

# An analysis of 1999 world health organisation (WHO) guidelines for drug donations for better donation practice in emergency situations

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## ABSTRACT

In disasters and emergency situations, a lot of drug and medical supplies comes to the affected area from local or international donors. But, those donations often generate more problems for the recipients. The WHO and major humanitarian organisations developed WHO Guidelines for Drug Donations in 1996. The guidelines based on four core principles which are all donation should benefit the recipient, respect for wishes and authority of the recipient, there should not be a double standard in quality, and effective communication between donor and recipient. The guidelines influenced positively to drug donation practices for several years until 2004. The drug donation practices during 2004 tsunami relief in Sri Lanka and Aceh (Indonesia) showed that the compliance with WHO Guidelines for Drug Donations was low. This study aim was to strengthen the effectiveness of WHO Guidelines for Drug Donations in disaster and emergency situations. While the objectives are to explore the strength and weakness of the WHO Guidelines for Drug Donations and to recommend how to improve the effectiveness of drug donations. In this study, the WHO Guidelines for Drug Donations were analysed using the model of health policy analysis from Walt and Gilson, which is specifically used for analysing health policies. The framework is viewed as a tool to describe the interactions and interconnections systems between content, context, process and groups of actors. The author concludes that presence of donation operator team for drug donations is needed during the emergency situations and it should be stated in the WHO Guidelines for Drug Donations. The WHO needs to encourage donors and recipients to refer to WHO Guidelines for Drug Donations when they are making their own guidelines. The guidelines can be strengthened at country level and adjusted to regulations in the countries. The WHO Guidelines for Drug Donations should state that donations are preferred in form of New Emergency Health Kit (NEHK) or cash donations, and the necessity of information and communication centre in the WHO Guidelines for Drug Donations.

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## 1. Introduction

During the disasters and other emergency situations, usually, a lot of aids will be sent to the affected areas by local or international donors. Those aids that come from the donors could be in form of goods, services or personnel (Hogerzeil, 1997). In the emergency situations, such as natural disaster, the donations are intended to provide medicines that were needed by the people affected to

alleviate the suffering. But, in reality, donations of drugs and medical equipment often generate problems for the recipients (Hogerzeil, 1997). As listed in the Merriam-Webster online dictionary, a donation can be defined as “the making of a gift especially to a charity or public institution” (Merriam-Webster, 2011). Another resource, such as Oxford Dictionary, defined it as “something that is given to a charity, especially a sum of money” (Oxford Dictionary, 2011).

A donation may take various forms, including cash, services, new or used goods including clothing, food and vehicles. It also may consist of emergency, relief or humanitarian aid items, development aid support, and can also relate to medical care needs (Wikipedia, 2011). During 1970's, several drug donation practices occurred and one of them is the Guatemala earthquake in 1976. About 6,000 – 7,000 boxes (a total of 100 tons) of unsorted drugs were delivered and after the emergency phase was over, the medicine was still coming in huge volumes. About 40 staff worked in 3 – 4 hours shifts to sort between 25 – 50 boxes per day (Benaragama, 2007). Similar to the 1970's, the practice of inappropriate drug donations during 1980's still continued. The Armenia earthquake in 1988, there were about 5,000 tons of medicine received by the authority and it took 6 months to sort the drugs (WHO, 1999; Benaragama, 2007). Twelve percent of the received drugs were unusable due to they were destroyed by the frost or passed their expiry date. From the 88% remaining medicine, only 42% that were relevant to the emergency situation and 30% were easy to identify. Most of these donated drugs were labelled by their brand names (WHO, 1999).

The first guideline for drug donations was developed in April 1988, by the Christian Medical Commission (CMC) of the World Council of Churches to address the 5 main complaints associated with drug donations in the 1970s and 1980s (Hogerzeil, 1997; WHO, 1999; Benaragama, 2007), which are:

1. Arrived after or near expiration dates,
2. Were inappropriate or unsuitable for the recipient country,
3. Sent without first asking the recipient about their needs,
4. Sent without prior notification or shipping documents,
5. Were inadequately packaged or labelled with no prescriber or patient information.

WHO re-look at the problems due to many reports in the mid-'90s about the continuing 'useless' and inappropriate drug donations practices, and identified 6 main problems which similar to the 5 complaints that identified by the CMC (Hogerzeil, 1997; WHO, 1999; Benaragama, 2007; Bero, 2010).

