320 churches. One of its unit, CMC, was set up to support and counsel the church-related health work. CMC has established in 1981 a pharmaceutical advisory group for the advocacy of the WHO essential drugs concept and the promotion of rational drug uses in the church-related health institutions. CMC was the first agency to develop guidelines for drug donations which were issued in 1988 and served as the basis for the WHO inter-agency guidelines.

WEMOS

Wemos is a Dutch development agency created at the end of the 80's. Wemos is involved in education and awareness raising in the Netherlands and in policy advocacy at the European level regarding health regulations. Five programmes are currently underway, including one on drug donation practices. Wemos is calling for stricter legislation on the export of pharmaceuticals, the provision of correct pharmaceutical information and higher quality in drug donations.

WEMOS and nine other Dutch organisations, including MSF-H, created a Working Group on Drug Donations in order to join efforts and collaborate on an awareness campaign in the Netherlands, to be carried out during the period July 1995-December 1996. This campaign is supported by the Dutch Drugs Inspectorate and the Dutch Pharmacists Association. The objective of the campaign is to advocate against the donations of unused drugs and inform potential donors on alternatives. The target groups are: (a) organisations and individuals involved in development aid, in particular those donating drugs, (b) pharmacists and GPs, and (c) the Dutch general public, in particular those returning unused drugs to the pharmacies.

In addition, Wemos is currently questioning the Dutch parliament regarding drug donations.

Health Action International (HAI)

Health Action International is an international informal network of some 100 consumer, health, development and other public interest groups involved in health and pharmaceutical issues in over 60 countries. HAI works through three coordination offices (Amsterdam for Europe and Africa, Malaysia for Asia and Peru for Latin America). HAI is raising awareness in Europe of drug issues in developing countries and promoting rational drug use in Europe through research, policy advocacy, public education and debate with industry.

An annual HAI-Europe meeting is organised every year. This year, in October, HAI is preparing a seminar on the World Trade Organisation Pharmaceutical Policies and Essential Drugs. HAI has also published several reports regarding pharmaceutical issues.

Pour une Information Médicale Ethique et le Développement (PIMED)

PIMED is a French association created in 1990 by health professionals from the NGO „Frères des Hommes". It works through research, advocacy, campaigning, training and networking in health and pharmaceutical issues. It is currently involved in three areas: (a) drug export to developing countries, (b) pharmaceutical advertising and (c) drug donations. PIMED has realised a survey on unused drugs in Europe and participated in a research on drug export/import legislation in Europe and developing countries [47].

Réseau Médicaments et Développement (ReMed)

ReMed is a French association created in 1983 and involved in research, networking and information services aiming at promoting appropriate pharmaceutical policies for developing countries. ReMed organises seminars and conferences and has been involved in several researches, such as the drug export/import legislation in Europe and developing countries [47], the private pharmaceutical trade sector in Africa, drug quality on the African market.

Healthnet International

HealthNet is a Dutch consultancy agency specialised in health issues. Healthnet is a member of the Working group on Drug Donations (see Wemos). Healthnet's representative in Rwanda is looking at drug donations issues in Rwanda.

International Committee of the Red Cross (ICRC)

ICRC developed its own guidelines for drug donations and participated in the development of the WHO inter-agency guidelines for drug donations. In Bosnia, one of ICRC medical coordinators carried out a general evaluation of the effectiveness of medical supplies donations to hospitals, concentrating mainly on ICRC donations and on the regions of Republika Srpska and Srpska Krajina, during 1994-1995. A summary report has been published in the JAMA [1].

Pharmaciens Sans Frontières (PSF)

PSF International, as signatory of the WHO inter-agency guidelines for drug donations, is advocating against the use of unused medicines for humanitarian purposes. PSF International therefore finds itself confronted to tense internal debates with most of the regional independent PSF agencies, scattered throughout France, still promoting the initial PSF principle of collecting unused medicines for humanitarian purposes.

PSF International is also campaigning against Cyclamed, an organisation created by the pharmaceutical sector for the collection and disposal of unused drugs, who is donating part of the collected medicines as humanitarian aid. In addition, PSF International is confronted to bad donation practices from Tulipe, a NGO created by the pharmaceutical industry. The agency is currently collecting evidences through its field offices on the negative impacts of inappropriate drug donations with the aim of carrying out an information campaign in France about this issue.

In the Netherlands, PSF-H has joined the campaign against the donations of unused drugs as a member of the Working group on Drug Donations (see Wemos).

Médecins Sans Frontières (MSF)

MSF-International participated in the development of the WHO inter-agency guidelines for drug donations. MSF-H is a member of the Working group on Drug Donations (see Wemos) and initiated with WHO the first evaluation workshop on the humanitarian assistance to former Yugoslavia. MSF-USA got involved in an investigation into drug dumping of American pharmaceutical companies which delivered humanitarian aid in Rwanda [8].

MSF-F, following the large quantities of unused drugs spontaneously donated to MSF-F, has created „ l'Entrepôt " in 1979, which subsequently became an independent centre, for sorting, organising and storing those medicines. Today, the „ Entrepôt " does not provide drugs to MSF missions abroad anymore but is still supplying a great number of associations active in Africa, Eastern-Europe, Latin America and Southeast Asia.

The pharmaceutical industry

The following elements illustrate some of the position of the Western pharmaceutical industry regarding drug donations:

- The pharmaceutical companies participating in the development of the WHO inter-agency guidelines for drug donations have created a strong lobby group, including some international relief agencies

(mostly Americans), to counteract WHO and other relief agencies willingness of tightening the guidelines recommendations.

- In a letter to WHO in March 1996, Dr. Arnold of IFPMA (the International Federation of Pharmaceutical Manufacturers Association) said that guidelines, „ could be a major deterrent to the massive donations of modern drugs which are currently made by the international industry " [24].
- The emergence of NGOs created under the auspices of pharmaceutical companies (e.g. Tulipe in France).

III. THE DRUG SUPPLY AND DISTRIBUTION SYSTEM IN BIH DURING THE EMERGENCY PHASE

III.1 BRIEF OVERVIEW OF THE HEALTH STATUS AND HEALTH CARE SYSTEM IN BIH

Before the war, former Yugoslavia enjoyed a high health status. Health care and pharmaceutical services, competence and infrastructure were well developed and the population enjoyed reasonable access to a comprehensive and well-staffed health care system: a dozen general or regional hospitals, 109 primary health care centres, called Dom Zdravlja, and 900 primary care settings, called ambulantas, with around 7000 doctors and 18,000 nurses. The organisational and managerial structure of the health system was divided among four levels: federal, cantonal, the Sarajevo district and municipalities [49].

The pre-war health system suffered from two major problems [50]:

a• a supply-dominated approach and a centralised decision-making process leading to bureaucratic bargaining rather than a rational assessment of needs and available resources and providing relatively little attention to primary health care or family practice;

b• an over-specialisation and high rates of utilisation, referrals and prescribing;

c• an hospital-centrist system.

The war in BiH (1992-1995) has claimed a high toll on the population: over two hundred thousand people were killed, one million became refugees while another one million were displaced within their own country [51]. The population has been suffering from, and is still experiencing, a dramatic decline in living conditions, a drastic reduction of access to health services, malnutrition and intense psychological stress.

The functioning of the health care services has been severely disrupted with the destruction and deterioration of health facilities and medical equipment, lack of medicines and consumable materials, collapse of the health care financing system and reduction of the number of health personnel [49, 50].

III.2 DRUG SUPPLY PATTERNS

III.2.1 Supply sources

Prior to the war, 80% of the pharmaceutical needs in BiH were covered by the high quality production of 16 specialised pharmaceutical companies within the former Yugoslavia. Strong regulations for pharmaceutical production existed. With the dissolution of Yugoslavia, BiH was left with four pharmaceutical plants and therefore a reduced availability of medicines, which had to be imported at world-market price or provided by foreign aid.

During the war, only two out of the four plants continued to function at reduced pace and could provide about 8% of needed drugs [49]. As a consequence, since the very beginning of the war in BiH, the regular supply of medicines was cut off and the health sector became completely dependent on foreign humanitarian assistance.

The suppliers of pharmaceuticals and medical items can be categorised in four groups:

⇒ The most significant contributors to pharmaceutical supplies were well-known large international agencies and NGOs, specialised in the health sector, such as WHO, PSF, MSF, MDM and ICRC. All those agencies had field offices in several locations in BiH. They regularly coordinated their actions with WHO and the health authorities. Their donations were made on a regular basis according to specific drug supply and distribution programmes, funded by multilateral and bilateral donors (ECHO, ODA, governments, etc.). Those agencies order medicines and medical material through their own procurement agency (e.g. CHMP for PSF, Transfer for MSF-B, etc.) or logistic department, who purchase supplies from recognised and registered pharmaceutical companies on the basis of quotations and quality/cost analysis. They generally do not accept in-kind donations. Donated drugs are of good quality, well packed and labelled. ICRC in particular get 90% of their supplies from Slovenian and Croatian companies, the rest (mainly fluids) was bought in Western Europe.

⇒ Other international NGOs such as Ordre de Malte, Caritas, World Vision, national Red Cross Societies, etc. have also provided large quantities of medicines. Some of them have little or no expertise in the procurement and management of pharmaceutical supplies. In general, they occasionally supplied unsolicited medicines, as part of a general aid programme (food, clothing, toys, etc.). Those agencies were usually represented in the field through their own field office(s) or through their local network (such as the local Red Cross Society, local Caritas, etc.). They delivered medicines which they received as in-kind donations from pharmaceutical companies or private donors, or which they purchased with funds collected through specific appeals for BiH.

⇒ Well-meaning associations of citizens, private individuals, health professionals as well as churches and small local or foreign charities delivered an important amount of unsolicited donations, generally on an *ad hoc* basis, unaccompanied and without prior notice. The great majority of those donations was inappropriate. The donations mainly originated from Western European countries and the Bosnian Diaspora and consisted of unused and mixed medicines, collected by non-professionals from private individuals, pharmacies or health facilities. Those suppliers have no or very little expertise in relief operations and were not represented in BiH.

⇒ Dubious transactions from private commercial companies (mainly US) and Western armies resulting in the procurement of expired or bad quality medicines. Mafia-type business is also included in this category. During our investigations in Belgium, we were informed about an organisation (Pharma Aid) who contacted the sole agreed Walloon company for the incineration of drugs (Meprec). Pharma Aid wanted to buy from Meprec its stocks of medicines to be disposed of and sell them back to Bosnia. They also approached some hospitals.

III.2.2 Accessibility

Throughout the war in BiH, the key entry routes for truck convoys to BiH were through the custom points in the city of Metkovic and Tomislavgrad and from there, through the self-proclaimed republic of Herceg Bosna in Western Herzegovina, which exercised tight customs regulations. Authorisations for passage for all donations regardless of their destinations were granted by the MoH of Herceg Bosna located in West Mostar, after receipt and approval of the lists detailing the content of the donations. The MoH of Herceg Bosna was only monitoring the quality and appropriateness of donations for their region, whereas donations for BiH were only controlled in terms of quantities more than quality (the objective was to analyse and compare what was delivered to Croatian Herceg Bosna in regard to Muslim Central Bosnia). Therefore the custom regulations did not hamper the arrival of inappropriate donations to BiH.

Within BiH, ever-changing routes were used according to fluctuating front lines and security situation. Some areas remained open and accessible throughout the conflict, such as Tuzla, Zenica, Western Herzegovina which had adjacent and supportive links with Croatia, whereas certain areas of Central Bosnia were difficult to reach or sometimes completely cut off by active front lines (Sarajevo, Mostar, Gorazde, Srebrenica, Zepa, etc.).

In the case of Sarajevo, which remained besieged throughout the war, only UNHCR and Unprofor convoys had limited access. This allowed for a better control of the quality of donations and most medical supplies that arrived in Sarajevo complied with WHO guidelines. Depending on front lines and security conditions, Sarajevo and other enclaves could be reached through "blue" roads, controlled by Unprofor who escorted private convoys. In that case no strict monitoring was enforced. In UNHCR and Unprofor convoys, priority was given to food and there was time when medical supplies could not be transported due to lack of space on convoys.

III.3 DRUG DISTRIBUTION PATTERNS

Prior to the war, medicines were bought by Intermedia, a parastatal agency, from the Yugoslav pharmaceutical companies and stored in

regional warehouses, called "veledrogerija". Hospitals, Dom Zdravlja and pharmacies ("apothekers") ordered medicines and consumable to the central warehouses, which were responsible for transport and delivery. Hospitals and Dom Zdravlja were only providing emergency drugs, injectables and dressing materials. Most oral medicines were distributed by pharmacies to patients upon prescriptions. Generally, medicines were prescribed by Dom Zdravlja and delivered in the pharmacies. The patients had to pay a symbolic price (5 to 10% of the value) and some specific drugs were free of charge (e.g. paediatric). For mental health drugs, there was a special procedure for prescribing, storing and recording (double prescription, special records, locked storage and monitoring by police). [37, 52].

During the war, a multi-layered uncontrolled distribution system replaced the centralised and organised existing distribution structure (procurement by the "veledrogerija", prescriptions by Dom Zdravlja and distribution by pharmacies).

International relief agencies were delivering medical supplies directly to hospitals and Dom Zdravlja. This approach was implemented for two reasons: on one hand, the central drug warehouses were either not accessible, nor did they have the logistic capacities (transport, staff, handling equipment, etc.) and the possibility to move around due to the security situation. On the other hand, relief agencies feared that medicines donated to the central structure would not be fairly delivered to the health facilities and that large quantities may be diverted by the authorities for military use. In addition, ECHO, the European Commission Humanitarian Office which funded large drug supply programmes, specifically requested in its funding agreement with NGOs that a direct delivery system should be implemented.

Most of the international relief agencies with specific drug supply programmes (MSF, PSF, ICRC, MDM and WHO on a lesser scale) had set up their own primary and secondary distribution system, with their own warehousing capacities, transport means and field staff. Needs were assessed through their field offices, coordinating, whenever possible (fluctuating security, accessibility and communication conditions), with the local health authorities and other agencies in the field involved in drug distribution. WHO was essentially distributing through UNHCR or other NGOs storage and transport facilities.

As a consequence of the influx of emergency aid, hospitals and Dom Zdravlja were directly receiving large quantities of medicines, disposable material and medical equipment. They had to shift from a basic role of prescribing medicines to active central points for distributing medicines whereas the role of "apothekers" decreased. Hospitals and Dom Zdravlja were ill-prepared to play such a role and lacked expertise, competence and facilities in drug management, storage, handling and transport.

In addition to the regular drug supply programmes of medical relief agencies, hospitals and Dom Zdravlja were confronted to large volumes of unsolicited in-kind donations, usually delivered without prior notice and unaccompanied. The "gifts" were generally "dumped" in the health facilities, which often had no choice but accept them. Sometimes also, convoys with such donations were arriving to MSF, ICRC or PSF field offices, asking whether they could take the donations and distribute them. These agencies always refused to take such loads and nobody knows what happened to those rejected donations afterwards... Private medical donations also arrived through UNHCR channel, resulting from UNHCR appeals for food aid and other material. These items were sent directly to WHO field stores or health facilities without prior notice [35].

III.4 PROBLEMS IN THE DRUG SUPPLY AND DISTRIBUTION PROCESS DURING THE WAR

III.4.1 Management problems

The geographical and cultural proximity of BiH and relatively easy access coupled with intense media coverage made the situation highly visible and triggered strong emotional involvement of the international community, the public in Western countries as well as the Bosnian Diaspora and refugees abroad. In 1992, only few relief agencies (the major international ones) were present. In 1993 and particularly 1994, a large scale international response was provided, with over 250 registered organisations, including more than 70 operating in the health field [38].

The security conditions which obviously put heavy strains on all involved in the relief efforts, added to the multiplicity of aid suppliers, made coordination and monitoring of aid extremely difficult, leading to a very chaotic supply and distribution of relief items and creating logistical and management problems at all levels, as indicated in the following table.

Table 3 - Factors limiting the effectiveness of the drug supply and distribution system

	Recipient level	***Donor level***
Policy level	Lack of clear procedures for drug donations	
	– Absence of a coherent and rational national drug policy – Lack of clear and coherent customs regulations	– Lack of regulations regarding the export of medicines for humanitarian purposes
Logistical level	Multiplicity of suppliers, providing supplies at different intervals and each offering a different range and volume of assistance	
	– shortage of transport – access to beneficiary areas hampered due to tense security situations and changing rules regarding movement of personnel and supplies (harassment or confiscation at checkpoints) – multiple supply channels leading to random deliveries to end-users generally ill-prepared to receive large volume of aid – absence of maintenance and repair of health facilities due to lack of resources – destruction due to shelling	– influx of drug donations delivered unannounced and unaccompanied – agencies did not provide technical support to the health facilities (such as equipment, storage space, personnel and training for sorting and organising the pharmaceutical stores)
Management level	Lack of a coherent and centralised system for the coordination and monitoring of needs, in-coming medical supplies and distribution of drug donations	
	The influx of large quantities of drug donations put an enormous strains on the management capacity of the health structures, confronted to : – lack of experienced professional health staff; – no tradition of store management, inventory control and needs assessment as, prior to the war, they were used to a central system; – inadequate working conditions: lack of storage space, poor infrastructure, lack of maintenance, lack of security, lack of equipment, lack of communication means.	– lack of proper needs assessment and coordination of requests – lack of expertise (no experienced health professionals) – high field staff rotation – lack of adaptability and flexibility of the drug supply programmes, making it difficult to respond efficiently to shortage or excess of supplies – lack of collaboration and coordination, each agency having its own scope of activities, defining its own policies and pursuing its own agenda.

III.4.2 Quantitative problems: surpluses and shortages of medical supplies

a. Supplies in excess

First of all, it is important to stress that the bulk of the appropriate medical supplies provided throughout the war is the merit of the international humanitarian health agencies such as WHO, MSF, PSF, MDM and ICRC. They supplied most of the pharmaceutical donations in the form of essential drugs in spite of the very harsh security and access conditions. This enabled the war-time health care system to meet a substantial proportion of its essential needs. The following table gives an idea of the scale of the medical assistance provided by the major international agencies involved in regular drug and medical material supply programmes.

However, although those agencies have gained large expertise in relief operations in developing countries in Africa and Asia, they found themselves confronted in the former Yugoslavia to a new context: a highly volatile conflict in a European country which used to have high health standards. Therefore, their initial response, mainly pre-packaged medical kits designed for refugee situations in the South, was partly not adapted to the needs of the Yugoslavian health structures.

As a consequence, some medicines were supplied in too large quantities or non-needed medicines were provided, such as:

- antimalarial drugs (chloroquine), chloramphenicol, oral rehydration salt, phenytoin, ketamine and gentian violet.
- narcotics, with sometimes non-respect of the international and national laws regulating this type of medicine.
- morphine (hydroxodon), to the extent that the Ministry of Health and the WHO had to intervene to prevent uncontrolled deliveries [53].

The cantonal minister of health in East-Mostar also emphasised that international NGOs had fixed programmes at the initial stage of the relief operation but quickly adjusted their donations to the needs, thanks to their presence in the field and on-going needs assessment and monitoring activities.

In Tuzla, the Chief Medical Logistician at the central warehouse (opened at the end of 1994), stressed that they are now stuck with big quantities of medicines approaching expiry dates which they cannot dispose of because relief agencies are supplying directly to the recipients, lack flexibility in adapting their fixed programmes to the overall demand/supply situation and do not closely coordinate with the central warehouse. She too reported over-supply of narcotics as well as problems of over-supply due to pre-packaged kits (as an example, they use only two out of the seven medicines provided in the WHO mental kit).

Relief agencies themselves, as reported by MSF-H and ICRC, were confronted in their own warehouses with surpluses of medicines, which subsequently expired over time. Several reasons explain that situation: irrelevant ordering and changes in need patterns (quantities were ordered to cover needs for 3 to 6 months but it happened that the situation changed dramatically between ordering and delivery, as in the case of the fall of Srebrenica and Srpska Krajina), high field staff rotation and lack of experience, lack of monitoring and coordination among agencies and sometimes, lenient inventory control and warehouses management.

On the other hand, there was an uncontrolled influx of large quantities of inappropriate and/or poor quality drug donations which led to the stockpiling of tons of irrelevant, useless and expired medicines (see § III.4.3 and Chapter IV).

Table 4 - Drug supply programmes of the major international medical agencies in BiH

Agency	1992 (1)			1993			1994			1995			January to mid 1996		
	m3	ton	m$(2)	m3	ton	m$	m3	ton	m$	m3	ton	m$	m3	ton	m$
WHO (3)	0	0	0	*1,400*	350	2,660	*2,404*	601	6,623	*1,236*	309	4,251	684	171	*2,134*
ICRC (4)	*744*	186	2,323	*3,856*	964	12,053	*3,648*	912	11,398	*3,640*	910	11,376	*1,500*	375	4,683
MSF-H (5)	*3,840*	*960*	*12,000*	*3,840*	*960*	*12,000*	*3,840*	*960*	*12,000*	*3,840*	*960*	*12,000*	*1,920*	*480*	*6,000*
PSF (6)	826	195	*2,438*	2,150	555	*6,938*	1,748	374	5,200	2,568	503	5,616	811	172	2,389

Agency	cumulated donations from 1992 to mid 1996 (1)		
	m3	ton	m$
WHO	*5,724*	*1,431*	*15.668*
ICRC	*13,388*	*3,347*	*41.833*
MSF-H	*17,280*	*4,320*	*54.000*
PSF	*8,103*	*1.799*	*22.581*
Total	***44,495***	***10,897***	***134.082***

(1) data in italics are extrapolated
(2) budget is in million US$
(3) from WHO annual reports
(4) transmitted by the Bosnia Desk in Geneva
(5) from reference E
(6) source PSF Operation Unit

b. Gaps and shortages

There were shortages of vital medicines and medical material. In Sarajevo, as reported by the Drug Advisor at the Ministry of health [53], missing items were: disposable material such as gauze, syringes, plastic tube for tracheotomy, abdominal and chest drains and medicines such as iv. fluids, antibiotics, non-toxic analgesic, parenteral and oral antimicrobial medicines. Another major gap consisted of medicines for chronic diseases: antihypertensives, antirheumatics, gastro-enterology drugs. In the case of Sarajevo, a besieged city for months on end, such shortages can be explained by the lack of accessibility and priority given to food items each time convoys could access the city.

In Mostar, main shortages were vaccines (e.g. German measles), laboratory reagents and medicines for chronic diseases, especially antihypertensives and insulin, but there was no shortage of TB drugs.

In Tuzla, drugs which were needed and not provided for were: cardiotonics, antiaryhtmics, antihypertensives, antianginics, ophtalmics, antirheumatics, spamolitics, etc.

WHO noted that in the case of some particularly vital materials (i.e. clinical chemistry and microbiology lab kits), the agency was reported to be the only supplier. On the other hand, there were major gaps which none of the kits filled like cytostatics, x-ray film and developing chemicals [33].

In the evaluation survey conducted by ICRC [1], lack of supplies was reported as an important limitation by 62% of respondents (hospital representatives).

III.4.3 Qualitative problems : useless/unusable medical supplies

The key problem, as stressed by MoH, MSF, PSF, WHO and health facilities, was created by the delivery of unsorted consignments of partially used medicines collected from private individuals, health professionals or health facilities and sent unaccompanied, without prior notification, by non-professional people or associations. Those donations especially originated from the Bosnian Diaspora and refugees abroad as well as French, German and Italian groups of citizens. Most of the time, donated boxes contained a mix of unused medicines, sometimes with food, and/or clothing items. They were badly packaged, with no identification documents and proper labelling.

Such donations created great logistical problems and overwhelmed the health facilities management capacities. With their already scarce resources, the recipient facilities were unable to tackle the huge task of organising and sorting those mixed boxes, knowing that they would have a very low probability of extracting useful items (it is estimated that 80% of unused drugs collected from private individuals must be destroyed (cf. §II.2) [42]).