1. Donated drugs are often not relevant to the emergency situation, for the disease pattern, or for the level of care that is available.
2. Many donated drugs arrive unsorted and labelled in a language which is not easily understood.
3. The quality of drugs does not always comply with standards in the donor country.
4. The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies.
5. Donated drugs may have a high declared value in the donor country than the world market price.
6. Drugs may be donated in wrong quantities creating disposal problems.

WHO and seven co-sponsoring organisations made the final text of Guidelines for Drug Donations after addressing comments from over 100 humanitarian organisations and individual experts (WHO, 1999; Benaragama, 2007). The co-sponsoring organisations were Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, the Office of the United Nations High Commissioner for Refugees, OXFAM and the United Nations Children's Fund. The guidelines based on four core principles:

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

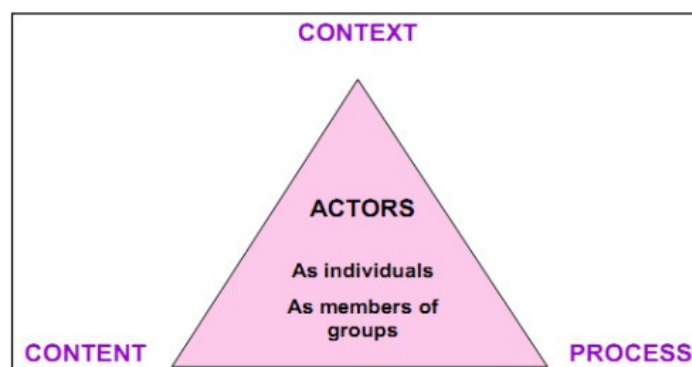
After the WHO Guidelines for Drug Donations revised in 1999, the practice of drug donations during disasters and emergency situations improved and considered appropriate for several years (Autier, 2002; Bero, 2010). But, during the devastating tsunami disaster in December 2004 that hit several countries in Asia, the appropriateness of drug donation practices declined (Benaragama, 2007; Fernandopulle, 2011; Snell, 2011).

This study aim is to strengthen the effectiveness of WHO Guidelines for Drug Donations in disasters and emergency situations. The objectives of this study review are:

- To assess or examine the effectiveness of guidelines for drug donations by using the case studies of Sri Lanka and Indonesia.
- To explore the strength and weakness of the WHO Guidelines for Drug Donations revised 1999.
- To recommend how to improve the effectiveness of drug donations practices.

## 2. Methods

In order to analyse a health policy, the author uses a model of health policy analysis from Walt and Gilson. This model introduced by Walt and Gilson in 1994 and specifically used for analysing health policies. The Walt & Gilson (1994) health policy triangle framework is used to analyse the implementation of WHO Guidelines for Drug Donations which is considered as one of international health policy. The framework is viewed as a tool to describe the interactions and interconnections systems between content, context, process and groups of actors, in terms of networks. The analysis is a retrospective analysis which also known as the analysis of policy (Buse, 2005). It looks back to learn does the implementation of WHO Guidelines for Drug Donations achieved its aim in emergency situations?



Source: Walt and Gilson, 1994

**Fig. 1.** Health policy triangle framework

The content of this study is the provisions of the 1999 version WHO Guidelines for Drug Donations. The context of this study is issues or specific situations that might facilitate or hinder the implementation of good drug donation practices based on the WHO Guidelines for Drug Donations during emergency situations. The issues can be cultural issues, financial issues, etc. This study review will also look at the process and the actors that involved in the drug donations practice. The process in this study is about how the WHO Guidelines for Drug Donations have been implemented in the emergency situations. In this study, the author will focus mainly on the 2004 tsunami in Sri Lanka and Indonesia. Process and actors are linked together since the process may also affect by actors' interests. In order to assess the effectiveness of the WHO Guidelines for Drug Donations, it is very important to understand the factors that affect the process in donating and receiving medicines during the disasters or emergency situations, as well as factors that encourage donors to

donate the medicines. The actors in this study are any parties that involved or influenced the process of implementation of the WHO Guidelines for Drug Donations during 2004 tsunami in Sri Lanka and Indonesia. In general, they are the donors, recipients and other stakeholders, such as the WHO and humanitarian relief organisations. Actors' interests are influenced by the surrounding context and affect different procedure of implementation.