Inappropriate drugs comprised useless and unusable medicines. Useless drugs included:

- Medicines irrelevant to the epidemiological context (e.g. for minor ailments, for a disease which does not exist in the country, etc.);
- Medicines unknown or not usually used by the local health professionals (not within the scope of the National and WHO Essential Drug Lists).

Unusable drugs comprised:

- Medicines already expired on arrival or expired over time (oversupply, too short expiry deadline);
- Unidentifiable medicines (e.g. delivered unsorted, labeled in unknown foreign languages);
- Medicines damaged during shelling of warehouses or spoilt by bad conditions of transport, handling, storage and/or bad packaging.

The following table summarizes information on the quality of drug donations collected from various sources during the field visit. These

data are gross estimates as no comprehensive and systematic evaluation has been carried out.

Table 5 - Estimates on the quality of donated drugs in BiH (as % of total volume)

Sources	Unusable	Not needed Irrelevant	Relevant but unsorted or not easy to identify	Immediately useful
WHO Zagreb	15%	30%	55%	
	45%			
Dr. Suko, East Mostar	20% expired on arrival	10% irrelevant	70% could have been used but problems with	
	30% not including unsorted drugs		unsorted drugs and unknown drugs	
T. Lucic, West Mostar	50%		50%	
MoH Tuzla	50%		50%	
WHO Tuzla	at least 30 to 40%		around 60 to 70%	
S. Lucic, Sarajevo	8 to 10% expired on arrival		around 60% of total drug supply was provided by international medical agencies: over 90% were of good quality and useful (a)	
PSF Mostar	among the 200-300T of unusable drugs resulting from PSF sorting programme in Mostar, an estimated 90% are unused mixed drugs			
WHO	70% of donations to Velmos hospital in Mostar were inappropriate and useless consignments			
ICRC [1]			93% of respondents indicated that donated supplies were appropriate (b)	

(a) Sarajevo was a besieged city throughout the war, with limited and controlled access: UNHCR and UNPROFOR airlift operations and escorted convoys only, which explains the high proportion of good quality donations.
(b) Bearing in mind that 80% of respondents were hospitals and war hospitals mainly supplied with ICRC surgical kits and medicines donated by international medical NGOs and that part of the health facilities in Central Bosnia were not accessible for the study.

From this table, it appears that inappropriate medicines represented between 30 to 70% of the donated drugs or, on average, 50-55% of all donations.

Comparing this table with table 1 (cf. §II.1), it is interesting to note the similarities in the figures, although the contexts of the emergency situations are very different from each other. Former Yugoslavia represents a conflict situation whereas Armenia (1988) and Guatemala (1976) represents cases of a natural catastrophe (earthquake). The situation in Georgia and Armenia (1994) are examples of countries with economic difficulties, benefiting from long-term aid. Therefore, it appears that inappropriate donation practices are the fate of all modern disaster situations, irrespective of their underlying cause.

III.5 MANAGEMENT OF USELESS MEDICAL SUPPLIES IN THE HEALTH FACILITIES

In general, given the high pharmaceutical standards prior to the war, expired medicines were put aside and not used. According to the health authorities, health facilities kept registers of expired drugs and destroyed them in conformity with the national regulations. In fact, expired and inappropriate medicines were either destroyed in existing incinerators (e.g. Sarajevo) designed for hospital wastes, either simply burnt in the domestic waste disposal facilities (around 10 tons every month as reported by the storekeeper at Tuzla hospital) or in the central heating system of the health facilities or even burnt and "recycled" into plastic (as reported in Tuzla by the local health authorities).

In Mostar, useless medicines are kept chaotically stockpiled in large storage rooms (see Chapter IV). A survey conducted in Tuzla canton by the Chief Logistician of the central warehouse [54] shows that between 0.5 to 5 tons of expired drugs are stored in each Dom Zdravlja (11 visited out of 14) and their disposal represents a big problem. The cantonal MoH has asked each Dom Zdravlja to register the expired drugs in the view of centralising storage and disposal, but apparently, the Dom Zdravlja are not ready to cooperate.

III.6 ACTIONS UNDERTAKEN IN BIH TO TACKLE THE PROBLEM OF INAPPROPRIATE DONATIONS

Throughout the war, the health authorities and international medical agencies gave several warning signals on the nature and quality of the medical donations provided to BiH and took a number of measures and initiatives to prevent the arrival of inappropriate donations. They are now looking for solutions for the management and disposal of the remaining amounts of useless medicines.

III.6.1 Health authorities

In 1992 already, the Ministry of Health in Sarajevo reported problems caused by inappropriate drug donations. The MoH in Sarajevo drew up list of needs for BiH every month. Those lists were disseminated through embassies and consulates still operating in BiH, relief agencies and NGOs as well as Bosnian diplomatic representations abroad. Because of the lack of communication and coordination during the war, we are doubtful about the reliability of the information they disposed, except for Sarajevo.

In addition, the Institute of Public Health in Sarajevo published throughout the war a weekly bulletin, reviewing the public health status, medical needs, etc. It continued to carry out drug quality control as well as research on medicines not familiar to health professional. The IPH worked in close collaboration with the MoH and the commission for the acceptance of medicines which existed prior to the war. As most relief agencies were delivering medical supplies directly to the health facilities, irrespective of the pre-war structure for drug supply and distribution, the IPH had to go and collect samples in the health facilities and sometimes directly from the patients. The IPH also drew up every year a report reviewing the emergency relief assistance. In coordination with the MoH, IPH is now preparing an evaluation of the relief operation in BiH which should be published in September 1996 and are planning an international seminar in Sarajevo by the end of 1996 to draw lessons.

Within the framework of the health reform and reconstruction programme, the federal MoH is currently developing a policy on pharmaceuticals with the assistance of WHO. As a result, a national list of essential drugs was drawn up and published in 1995 [55].

III.6.2 International relief agencies

At an early stage in the conflict, WHO was asked to coordinate unsolicited medical donations arriving from agencies without representation in BiH. WHO made an agreement with UNHCR that all in-kind donations be referred to WHO for approval. In 1993, WHO issued and disseminated donor guidelines outlining the criteria for accepting donated drugs and instructions regarding packaging, labelling, documentation, etc. [33]. The guidelines were subsequently revised and expanded in 1994 and finally led to the new inter-agency guidelines for drug donations issued in May 1996. Regional guidelines were also issued, for example in Mostar and Zenica .
WHO also drew up a list of "priority medical needs" on a monthly basis from information supplied by WHO field offices [33].
In Mostar, the Mayor of Mostar wrote a letter in October 1995 severely criticising the donation practices of the Western countries [14].

In August 1995, PSF and WHO launched a drug management programme for Mostar including physical rehabilitation of warehouses, sorting of medical supplies, installation of computerised inventory control and stock monitoring systems and training of personnel. PSF is planning a similar programme in Gorazde. At the end of 1995, a Medical Coordination Committee was set up with responsibility for issuing regular up-dated lists of medical needs for the Mostar region and authorising the arrival of donations [43].
WHO is currently looking into hospital waste management and planning a programme for the construction of incinerators, to be partly implemented by MSF-B.

IV. EVIDENCES COLLECTED FROM FIELD VISITS

IV.1 INTRODUCTION

Within the limits of the human, financial and time resources allocated to this mission, an extensive and quantitative evaluation of the medical emergency aid in BiH was impossible. In addition, the nature and evolution of the emergency situation in BiH (multi-focused conflict spread out over a period of three and a half years, variability of access, movements of front lines and field hospitals, diversity of aid in nature and quantities according to places, etc.) made it impossible to carry out an extensive analysis of the medical aid, as the one realised after the earthquake in Armenia [5].

The choice of the sites to be investigated was guided by the possibility of accessing pharmaceutical warehouses (whether total or partial access). This condition was a prerequisite as, without any tangible material elements, the research would have been limited to general statements and a compilation of existing reports and articles. To our knowledge, such an analysis, although limited, has not yet been conducted in the former Yugoslavia.

The research is therefore limited to a sector-related investigation and is not representative of the whole medical aid supplied, neither from a quality, nor from a quantity standpoint. It analyses what is remaining from the total aid received in some of the warehouses and is therefore representative of what has not been used, whatever the reasons.

IV.2 MATERIAL AND METHODS

IV.2.1 Choice of the sites

Prior to the consultants arrival, contacts were made by MSF/B with the health authorities of the districts where MSF/B is working. They were informed on the objectives of the investigation and their assistance was sought. Only the health authorities in East-Mostar (thanks to PSF's assistance) and in Tuzla reacted positively. In Gorazde, reactions were negative and access to warehouses impossible. In Sarajevo, the federal MoH was rather reluctant to collaborate and mentioned that they were carrying out their own evaluation of the medical aid supplied to BiH during the conflict and do not wish to communicate their information. Bihac was not visited due to lack of time and the distances involved.

IV.2.2 Background of the sites

a. Mostar

The most difficult period in Mostar was in 1993, when almost no medicines were coming in (some from MSF-H, PSF, MDM and WHO laboratory kits). Between July 1993 to January 1994, aid could only come in through Unprofor and ECTF (European Community Task Force). Basic needs were covered. In the first half of 1994, WHO supplied good quality medicines through Unprofor. During the second half of 1994 (re-opening of the roads in the summer) until the end of 95, East-Mostar was overwhelmed with private donations of inappropriate drugs. Consignments were delivered directly to hospitals and health facilities. There was practically no control (cf. §III.2 and §III.3). Today, the city remains fragmented along ethnic lines (Bosnians on the East side, under the federal government of BiH, and Croats on the West side, under the self-proclaimed government of Herceg Bosna) and there are therefore two separate health care services and management systems.

In West-Mostar, the fact that all medical consignments entering BiH was control by the health authorities of West-Mostar (cf. §III.2 and §III.3), coupled relatively easy accessibility, explains the particularly important concentration of medical donations to this area. Therefore, what was observed in West-Mostar is probably not representative of the other areas in terms of quantity, but significant in terms of quality. Field observations in Tuzla confirmed this statement.

b. Tuzla

Tuzla remained accessible throughout the conflict. The greater part of the medical aid was supplied through Metkovic (as for Mostar) and Tomislavgrad. A smaller quantity came via Zagreb. Tuzla did not experienced direct confrontations between the communities living in the city but was shelled by the Serbs from Republika Srpska.

IV.2.3 Visit and working conditions

Four warehouses could be visited. Visit and working conditions are detailed hereafter.

Table 6 : Summary of the visit and working conditions

	access	duration of the visit	sampling	photos	consultation of documents
a. WEST MOSTAR Bjieli Brijeg hospital warehouse	100 %	2 hours	yes	yes	no
b. EAST MOSTAR Zalik warehouse	50 %	1 hour	no (not useful)	yes	no
c. TUZLA Federal Drug Logistic Centre	100 %	1 hour	no	yes	yes
d. TUZLA Hospital Warehouse	100 %	½ hour	no (not useful)	not allowed	no

a. Bjieli Brijeg hospital warehouse (West-Mostar): semi-oriented sampling

Address: Klinicka Dolnica
Bjieli Brijeg
Mostar West

Bjieli Brijeg is the main warehouse in West-Mostar. We were able to visit this warehouse thanks to PSF. It was an informal visit. Contacts taken subsequently with the MoH of the republic of Herceg Bosna, confirmed that an official request for visiting the warehouse would have been denied.

In Grude (30 km from Mostar), it has been reported by PSF that a large pile of expired drugs is lying in the open air. We did not visit this place but PSF did and they saw over 30 m^3 of rejected medicines.

Time limit and the chaotic organisation of the Bjieli Brijeg warehouse kept us from performing a systematic exploration. Since we were not allowed to consult the inventory documents, our method consisted in walking throughout the warehouse. We systematically recorded all the sorted items present in significant quantities (at least around 0.5 m^3). We identified each item and the kind of packaging, assessed the volume, took samples and photos, and noted down relevant information, in particular the origin (company, country, provider, etc.), as well as the comments of the storekeeper or other persons present. Looking around, we have performed, in an empirical way, a sampling of the warehouse, allowing us to carry out a typology of the unused drugs.

b. Zalik warehouse (East-Mostar)

Address: Herzegovina Lijek
Muje Pajica 5
Zalik
Mostar East

This facility is the cantonal warehouse. We visited this warehouse after a meeting with the cantonal Vice-Minister of Health. The warehouse of Velmos Hospital was not visited because of the lack of time, but we obtained some reliable data from PSF who are working there and carried out a sorting programme.
We investigated the main room were rejected medicines were stockpiled. The bulk of the content was mixed unused medicines. Therefore, we just took photos and did not pick up any samples as it would not have been representative. We also investigated an adjoining small room. We were not able to visit the last room containing rejected medicines, nor the operational room, where useful medicines and supplies are sorted and organised for supplying the cantonal health facilities. This is due to the fact that our visit took place together with a team of journalists who were rapidly filming each room without detailed observations. PSF therefore provided further information on the rooms which were not visited.

c. Federal Drug Logistic Centre of Tuzla

Address: Grmecka bb, 75000 Tuzla
Phone: +387 75 236 499

The Federal Drug Logistic Centre was opened as a central warehouse for the canton in October 1994. It is a building placed at the disposal of the health services by a local pharmaceutical company. It receives mainly WHO supplies on a regular basis and sometimes, one-off or irregular donations from non-medical international relief agencies. Up to the end of 1995, they received some donations of mixed unused drugs from local, private or clerical charities and the Bosnian Diaspora. The manager of the central warehouse reported that when temporary war hospitals were closed down, the remaining drugs, among which a lot of expired ones, were dispatched back to permanent health facilities, especially Dom Zdravlja.

The management is computerised. Medicines are sorted and well-ordered on shelves. Expired drugs are removed as and when required. We were allowed to take photos and the person responsible of the warehouse gave us all the information we needed as well as some relevant documents.

d. Tuzla Hospital warehouse

Address: Central Hospital Gradina Tuzla
Phone: 33.171

This is a huge warehouse in the basement of the hospital with impressive stockpiling of items. Contrary to all expectations, the hospital director allowed us to visit it, accompanied by a WHO consultant (we were amongst the first to visit this centre). We were guided by the chief-pharmacist who gave us some information. The visit lasted only half an hour. We were not allowed to take photos nor samples (except a second World War Bandage and dental floss). We could not consult any document. We were able to make some rough estimations on what we saw.

IV.3 RESULTS

IV.3.1 Quantitative data

Table 7 : Summary of findings in terms of volume and weight of medical supplies

	access	total volume	estimated occupied volume	average specific weight (*)	estimated weight	estimated volume to be disposed of		estimated weight to be disposed of	

	%	m^3	m^3	kg/m^3	ton	m^3	%	m^3	%
WEST MOSTAR Bjieli Brijeg hospital warehouse	100	7,600	1,100	200 250	245	850	77	183	75
EAST MOSTAR Zalik warehouse	50	680	240	200	48	220	92	44	92
TUZLA Federal Drug Logistic Centre	100	2,100	1,050	250	263	0	0	0	0
TUZLA Hospital Warehouse	100	9,000	3,000	250	750	ND	-	ND	-

(*) Weight is estimated in regards of volume. The volume of medical supply was roughly assessed comparing the total volume of the warehouse to the occupied volume. The specific weight is estimated according to the average specific weight collected from some of the main agencies involved in drug supplies. A specific weight of 250 kg/m^3, unless otherwise specified, has been used (Annex 5).

IV.3.2 Qualitative observations

a. Bjieli Brijeg hospital warehouse

Mixed products, about 60% of the total, were not recorded because of their nature in itself. Total volume of sampled items represents 75 m^3, that is to say 7% of the total content, and more than 10% of the sorted elements.

Table 8 : Evidences collected in Bjieli Brijeg hospital warehouse

	Composition	*Manufacturer*	*Vol.* m^3	*Exp. date*	*WHO EDL*	*MoH EDL*	
1. Drugs							
Actigrip	triprolidin, pseudoephedrin, paracetamol	Wellcome Italia	2.0	09/94 05/95	N	N	(1)
Cardura	doxazozin mesylate	Pfizer Inc. USA	0.5	09/96	N	N	(2)
Clinoril	sulindac	Merck Sharp Et Dome USA USA	3.0	?	Y	N	(3)
Comhist	chlorpheniramine phenyltoloxamine phenylephrine	Procter Et Gamble USA	1.5	12/92	N	N	(4)
Dapsone	dapsone	Weiders Pharmasoy-tiske A/S Norway	1.5	08/95	Y	N	(5)
Goodys headache powder	aspirin acetaminophen caffeine	Goodys manuf. corp. USA	1.0	12/97	N	N	(6)
Mevacor	lovastatin	Merck Sharp Et Dome USA	2.0	10/93	N	N	(7)
Mycostatin vaginal tablets	nystatin	Squibb Et sons USA	1.0	12/92	Y	Y	(8)
Pamprin menstrual relief capsules	acetaminophen parabrom pyrilamine	Chattem USA	1.0	11/94	N	N	(9)
Seldane D	terfenadine, pseudoephedrin	Merrel USA	2.0	04/90	N	N	(10)
Sine Cod	benzoxonium	Zyma Italia	7.0	01/95	N	N	(11)
Tussin Liquid Gelcaps	guaifenesin, pseudoephedrin, dextromethorphan	Maxi Drugs, Inc. USA	3.0	01/96	N	N	(12)
Tylenol children's	acetaminophen	McNeil USA	4.0	11/95	Y		
Tylenol CtF	acetaminophen, pseudoephedrine, dextrometorphan	McNeil USA	3.0	08/93	N		(13)
Velonarcon	ketamine	VEB Berlin-Chemie Germany	0.3	02/95	Y	Y	
Zinkoxidsalbe	zinc oxide paste	Germed Germany	3.0	12/45	Y	N	(14)
2. Non drugs							
Biosearch Enteral Pump	enteric nutrition infuser	Biosearch USA	2.0	?	-	-	(15)
Kenguard	irrigation tray	Kendall Healthcare Products Co USA	2.0	12/95	-	-	
Breast Pads		N.D.	8.0	?	-	-	(16)
Selfgrip all in one sport tape / bandages	self-adhesive tape	LMA (distribution) USA	25.0	?	-	-	(17)
V7 Gipsbanden®	plaster tape 10x300cm	Germany	2.0	12/61	-	-	(18)

(1) symptomatic relieve of minor ailments; this association is rarely recommended
(2) does not belong to first-line antihypertensive drugs
(3) although expiry date was not collected, the drug was still valid at the time of visit
(4) symptomatic relieve of minor ailments; likely to have expired on arrival
(5) besides the dapsone stickers, the barrels also carried paracetamol stamps (with expiry date 07/93) so that confusion was at its peak; anti-leprosy drugs are definitely useless in BiH
(6) not practical and outdated packaging; this association is rarely recommended
(7) definitely a non-essential drug in war-time, in particular when a country is rife with malnutrition and starving, the latter receiving international media-coverage
(8) likely to have expired on arrival
(9) symptomatic relieve of minor ailments; this association is rarely recommended
(10) symptomatic relieve of minor ailments; this association is rarely recommended; stickers extending the expiry date were masking the genuine expiry date (04/93)
(11) symptomatic relieve of minor ailments; no proof of efficacy
(12) no clear advantage of this kind of association; not recommended
(13) symptomatic relieve of minor ailments; this association is rarely recommended; the NGO which help sending the aid too part in set up the WHO Guidelines on Drug Donation
(14) such outdated items were regularly found throughout this inspection; most likely a World War II leftover
(15) those infusers require special tubing that was not available; run on 110 V; a significant number of those infusers wore a „ out of use " warning"
(16) usefulness definitely debatable
(17) tapes were no longer adhesive, many were retracted; the bulk of them accounted for one third of total sampling volume
(18) provided by the International Red Cross Federation, who contributed to the WHO Guidelines for Drug Donation

The warehouse consists of two main rooms, one on the ground floor, the second one just below.

Table 9 : Volume and weight of medical supplies in Bjieli Brijeg warehouse

	total volume m^3	estimated occupied volume m^3	average specific weight kg/m^3	estimated weight tons	estimated volume to be disposed of m^3	estimated weight to be disposed of tons
local 1 ground floor	5,600	600	200	120	all = 600	120
local 2 basement	2,000	500	250	125	min. 50% = 250	63
TOTAL	7,600	1,100		245	850	183

A rough assessment indicates that 40% of the content is sorted items clearly identifiable (the part we sampled) and 60% is mixed drugs in bulk, non-identifiable. From the drugs we sampled, we can observe that:

- 69% (11/16) are US products
- 38% (6/16) belong to the WHO Essential Drugs List
- 19% (3/16) belong to the Bosnia-Herzegovina Essential Drugs List
- 44% (7/16) are multicompounded drugs (whom 6 are US products) for minor ailments
- 94% (15/16) are expired drugs at the time of visit
- 81% (13/16) have household or sample packaging

b. Zalik warehouse

Table 10 : Volume and weight of medical supplies in Zalik warehouse

	total volume m^3	estimated occupied volume m^3	average specific weight kg/m^3	estimated weight tons	estimated volume to be disposed of m^3	estimated weight to be disposed of tons
Zalik room 1	540	200	200	40	200	40
Zalik room 2	140	40	200	8	20	4
Zalik room 3	UK	53	200	11	53	11
Zalik room 4	UK	max. 100	200	20	0	0

Rooms 3 and 4 were visited. The main content of the visited stores consisted of mixed unused drugs thrown away after rough sorting between sorted and unsorted. Most of the boxes were damaged. The greater part is unsorted packaging totally inappropriate for emergency purposes (mixture of many different brands and professional samples, sometimes partly used. Very few packages were coming from well known agencies (MSF, MDM, Caritas etc.). There was a large proportion of non essential drugs irrelevant to the emergency and local health conditions. Some boxes of plaster tapes (the same were found in the other warehouses).

c. Federal Drug Logistic Centre of Tuzla

About 10% of the content is occupied by US medicines. Most of them are the same we observed in West-Mostar. We noticed at random :

Drugs	*Composition*	*Manufacturer*	*quantity*	*WHO EDL*	*MoH EDL*
Clinoril	sulindac 150 mg	Merck Sharp Et Dome, USA	20.000 tablets	*Y*	*N*
Robitussin Max Strength Cough Et Cold Adults	guaiphenesin - pseudoephedrine - codeine	Robins, USA	2.580 syrup bottle arrived 10/05/96	*N*	*N*
Pamprin Multi-Symptoms	acetaminophen - parabrom - pyrilamine	Chattem USA	27.000 tablets	*N*	*N*
Dimetapp DM Elixir	brompheniramine, phenylephrine, phenylpropanolamine, dextromethorphan	Robins, USA	3.048 syrup bottle arrived 05/96	*N*	*N*
Motrin IB Sinus	ibuprofen 200 mg-pseudoephedrin 30 mg	Upjohn USA	264.000 capsules arrived 10/05/96	*N*	*N*
Tylenol Extra-Strength	acetaminophen 500mg	MacNeil Consumer, USA	ND	*Y*	*Y*
Stanback	acetaminophen 950mg	ND	ND	*Y*	*Y*

Three of those branded products were also found in Mostar, but, when identified, it was not the same NGO providing them (World Vision International in Tuzla and Catholic Mission Board N.Y. in Mostar). The same remarks as those made in Mostar apply to Tuzla :

- multicompounded drugs;
- mainly non essential;
- little size packaging;
- not requested.

We must point out that in the visited warehouses some drugs and medical materials provided by Muslim countries were encountered, representing less than 5% of the total. Regarding what we saw, there are no particular critics to formulate in terms of content and packaging.

d. Tuzla Hospital Warehouse

The bulk of products in this warehouse is composed of closed boxes originating from the main donors of the conflict (WHO, UNHCR, MSF/H, PSF, ICRC, governments).

The expired medicines and products, had been disposed of on a regular basis. They showed us some expired products that were still to be disposed of, representing a maximum of 5% of the total volume. The hospital pharmacist , who was with us, told us that 70% of the volume of medicine and products was unusable (mainly mixed medicines). She also added, that since 1992, they have had to dispose of a volume of two truckloads per month (if we consider a weight of 2 tons per truck, it represents a weight of 48 tons per year and close to 500 tons to this day). It seems that the sheer quantity of donations submerged the capabilities of the local management system and probably exceeded part of the needs, as seems to indicate the large portion of unopened boxes originating from the major agencies, and whose contents are generally relevant and usable.

It is worth mentioning the following interesting discoveries : over 10 m³ of cardboard boxes containing small boxes of dental floss, a little over 250.000 (Manufacturer Johnson & Johnson USA, origin USAID). Various flavours are available (Cinnamon, mint, ...). In total, about 1700 km of dental floss at an average of 6.7 m per box. We have samples (n° 28).

The pharmacist told us that they had received during the conflict 9 truckloads from Sweden of Second World War medical supplies, for the main part consisting of bandages that turned to dust when unpacked. Most of this has been burned. During our visit, we noted some products coming from this donation (In particular some sterile compresses 20X30 cm dated 1940, sterilised again in 1969, coming from the Swedish army and field dressing „ joint services, dressing first aid, field, camouflaged " not dated, but most probably from the same period).

IV.3.3 Summary of findings

The general consensus is that within the unusable medicines, unsorted unused medicines, in bulk and small packaging, represent the essential problem in terms of volume. We were able to ascertain this in Mostar and Tuzla, taking into account sorted volumes and/or destroyed volumes.

Bjieli Brijeg warehouse	50% of content are mixed products. A great volume of unusable aid, unused medicines for the most, has been forwarded to GRUDE in a makeshift depot. There would still be about 30 tons, a big proportion having been destroyed.
Zalik warehouse	Over 90% of the products seen and to be destroyed in the 2 warehouses we visited are unused drugs.
Federal drug logistic centre of Tuzla	Opened in October 1994. Practically no unused medicines in the warehouse, as the unusable arrivals (about 50% from what the responsible told us), mostly unused medicines, were refused or immediately destroyed.
Tuzla hospital warehouse	500 tons of medicines apparently have been destroyed since the beginning of the conflict, mainly unused medicines (the equivalent of 2 truck loads per month) During the visit, the content of the warehouse was estimated at 750 tons. For the essential crates originating from the main agencies (UN and NGOs) or from governments. The used or dispatched volume during the conflict is unknown.

V. CONCLUSIONS ON THE DRUG DONATIONS PRACTICES IN BIH

The following analysis draws qualitative and quantitative conclusions from the evidences collected during the field study.

It proposes:

a• a typology of the donation practices with a description of their characteristics (Table 12) and an evaluation of their disadvantages and advantages (Table 13);

b• an estimation of the total volume of medical supplies delivered to BiH during the war and the proportion of appropriate and inappropriate medicines (Table 14);

c• an economic appraisal: opportunity cost of drugs to be disposed of (Table 15) and cost/benefit analysis for the donor and the recipient (Table 16).

V.1 TYPOLOGY AND CHARACTERISTICS OF THE DONATION PRACTICES

Visits to warehouses and analysis of gathered information permitted the identification of three types of donation practices:

1• ***Good donor practices***, in accordance with WHO inter-agency guidelines for drug donations.

2• ***Donations of mixed unused medicines***, i.e. delivery of small and non-professional consignments of unsorted medicines and free samples collected from private homes, health professionals and charities.

3• ***Drug dumping***, i.e. deliberate or well-intentioned donations of large quantities of useless or unusable medicines, generally under the form of large packaging units or hospital conditionings.

The following table illustrates some examples drawn from the field study.

Table 11 - Examples of drug dumping donations as observed during the field study

Expired on arrival	*Irrelevant to the situation*	*Professional samples*
World War II army medical supplies (1940)	multicompounded medicines(*) (Tylenol®, Goodys®, Tussin®, Actigrip®, Pamprin®, Seldane®, Comhist®)	Comhist® (expired 12/92) (*)
Plaster tapes (1961)	Dental floss (*)	Tylenol® (expired 08/93) (*)
Seldane® in sample format (1990 concealed by a sticker indicating 1993) (*)	Mevacor® (*)	Cardura® (1996)
Biosearch® enteral pump	Dapsone	Seldane® (*)
Selfgrip® sport tape	Sine Cod® throat pastilles (*)	
	Breast pads	

(*) not in WHO essential drug list

Table 12 - Typology and characteristics of drug donation practices in BiH

Donations practices and suppliers	Characteristics of suppliers and programmes	Characteristics of donations	Characteristics of the supply and distribution practices
I• Good donor practices conform to WHO guidelines ⇒ UN agencies (WHO, UNICEF, UNHCR) ⇒ International medical relief NGOs ⇒ (ICRC, MSF, PSF, MDM) ⇒ Bilateral aid	*gramme practices* – specialised drug supply programme with regular large scale deliveries, planned distribution schedules (sometimes including technical assistance to health structures) – deliveries – expertise in health and pharmaceuticals – represented in the field – participation in coordination efforts – monitoring activities *nding practices* funding from governmental and/or intergovernmental donors (e.g. ECHO, ODA, Scandinavian governments)	– based on needs assessment and requests from the beneficiaries – only essential drugs – high quality and reliability of medicines – relevant to emergency situations – often pre-packaged kits in the initial phase (with sometimes problems of medicines in excess or irrelevant to the local conditions) and in the second stage supplies responding to specific requests and needs – proper labelling and packaging	*Procurement practices* – ordered through own procurement centre or logistic unit with specific expertise in purchasing pharmaceuticals *Distribution practices* – own distribution channel and logistic centres in the field monitoring arrival, storage and dispatch of consignments to beneficiaries – direct distribution to final beneficiaries – transport costs are covered up to final beneficiaries – deliveries are made according to planned distribution schedules – deliveries usually cover several health facilities in one specific area or several areas
II. Donations of mixed unused medicines in small quantity packs ⇒ Private individuals, mainly from France, Germany and Italy ⇒ Bosnian Diaspora and refugees abroad ⇒ Small charities	*gramme practices* – emotional response of well-meaning private individuals – no expertise in health and pharmaceuticals – not represented in the field – small scale programme with one-off or several irregular deliveries – no support to local health structure – no participation in coordination efforts – no monitoring activities *nding practices* lecting medicines and funds from private individuals	– unsolicited – unannounced – unsorted packaging totally inappropriate for emergency purposes (mixture of partly used packages of many different brands and professional samples; sometimes drugs are mixed with other relief items) requiring significant resources for sorting and repackaging – large proportion already expired on arrival – full course not available large proportion of non essential drugs irrelevant to the emergency situation and local health conditions	*Procurement practices* non-discriminatory collection of unused drugs from private individuals and/or GPs and pharmacies *Distribution practices* – consignments usually arrive unaccompanied straight to a selected health facility or without any definite destination and therefore delivered at random to a health facility or to a central warehouse (e.g. UNHCR logistic centre, relief agencies warehouses, health authorities, etc.) – transport costs to the recipient country are covered by the individuals organising the action
III. Dumping of large quantity packs of inappropriate medicines A. Usually through well-meaning international relief agencies (World Vision International, Ordre de Malte, Caritas, national Red Cross Societies) B. Sometimes directly from ⇒ Health professionals ⇒ Pharmaceutical companies ⇒ Foreign armies (Sweden, Germany) A• Dubious commercial transactions Note: characteristics are not detailed for B. and C.	*gramme practices* – one-off or irregular deliveries, usually unplanned and part of a general relief programme (food, shelter, psychological support, sanitation, etc.) – usually not represented in the field – no support to local health structure – little participation in coordination efforts – no monitoring activities *nding practices* – receiving in-kind donations from health professionals and pharmaceutical companies – funding from public fund-raising but also governmental and sometimes intergovernmental donors (often US)	– often unsolicited and unannounced – huge quantities of sorted useless medicines, especially from US companies – mainly non essential drugs (often multicompounded formula) – pharmaceutical samples or household packaging from health facilities and pharmaceutical companies – often unknown by local health professionals or irrelevant to an emergency situation – sometimes already expired on arrival or more often close to expiry date (shell life < 1 year) labelling: ambiguous, non-informative, without generic names, languages not understood locally, without package inserts, etc.	*Procurement practices* either indiscriminately accepting in-kind donations from hospitals, health professionals and pharmaceutical companies, either purchasing medicines, without specific expertise and well-established procurement practices for pharmaceuticals *Distribution practices* – some agencies may have a distribution and logistic base in-country but usually consignments arrive unaccompanied and are either delivered to a selected health facility, either arrive without any definite destination and are therefore delivered at random to a health facility or to a central warehouse (e.g. UNHCR logistic centre, relief agencies warehouses, health authorities, etc.) – transport costs to the recipient country are usually covered

Table 13 - Advantages and disadvantages analysis

Donations practices	Advantages / Disadvantages analysis			
	Advantages		Disadvantages	
	Donor	Recipient	Donor	Recipient
I. Good donor practices conform to WHO guidelines	At NGO level: – Fulfilling their humanitarian objectives – High visibility & media coverage At financial donor level: – Political interest – High visibility & media coverage	Receiving appropriate assistance alleviating suffering	restraint to conform to good-practices (locking system)	Sometimes the donated drugs are not always adapted to the local needs, particularly in the case of pre-packaged kits.
II. Donations of unused medicines	At individual or NGO level: – self-satisfaction of doing good At country level: – Avoiding pollution caused by wasted medicines – Saving costs on the collection and destruction of unused medicines	marginal	At country and NGO level: Negative public image of donor countries and NGOs (the local population may feel very negative about inappropriate foreign assistance and such practices detract from the positive elements of international relief operation.) At the financial donor level (if any): they have paid for useless actions	– Stockpiling of unusable drugs cluttering up storage depots, resulting in shortages of space for essential medicines – Handling and sorting such mixed boxes is time and resource consuming for local professionals – The collection, storage and destruction of useless donations request important financial, human and technical resources, often not available in the stricken country – Health and environmental hazards
III. Drug dumping	At the pharmaceutical company level: – tax reductions (US) – avoiding disposal costs in case of donations of expired medicines or surpluses of unusable medicines – visibility & media coverage – creating through donated medicines new consumption habits and brand dependence at the recipient level	very marginal	At the company level: – risk of media scandal and negative public image At the country level: – Negative public image of donor countries and NGOs (the local population may feel very negative about inappropriate foreign assistance and such practices detract from the positive elements of international relief operation.) he financial donors level (if any): have paid for useless actions	– Stockpiling of unnecessary or expired drugs cluttering up storage depots, resulting in shortages of space for essential medicines – Handling such donations is time and resource consuming for local professionals – The collection, storage and destruction of irrelevant and expired medicines request important financial, human and technical resources, often not available in the stricken country – Health and environmental hazards

V.2 ESTIMATED VOLUME OF MEDICAL SUPPLIES DELIVERED TO BIH

The total volume of medical supplies delivered to BiH throughout the war has been estimated according to the following conclusions and hypothesis drawn from the information and data presented in this report:

A. The bulk of the donations in accordance with WHO guidelines were delivered by four professional international relief agencies (MSF/H, PSF, ICRC and WHO). As calculated in Table 4 (cf. §III.4.2), their contributions amounted to a total of **11,000 tons**.

B. Other international agencies (such as MDM, MSF/F, MSF/B, Handicap International, the National Red Cross and Red Crescent Societies, AICF, UNICEF (vaccines) and UNHCR) also delivered supplies in conformity with WHO guidelmines, but on a lower scale. They could not provide a detailed account of the volume of medicines they delivered throughout the war. Based on general information they provided, their contributions were estimated at no more than 20% of the total quantity donated by the four agencies. Thus, their donations totaled 20% of 11,000 tons; that is to say **2,200 tons**.

C. Therefore, donations in conformity with WHO guidelines (cf. §V.1) amounted to around **13,200 tons**.

D. However, about 5% of these donations were considered inappropriate, partly because initial supplies mainly consisted of pre-packaged medical kits designed for refugee situations in developing countries and thus not fully adapted to the health needs of former Yugoslavia, and partly because some medicines were in excess while there were shortages of others (cf. §III.4.2).

E. As for the other suppliers (most of the non-specialised agencies, the foreign armies, the Bosnian Diaspora and other sources (cf. §III.3 and §V.1), they delivered aid according to donations practices II and III (respectively donations of mixed unused medicines and drug dumping). We considered that all donations resulting from drug dumping were inappropriate. Based on Table 2 (cf. §II.2.2), we assumed that 10-15% of the mixed unused drugs were appropriate.

F. Finally, we estimated that donations of mixed unused drugs accounted only for a marginal part (a maximum of 10%) of all appropriate donations; the bulk of which (at least 90%) resulting from donations in accordance with WHO guidelines.

G. As indicated in Table 1 (cf. §II.1) and Table 5 (cf. §III.4.3) on the quality of drug donations, we estimated that 50 to 60% of drug donations to Bosnia and Herzegovina between 1992 and mid-1996 were inappropriate.

Based on these conclusions and estimates, the total volume of drug donations delivered to BiH was compiled. The key results are shown in Table 14. Calculations are detailed in Annex 6.

Table 14 - Estimations of drug and medical material donated by international aid to BiH from 1992 until mid-1996

Types of donation practices	Donations in tons	% of total donations	Inappropriate donations in tons	% of total inappropriate donations
I. In accordance with WHO guidelines	13,200	38 to 48%	700	5%
II. Mixed unused drugs	9,300 to 14,000	33 to 40%	7,900 to 12,600	60%
III. Suspected drug dumping	5,300 to 7,600	19 to 22%	5,300 to 7,600	35%
Total	**27,800 to 34,800**	100%	**13,900 to 20,900** (average of 17,000 tons)	100%
% of total donations			***50 to 60%***	

In conclusion

- **International aid to Bosnia and Herzegovina donated an estimated quantity of 27,800 to 34,800 tons of medical supplies in 4.5 years, i.e. 2.3 to 2.9 kilograms per person per year** (based on the United States Census Office projection of 2,656,240 inhabitants in BiH in 1996). For the sake of comparison, in 1989, Armenians affected by an earthquake received 7.1 kilograms per person over one year [5], and the total quantity of drugs sold each year in france represents 1 kilogram per person [42].
- **Useless and unusable medicines represented 50 to 60% of the donations, averaging 17,000 tons.**
- **Mixed unused drugs accounted for 60% and dumping practices for 35% of all inappropriate donations.**
- **Four international agencies with health relief expertise, together with smaller organisations, contributed more or less 40 to 50% of all donations, delivering around 13,200 tons of medical supplies, out of which 95% were considered appropriate.**

V.3 ECONOMIC APPRAISAL

The monetary valuation of drug donations is based on the following unit costs per ton of medicines:

- market value: 12,200 USD (source: Annex 5)
- destruction cost: 2,000 USD (source: waste management expert)
- transport by truck from Western Europe to Sarajevo, insurances, local transport, handling and distribution costs: 500 USD (source: MSF-B).

Therefore, the 27,800 to 34,800 tons of medical supplies donated to Bosnia and Herzegovina in 4.5 years of relief efforts represented an overall market value of 339 to 425 millions USD.

a. Opportunity cost of the inappropriate donations

The 17,000 tons of inappropriate drugs to be destroyed represent an opportunity cost of 250 millions USD, taking into account direct costs only (as shown in Table 15). In addition, institutional donors are currently funding programmes for managing and sorting useless and unusable medicines and finding solutions for proper disposal of these inappropriate donations (cf. §III.5 and III.6). This amount of money could have been used for better alternative assistance. As an indication, an amount of 250 millions USD would have allowed the reconstruction of around 26,000 houses (including schools, health facilities and roads) for 129,000 persons.

Table 15 - Opportunity cost of drugs to be disposed of in BiH (value as of September 1996).

Cost item	In million USD
Market value	207.5
Transport and distribution costs	8.5
Destruction costs	34.0
Total	250.0

b. Cost/benefit analysis for the donor and the recipient

Table 16 compares for the donor and the recipient the direct financial impact of a donation of one ton of medicines supplied by trucks from Western Europe according to each of the three donations practices. It clearly indicates that donations of inappropriate drugs cause more harm than good for the recipient country. For each donated ton of mixed unused drugs drugs, the recipient must face a loss of at least 2,000 USD/ton representing the destruction costs of the unusable medicines while the donor country gains 1,500 USD/ton, as it saves destruction costs of unused medicines. In the case of drug dumping, the result of the cost/benefit analysis is even more dramatic as it shows the huge gain humanitarian donations bring to the donor without doing any good at all to the recipient country which has to pay for the destruction of the useless medicines.

Therefore, 17,000 tons of inappropriate medicines represented at least a gain of 25.5 millions USD and a loss of 34 millions USD for Bosnia and Herzegovina. Moreover, donors may also benefit from tax deductions resulting from „humanitarian gifts" [8]. For the recipients, additional costs may be added such as collecting, storing, handling, sorting and managing useless and unusable medicines. Health and environmental hazards should also be taken into consideration: pollution, erroneous utilisation of medicines, poisoning, disincentive effects on good prescription and/or consumption habits as well as the risk of fuelling black market practices.

Table 16 - Cost/benefit analysis in USD for the donor and the recipient based on 1 ton of donated drug

DONATIONS PRACTICES	DONOR	RECIPIENT
Donation practice I eg. 1 ton of pre-packaged kit	***Costs: 12,700*** Purchase of drugs: 12,200 Transport and distribution: 500 ***Benefits: 0***	***Costs: 0*** ***Benefits: 12,700*** Value of appropriate donations
Cost/benefit balance	***- 12,700 USD***	***+ 12,700 USD***
Donation practice II eg. 1 ton of unused drugs collected from private homes by a well-meaning association of citizens	***Costs: 500*** Purchase of drugs: 0 Transport and distribution: 500 ***Benefits: 2,000*** Avoiding destruction costs	***Costs: 2,000*** Destruction costs ***Benefits: 0***

Cost/benefit balance	***+ 1,500 USD***	***- 2,000 USD***
Donation practice III eg. 1 ton of nearly expired drugs donated by a pharmaceutical company	***Costs: 500*** Market value of donated drugs is 0 (they cannot be sold as they are due to expire) Transport and distribution: 500 ***Benefits: 14,200*** Avoiding donating good drugs (thus, avoiding the loss of sale of 12,200) Avoiding destruction costs: 2,000	***Costs: 2,000*** Destruction costs ***Benefits: 0***
Cost/benefit balance	***+ 13,700 USD***	***- 2,000 USD***

VI. RECOMMENDATIONS FOR IMPROVING QUALITY AND EFFICIENCY OF DRUG AND MEDICAL MATERIAL DONATIONS IN EMERGENCY SITUATIONS

Recommendations are made at three levels:

1. the policy level (international guidelines and regulations, national drug policies, regulations for drug donations and disposal of pharmaceutical waste in donor and recipient countries);
2. the advocacy and information level (awareness raising and campaigning activities, international monitoring of drug donations);
3. the operational level (coordination and management of medical donations, guideline for efficient drug donation programmes).

VI.1 RECOMMENDATIONS AT THE POLICY LEVEL

VI.1.1 Actions at international level

a. International adherence to and compliance with the guidelines for drug donations

Governments, pharmaceutical companies and NGOs are urged to adopt drug donation policies and mechanisms which strictly comply with the WHO inter-agency guidelines for drug donations.

It is encouraging to see that, among the hundred individuals who contributed to the development of those guidelines, were present not only representatives of intergovernmental agencies, but also members of large NGOs, universities and major pharmaceutical companies. On the other hand, the fact that inappropriate medical supplies produced by those pharmaceutical companies and delivered through some of those NGOs still continue to be found, is baffling and raises concern regarding the adhesion of those companies and NGOs to the guidelines principles and recommendations.

It is essential that the WHO inter-agency initiative does not remain limited to intention, with limited dissemination. Similar initiatives have previously been developed (such as CMC and ICRC guidelines) without any significant achievements to improve in the quality and appropriateness of donations in subsequent crisis and disasters. Bosnia is sadly just one more example of large scale „misdonations".

b. International convention enforcing the guidelines for drug donations

The ultimate goal of „good donation practice" promoted by the WHO inter-agency guidelines is not only to achieve better efficiency but also to pave the way for the development of genuine ethics for medical emergency relief.

Therefore, the prime objective of authorities at the international and national levels should be to enforce those guidelines. Several international and national regulations and policies regarding import/export of pharmaceutical supplies and movement of medical waste are already in place and should be implemented in case of drug donations with necessary adjustments to specific conditions of emergency and development aid. The fact that double standards still exist, allowing everything labelled „for charity purposes" to officially leave donor countries almost uncontrolled and be dumped in recipient countries, generally ill-prepared and overwhelmed in times of emergency, is all the more unacceptable whereas circulation of expired drugs and products inside and outside signatory countries to the Basel Convention is very strictly regulated.

Concrete proposals for institutionalising the guidelines and regulating donation practices are as follows:

1. to develop an international convention regulating the international movement of pharmaceuticals and medical products for humanitarian purposes in acute emergency or as part of development aid in non-emergency situations. The convention should make into force of law the following recommendations given in the guidelines:
   - enforcing WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (guideline 4);
   - prohibiting drugs that have been issued to patients and returned to a pharmacy or elsewhere or given to professionals as free samples (guideline 5);
   - prohibiting drugs with a remaining shelf-life of less than a year (guideline 6);
   - enforcing proper labelling (guideline 7);
   - enforcing proper packaging (guideline 8).
2. to strictly apply the international agreement regulating the movement of toxic and/or dangerous waste, known as the „Basel convention", to charitable drug donations, including the case of donations to non-signatory recipient countries.

VI.1.2 Actions at donor level

a. Rationalising national drug policies

Humanitarian donations of huge quantities of partly used drugs collected from private homes is the result of health systems and pharmaceutical policies in Western countries which lead to around 40% of distributed medicines never being used [42]. This raises the question of the collection and destruction policies of those unused medicines. Organising systematic and proper collection and destruction is very expensive for the authorities. In the end, doesn't the evacuation of unused drugs through the humanitarian channel suit everybody with, in addition, the (feigned or genuine) feeling to do good ?
Humanitarian donations of surpluses from health facilities and pharmaceutical companies raise similar concern regarding pharmaceutical production policies, drug procurement and management procedures of health care systems as well as tax benefits for exports of drugs for charitable purposes. Cheap and easy clearing of excess stock and costs saving on expensive waste disposal results in evacuating surpluses and expired drugs through the humanitarian channel ?

Relevant authorities are urged to rationalise national drug supply, distribution and consumption policies at the manufacturer, prescriber and consumer levels, as recommended for several years by WHO in its essential drugs principles. This will significantly reduce the quantity of wasted drugs and therefore the resulting „humanitarian dumping".

b. National regulations for the disposal of pharmaceutical waste from households and health professionals

In addition, authorities are urged to define clear and appropriate measures and regulations ensuring the proper management and disposal of unused pharmaceuticals from households and health professionals (GPs and pharmacies), and prohibiting the collection and delivery of those medicines for humanitarian purposes. The only way to dispose of unused medicines should be to destroy them.

c. National regulations enforcing the guidelines for drug donations

Relevant authorities in donor countries are urged to enforce WHO standards and guidelines and therefore:

- to apply existing national export regulations to the delivery of medical consignments for charity purposes, after reviewing and adjusting those regulations to WHO principles and to the conditions of emergency situations;
- to review procedures for granting tax benefits in case of charitable gifts, in order to avoid incentives for inappropriate drug donations, and enforce stricter control on the quality and appropriateness of the donations.

d. Funding procedures for drug donations

- Intergovernmental and national funding agencies (e.g. ECHO, UN, governments, foundations, etc.) should review and revise their procedures for granting funds for drug donation projects to ensure that implementing agencies comply with the WHO inter-agency guidelines and have expertise in that field.
- Intergovernmental and national funding agencies should integrate in their funding policies provision for supporting central coordination efforts in times of emergency (refer to recommendation VI.3.2).

VI.1.3 Actions at recipient level

Relevant authorities in recipient countries are urged to develop measures and regulations promoting good quality drug donations and ensuring stricter control upon foreign humanitarian medical assistance, such as:

- establishing a National List of Essential Drug based on WHO's model list and accepting only medicines included in that list;
- developing a policy on donations of pharmaceutical supplies enforcing the WHO inter-agency guidelines for drug donations, including:
- specific custom regulations and quality control adjusted to emergency situations;
- procedures for being advised in advance of the donations characteristics;
- procedures for refusing entry of humanitarian consignments deemed inappropriate;
- procedures for disposal of pharmaceutical waste.
- implementing emergency preparedness programmes in disaster-prone areas (ref. PAHO, UNHCR, WHO guidelines);
- at the onset of an emergency, setting up an operational medical coordination centre in collaboration with the international assistance, with prime responsibility for coordinating and managing in-coming aid as well as informing donors on needs and priorities (refer to recommendation VI.3.1).

VI.2 RECOMMENDATIONS AT THE INFORMATION AND ADVOCACY LEVEL

VI.2.1 Actions at international and donor levels

a. Networking, centralising information and monitoring

NGOs and health networks are urged:

- to create a non-governmental advisory committee to WHO should be created to assist WHO in monitoring drug donations practices and compliance with the international guidelines and regulations on drug donations and, where appropriate, review guidelines and regulations. The committee should comprise major operational relief and development NGOs as well as health networks actively concerned with the issue of drug donations (ICRC, IFRC, MSF, PSF, WCC, OXFAM, WEMOS, AEDES, HEALTHNET, HAI, ReMed, PIMED, etc.). One organisation should take the lead in setting up such a committee and coordinating activities.
- to establish a central point where information, data, reports, guidelines, policies, etc. related to the issue of drug donations could be reported to, collected, recorded, sorted and stored in a systematic way. The centre should act as a reference library on drug donation issues. WEMOS is particularly interested to promote this idea.
- to create national working groups following the initiatives implemented in the Netherlands (refer to Chapter II) or eventually expand the Dutch working group into a European group.
- to conduct regular and systematic evaluations of drug donation programmes, comprehensive analytical studies (e.g. the Armenian study [5]) as well as fact-findings activities in order to monitor drug donation practices and assess the use and the impact of guidelines and regulations concerning drug donations.

b. Raising awareness and information

- Whenever a disaster strikes, governments, NGOs and media are urged to provide accurate public information on priority needs, appropriate kinds of items to be donated, recommended channels of distribution and established policies and regulations in donor and recipient countries.
- Governments, NGOs and media should join efforts to raise awareness among the general public about good donor practices and the negative impacts of collecting and donating unused drugs, unsold surpluses, expired drugs and pharmaceutical samples (e.g. initiatives of the Dutch government and the Dutch NGO working group should be followed).
- Health networks, intergovernmental agencies and NGOs are urged to develop advocacy, campaigning and lobbying actions on the use, supply, distribution and donation of medicines. Coordination of efforts and active participation in existing networks are strongly recommended.
  Individual and joint actions should be targeted at the international community, governments of donor and recipient countries, the pharmaceutical industry, the health care sector in donor and recipient countries, as well as the general public in donor and recipient countries. They should particularly aim at:
  - drawing attention to abuses and problems caused by inadequate and unsolicited drug donations;
  - promoting and disseminating WHO's essential drugs concept and inter-agency guidelines for drug donations;
  - calling for the development of an international convention and national regulations enforcing the guidelines and prohibiting bad donation practices.

VI.2.2 Actions at recipient level

It is the prime responsibility of recipient countries, which should ask for WHO assistance, to specify their needs, to request foreign assistance and to clearly inform donors on needs and priorities.
Health authorities are urged to report cases of inappropriate donations and to encourage foreign agencies as well as journalists to investigate and monitor drug donation practices.

VI.3 RECOMMENDATIONS AT THE OPERATIONAL LEVEL

VI.3.1 Coordination and management of the medical emergency assistance

a. Central medical coordination

From disaster to disaster, it has been endlessly repeated that the single most important step to ensure the best response in times of emergency is to centralise the coordination of the relief activities. It is deemed essential to repeat it again!

A pro-active ***Emergency Medical Coordination Centre*** should be set up in the recipient country at the onset of a disaster. It should be implemented under the auspices of the national MoH with the assistance of WHO and actively involve the major medical relief agencies implementing programmes in the field. Under its supervision, ***Regional Medical Coordination Centres*** should be established in each region (province, canton or district) and comprise representatives of the regional (provincial, cantonal or district) health authorities, directors of major health care services and medical field coordinators of relief agencies.

The role of the Emergency Medical Coordination Centre is to be the single focal point for medical coordination. Its key tasks should be:
- to establish clear overall direction and set priorities for external emergency health operations;
- to develop and disseminate appropriate guidelines and instructions to all those engaged in health-related activities;
- to ensure adequate monitoring of the health care situation, emergency health care activities and offers of external medical assistance;
- to coordinate between donors, implementing agencies and beneficiaries;
- to issue clear news releases.

Several guidelines for the coordination and management of medical aid in times of emergency exist and should be referred to (ref. PAHO, UNHCR, WHO, etc.).

b. Coordination and management of medical supplies

Regarding the coordination and management of medical supplies, the Emergency Medical Coordination Centre should create a ***Central Drug Management Committee*** responsible for ensuring consistency in the drug supply, distribution, management and monitoring chain. Its tasks should comprise:
- developing (if it does not exist yet) a national list of essential drugs in conformity with WHO recommendations;
- issuing clear guidelines for the proper channels of procurement, storage and distribution of medicines and medical material;
- accurately brief all potential donors, diplomatic missions, NGOs, media, etc. on the pharmaceutical needs and procedures for external assistance;
- ensuring coordinated and on-going needs assessment;
- centralise the collection, processing and analysis of data on pharmaceutical donations, needs and requirements;
- setting up standard formats for the surveillance and reporting system of drug donations;
- encouraging integration of emergency medical supply and distribution assistance within the traditional supply and distribution structures of the recipient country and encouraging the reinforcement of the traditional supply, distribution, storage and cold-chains capacities of the recipient country;
- establishing clear regulations for the management and disposal of useless or expired drugs;

- supporting the establishment of ***Regional Drug Management Committees***.

The Regional Drug Management Committees should involve the Drug Advisors or Chief Pharmacists of the local health authorities, major health care facilities and pharmacists or medical coordinators of relief agencies implementing specific drug supply and distribution programmes. These committees should act as a clearing-house for all in-coming medical donations in their region.

Their responsibilities should include [5, 56]:

⇒ registering all available information on pharmaceuticals in the region:

- needs and requests from local health services;
- ordering and distribution plans of relief agencies;
- arrival and destination of incoming medical supplies and donations locally; in order to provide on a regular basis:
- running lists of local drugs and medical material available;
- up-dated lists of local medical needs.

⇒ coordinating external procurement to avoid duplication, overlapping and gaps:

- inform recipients of what is available where;
- inform suppliers of what is needed where and what is already procured for;
- request to be informed in advance of the details of shipments and swiftly approve, reject or dispatch medical donations.

⇒ monitoring the drug supply and distribution in the region:

- to keep recipients and suppliers informed of guidelines, procedures and standard formats regarding medical supply assistance;
- to provide technical assistance to managers of local medical stores in the form of standard formats for inventory control, cross-indexes for drug identification, notices and labels in local languages for unfamiliar medicines, instruction leaflets for efficient drug usage, etc.
- to regularly liaise with and report problems with donors and suppliers to the Central Drug Management Committee;
- to monitor surpluses, duplication and shortages of medicines;
- to collect and centralise unsolicited gifts and useless supplies in a central warehouse where they should be recorded, safely stored and disposed of.

VI.3.2 Role of the international community in the coordination and management process

a. Funding coordination activities

Donors should include, in their funding strategies for emergency situation, provision for coordination programmes. They should encourage, at the onset of a disaster, competent agencies (WHO or another agencies to be assigned) to design and submit, in collaboration with the health authorities in the recipient country, proposals for the creation and management of operational coordinating bodies such as the Emergency Medical Coordination Centres and Drug Management Committees as explained here above.

In an emergency situation, there is a need for one international agency to be assigned the leading role in assisting the local authorities in the central coordination of medical assistance. At regional level (provincial, cantonal or district), specific relief agencies with adequate competence and operational capacities should lead the regional coordination in collaboration with the regional health authorities. Logically, WHO should be assigned as the leading agency for coordination at central and regional level, but to achieve efficiently this role, WHO should, on one hand, receive adequate financial support to set up efficient coordination centres (staff, vehicles, communication equipment, computers) and, on the other hand, seriously increase its competencies and capacities to become rapidly operational in the field in times of emergency. WHO could also delegate field operational coordination activities to well-known medical relief NGOs (such as PSF, MSF, etc.) and keep a strategic supervisory, advisory and policy role.

b. Setting up standard coordination practices

Under WHO auspices, UN agencies, relief NGOs and representatives of the health authorities of recipient countries should meet and share their experiences in drug donations in times of emergency with a view to set criteria and standards for coordination activities, establish pre-determined coordination structures, develop tools and software for the management of drug donations (standard inventory control, data gathering, record keeping instructions, ordering procedures, etc.).

VI.4 RECOMMENDATIONS FOR EFFICIENT DRUG DONATION PROGRAMMES

This guideline is intended for organisations and individuals setting up drug donations activities in response to an emergency.

Organisations or individuals wishing to get involved in drug donation activities should always strictly comply with the WHO inter-agency guidelines for drug donations, paying particular attention to the type of drugs, identification of drugs, labelling and packaging.
In addition, prior to any drug donation programmes, organisations and individuals should carefully take into account the following elements:

1• Type of supplies

- External drug supplies are needed only when local production cannot meet the initial demand. Therefore, as far as the context allows it, restoring or reinforcing local pharmaceutical production capacities as soon as possible is a priority.
- In the initial phase of an emergency, it is recommended that suppliers only deliver essential drugs, preferably in the format of pre-packaged emergency kits, to be adapted to the local conditions and type of disaster (natural, conflict, health status, etc.). This particularly falls into the competencies of specialised relief agencies such as ICRC, PSF, MSF, WHO, UNHCR and MDM.
- Once the acute emergency phase is over, suppliers should review their programmes towards the regular provision of specific pharmaceutical needs and delivery of bulk supplies rather than pre-packaged kits.
- Suppliers should always carefully check the quality, expiry date and appropriateness of all in-kind donations of medicines they may receive or collect. They should strictly refuse pharmaceutical samples, non-essential drugs, partly used medicines in mixed boxes and unsold surpluses of expired or inappropriate medicines.

2• Needs assessment

Coordinated assessment of needs is a prerequisite for efficient assistance. Potential suppliers should identify and take into account local priorities and any established local practices, mechanisms and policies put in place in the recipient country (such as the national list of registered drugs, drug policies and regulations, drug supply and distribution patterns and channels) in order to conform to and not to by-pass the medical supplies management system of the recipient health authorities.

3• Management

- Suppliers should closely cooperate with the Emergency Medical Coordination Centre and Drug Management Committee set up in the recipient country and strictly conform to their recommendations.
- Suppliers should always notify the recipient (the end-user but also the Drug Management Committee) in advance of the content and shipment of their donations (detailed shipping list and adequate information in a language understood in the recipient country) and comply with the recipient's recommendations for delivery.
- Drug donation programmes should be designed and monitored under the supervision of an experienced health professional (ideally a pharmacist) based in the field throughout the duration of the programme, avoiding field staff rotation as much as possible.

4• Logistics

- Suppliers should pay attention to the logistical capacities of the recipient health facilities regarding drug management (availability of staff, storage, handling, transport and monitoring resources). Where appropriate, drug donation programmes should incorporate technical assistance providing for experienced expatriates (pharmacists, logisticians), recruitment of additional local personnel, rehabilitation of infrastructure, storage and handling equipment, transport and telecommunication means, efficient inventory control system (computerised or manual) and training of pharmacists, storekeepers and logisticians.
- Suppliers should always accompany their donations up to destination.

ANNEXES

ANNEXES

ANNEX 1 : PERSONS MET IN BIH

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ANNEX 3 : EXAMPLES OF PROBLEMS WITH DRUG DONATIONS

Remark: text in italics is extracted from the inter-agency guidelines for drug donations, May 1996.

Nicaragua, 1974
In the aftermath of the earthquake, it was reported that all the supplies stored in a large government warehouse had been destroyed. No one checked this information and, once the emergency efforts were over, around US$ 1,000,000 worth of salvageable supplies, which were needed during the relief operation, were finally discovered in that warehouse. This is a classic example of lack of coordination in the management and monitoring of drug donations. [56]

Guatemala, 1976
Unsorted drugs represented over 90% of the volume of drugs donated to the country after the earthquake. Two weeks after the earthquake had struck, 100 tons of unsorted medicines had been delivered, that is between 6,000 to 7,000 boxes. Huge volumes were still coming even though the acute emergency was over for a week. Up to 40 students supervised by three pharmacists were working by 3-4 hours shifts to sort between 25-50 boxes a day: a formidable task for months ahead. [2, 3]

Guinea Bissau, 1983
*In September 1983 eight tons of donated drugs were sent; all were collected from pharmacies in quantities 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. [*6]

Mexico, 1985
Priorities and requests for assistance following the earthquake were for specialised teams and equipment for rescuing trapped people and for water supply. There was no shortage of emergency drugs and medical supplies. In spite of that, one third of the total volume of international aid brought in were plasma, blood, intravenous solutions and drugs; items which were not requested by the country's authorities. Due to the large quantities of blood and plasma received, the authorities had to inform the population, as of the second day of the disaster, not to volunteer to donate blood anymore. They also had to lyophilise plasma and create an albumin bank. [4]

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 percent of the drugs had expired on arrival, and 4% were destroyed by frost. Of the remaining 88%, only 30% were easy to identify and on,ly 42% were relevant for an emergency situation. The majority of the drugs were only labelled with brand names. [5]

Eritrea, 1989
During the war for independence, despite careful wording of appeals, many inappropriate donations were received. Examples were: seven truck loads of expired aspirin tablets that took six months to burn; a whole container of unsolicited cardiovascular drugs with two montls to expiry; and 30,000 half-litre bottle of expired amino-acid infusion that could not be disposed of anywhere a settlement because of the smell. [21, 22]

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 stimulant, 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. [25, 26]
France,1991
Pharmaciens sans Frontières collected 4 million kg 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. [43]

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; triamtene and spironolactone as diuretics; pancreatic enzyme and bismuth preparations as the only gastrointestinal drugs. [27]

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 withour product information or package insert, and doctors had tried to identify the product by matching its name with those on leaflets of other products. [28, 29]

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. By the end of 1995, 340 tons of expired drugs were stored in Mostar. Most of these were donated by different European nations. [9, 10, 11, 14, 15]

Rwanda, 1994
At the peak of the refugee crisis, the pharmaceutical giant Eli Lilly proudly announced "the largest one-time pharmaceutical donation ever." Six million pills of antibiotic CeclorCD, which because of the risk of causing resistance to more valuable drugs commonly used in the region, will not be prescribed. As a result, today, the local authorities are still trying to figure out how to dispose of the donation, most of it expired. [8]

India, 1996
On April 1, 1996, amongst much fanfare, an airlift of 50 tons of medicines was received from the USA at Calcutta airport. An analysis of the drugs received revealed that $7.4 million of the $10.5 million worth of drugs donated have either expired already at the time of arrival at Calcutta airport or would expired before March 1997. In addition, 30 out of the 46 types of drugs brought in are non essential medicines [30, 31, 32].

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ANNEX 5 : WEIGHT ASSESSMENT & VALUE ESTIMATION

A. Weight Assessment

Weight assessment was based on the observed volume in the warehouses.

The estimation of the average specific weight was based on several informations provided by the main organisations involved in drugs and medical supplies donations during the war.

MSF („ Kits logistiques et médicaux " 1994)

new emergency health kit	229 kg/m³
basic medico-surgical kit	230 kg/m³
surgical kit	287 kg/m³
hospital kit	289 kg/ m³

TRANSFER (personnal communication)

average specific weight (drugs + medical supplies)	286 kg/ m³
average specific weight (only essential drugs)	333 kg/ m³

PSF (rapport P.S.F.C.I. Bosnie-Herzegovine 1992-1996)
(average during 4 years, on the basis of 1.800 tons provided representing 8.102 m³)

average specific weight	222 kg/ m³

WHO Emergency Kits (WHO Zagreb „ Medical kits for former Yugoslavia " 09/94)

new emergency kit	192 kg/ m³
surgical kit (only disposable medical equipment)	124-131 kg/ m³
parenteral fluids	317-352 kg/ m³
anesthesic kit	175-235 kg/ m³

IDA (IDA informations, gathering 1995-96 datas about former yougoslavia)

407.550 kg for 1.340 m³, this means	304 kg/m³

Specific weights applied in the frame of the mission

Sur base de ces informations, le poids volumique moyen est d'environ 262 kg/m³. Nous avons, sauf exception, appliqué un poids volumique de 200 kg/ m³ aux volumes observés, soit 24% de moins, du fait de la proportion de médicaments en petits conditionnements, ainsi que des volumes supérieurs occupés par des colis „ déconditionnés ". Dans certains cas, nous avons pris 250 kg/ m³ comme référence, auquel cas nous nous en justifions (conditionnements hospitaliers encore intacts, proportions de solutés ou d'autres produits „ lourds " etc.).

B. Value Estimation

The estimation of the average value of 1 ton is based on several informations provided by several organisations involved in drugs and medical supplies donations during the war.

PSF (rapport P.S.F.C.I. Bosnie-Herzegovine 1995-1996)

675 tons provided representing 40.000.000 FF,	
this means	11.852 $/ton

WHO (WHO: activities report 1993 to 1995)
1.431 tons provided representing 15.668 M$ 10.949 $/ton

IDA (IDA informations, gathering 1995-96 data about former yougoslavia)

ICRC (informations from april 1992 to 1996)
3.347 tons provided representing 41.933 M$ 12.499 $/ton

World Vision (cfr packing list 05.02.96)

11.8 tons provided by MAP International,	
representing 110.568 $	9.370 $/ton

ANNEX 6 - EXPLANATIONS ON THE CALCULATION FOR THE ESTIMATED VOLUME OF MEDICAL SUPPLIES DELIVERED TO BIH

The total volume of medical supplies delivered to BiH from 1992 to mid 1996 is named Y and can be divided as follows:

I. Good donor practices conform to WHO guidelines	80 to 100% of Yg *95% of X_1* X_{1g} **50 160 m³**	*5% of X_1* X_{1b} **2 640 m³**	X_1 **52 800 m³**
II. Donations of mixed unused medicines in small quantity packs III. Dumping of large quantity packs of inappropriate medicines	20 to 0% of Yg X_{2g}	X_{2b}	X_2
	Y_g 60 to 40% of Y	Y_b 40 to 60% of Y	**Y**

Ygood = Yg = total volume of appropriate medicines donated to BiH
Ybad = Yb = total volume of inappropriate medicines donated to BiH

X1 = total volume donated according to practice n° I
= total of useful medicines (X1g) + total of inappropriate medicines (X1b)

X2 = total quantity donated according to practices n° II and III
= total of useful medicines (X2g) + total of inappropriate medicines (2b)

➔ we will work with the following formulas

- Y = Yg + Yb
- Y = X1 + X2
- X1 = X1g + X1b

Calculation of X1

X1 is the total volume of medicines donated by the four main specialised agencies plus other agencies which contributed on a lesser extent.
As indicated in Table 4, the contribution of the four main agencies (MSF/H, PSF, ICRC and WHO) amounted to around 44,000 m³.
To this amount, we must add the donations from other international medical agencies such as MDM, MSF/F, MSF/B, Handicap International, the National Red Cross and Red Crescent Societies, etc. for whom we do not have a detailed account of what they donated. We estimate their contribution at 20% of the volume donated by the four main agencies; which therefore amounts to 20% * 44,000 m³ = 8,800 m3.
Therefore, **X1 = 44,000 m³ + 8,800 m³ = 52,800 m³**.

Breakdown of all donations into 'good' and 'bad' supplies

From the data and estimations provided in Table 1 and Table 5, the appropriate donations (Yg) can be estimated at 60 to 40% of the total volume (Y); and therefore the inappropriate donations (Yb) represent 40 to 60% of the total amount.

In the simulation, we will estimate the total volume Y and the volume X2 (donations resulting from practices n° II and III) according to three hypothesis as follows:
1• H1: Yg = 60% of Y
2• H2: Yg = 50% of Y ➔ the most probable
3• H3: Yg = 40% of Y ➔ the most pessimistic/maximalist

Breakdown of the donations according to practice n° I into 'good' and 'bad' supplies

Donations according to practice n° I were made by international medical relief agencies (as detailed in Table 12) which donated essential drugs within planned drug supply and distribution programmes. We consider that a part of what they provided was not useful or inappropriate and that it represented a maximum of 5%.

Therefore, we take the hypothesis that at least 95% of the volume delivered by those agencies was appropriate.

This means that:

- X1g = 95% of X1 = 95% * 52,800 m³ = 50,160 m³
- X1b = 5% of X1 = 5% * 52,800 m³ = 2,640 m³

Breakdown of the total volume of good donations into appropriate donations resulting from practice n° I and from practices n° II and n° III

According to common sense and what has been mentioned in Table 5 for Sarajevo (90% of the donations from international agencies were appropriate), we take the hypothesis that the donations according to practice n° I represented at least 80% of the total volume of appropriate donations delivered to BiH; and that donations according to practices n° II and III accounted for a maximum of 20%.

In addition, as shown in the simulation table, more we reduce the proportion of appropriate donations resulting from practice n° I, more we increase the total volume of drugs delivered to BiH.

Therefore, in the simulation, we will estimate the total volume Y and the volume X2 (donations resulting from practices n° II and III) according to three sub-hypothesis as follows:
1• h1: X1g = 80% of Yg
2• h2: X1g = 90% of Yg
3• h3: X1g = 100% of Yg ➔ the least probable

Given that **X1** = **52800 m³**
Given that **X1g = 95% of X1 = 50160 m³**

	H1: Yg = 60% of Y			H2: Yg = 50% of Y			H3: Yg = 40% of Y		
therefore	Y = Yg / 0,6			Y = Yg / 0,5			Y = Yg / 0,4		
	h1	h2	h3	h1	h2	h3	h1	h2	h3
	X1g = 80% of Yg	X1g = 90% Yg	X1g = 100% Yg	X1g = 80% of Yg	X1g = 90% Yg	X1g = 100% Yg	X1g = 80% of Yg	X1g = 90% Yg	X1g = 100% Yg
therefore	Yg = X1g/0,8	Yg = X1g/0,9	Yg = X1g	Yg = X1g/0,8	Yg = X1g/0,9	Yg = X1g	Yg = X1g/0,8	Yg = X1g/0,9	Yg = X1g
therefore Yg =	62700	55733	50160	62700	55733	50160	62700	55733	50160
Y =	**104500**	**92889**	**83600**	**125400**	**111467**	**100320**	**156750**	**139333**	**125400**
X2 = Y - X1	51700	40089	30800	72600	58667	47520	103950	86533	72600
Ybad = Y - Yg	41800	37156	33440	62700	55733	50160	94050	83600	75240
					the most probable		the most pessimistic and maximalist		

From this simulation, we draw the conclusion (as indicated in § V.2) that the minimum of the total volume of medical supplies delivered to BiH from 1992 to mid 1996 can be estimated to at least 100 000 m³ from which around **50%** are inappropriate supplies to be disposed of