By using health policy triangle framework, the author tries to explain how the components affect the guideline implementation in the field. This review study is based on secondary data that obtained from published and unpublished literature, electronic and non-electronic sources. The author searched for academic and literature to identify reports and research on drug donation practices in an emergency situation that occurred after 1996, the year when the WHO Guidelines for Drug Donations were issued, until 2010. The author searched electronic literature through some databases such as WHO Library, PubMed and Google Scholar. Some electronic journals also used to find articles that related to the topic, such as New England Journal of Medicine (NEJM), etc. Data were collected paper-based documents and articles from WHO and Médecins Sans Frontières (MSF) Headquarters in Geneva, Switzerland.

The author searched the academic literature and database using selected keywords and performed snowball searches method. Several keywords were used to find articles that related to the topic. The keywords are drug donation, guideline, inappropriate, programme, donor, emergency, disaster, compliance and humanitarian aid. Throughout the searching, keywords truncation and combinations were used. In PubMed database, firstly author used 'drug donation' as the main keyword and got more than 1,000 articles in the result. The author tried to narrow the search by adding and combining with other keywords. In the next step, the combination keywords of 'drug donation' and 'guideline' provided 13 articles. The author continued to add another keyword such as 'programme', 'inappropriate' and 'disaster', respectively. While getting the result, using 2 keywords or more, the author also tried to exclude articles with titles that related to clinical sciences.

The author used a similar method of searching, but in Google Scholar, the author used the advanced scholar search option and only search in the area of administration, social sciences and humanities. We excluded the articles from medicine area and patents, so the result would be limited to articles and books only. Among 52 articles obtained from PubMed, 6 articles were met by the inclusion criteria. The inclusion criteria are:

- Articles written in English or Indonesian language.
- Articles discuss about drug donation practices in disasters or emergency situations. The screening was done by reading the abstract of articles found.

During the literature searching, the author found some articles related to the topic that written in French and Chinese. Inclusion criteria such as articles written in English or Indonesian language might limit the author from getting some reports that could be useful for analysis. Most of the published articles emphasise the negative effect or impact of drug donation practices and none of the articles was discussing from the perspective of donors, such as pharmaceutical companies. During the research, the author was not able to find literature which analyses the WHO Guidelines for Drug Donations. Most of the literature were analysing the practice of drug donations.

### 3. Result

#### 3.1. Guidelines Analysis

It has been over 10 years since the WHO Guidelines for Drug Donations were first issued and since then, the practice of drug donations in response to emergency situations have not met their objectives (Pinheiro, 2008; Bero, 2010). In most instances of drug donations, donors only comply with a few provisions of the guidelines. This condition is worsened by the inadequate or absent disaster preparedness systems in the recipient country. For example, recipient countries that do not have a national essential medicines list (NEML), fail to meet the basic requirements of the guidelines.

The absence of NEML is contrary to the aim of the WHO Guidelines for Drug Donations which is to maximise the positive impact of drug donations. Countries can achieve the aims of these guidelines by avoiding donations of unnecessary or dangerous medicines, avoiding donor driven

donations, avoiding double standards in medicine quality and by creating effective communication between donors and recipients (Hogerzeil, 1997; WHO, 1999). In previous drug donations practices, some pharmaceutical companies might have their own guidelines for drug donations. Those who had their own guidelines were hesitant to use the WHO Guidelines for Drug Donations (Asher, 2000). They also claimed that their guidelines were internal documents and not subject to external distribution, which makes it difficult for other researchers to study whether the documents were in accordance with WHO Guidelines for Drug Donations.

In every circumstance, donors should refer to each point of the WHO Guidelines for Drug Donations when they want to provide assistance by sending medicines to the recipients. The WHO guidelines should be adhered by donors to ensure the quality of drug donations because using guidelines other than WHO Guidelines for Drug Donations might conflict with the purpose of the WHO guideline. Unlike regulations, there is no penalty for infringement or violations of the guidelines. It means that the WHO Guidelines for Drug Donations has no ability to enforce the donors and recipients to follow each of its provisions.

<b>Guidelines for Drug Donations</b>	
<b>Selection of drugs</b>	
1.	All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.
2.	All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.
3.	The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.
<b>Quality assurance and shelf life</b>	
4.	All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.
5.	No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.
6.	After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year. An exception may be made for direct donations to specific health facilities, provided that: the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf-life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases it is important that the date of arrival and the expiry dates of the drugs be communicated to the recipient well in advance.
<b>Presentation, packing and labelling</b>	
7.	All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.
8.	As much as possible, donated drugs should be presented in larger quantity units and hospital packs.
9.	All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.
<b>Information and management</b>	
10.	Recipients should be informed of all drug donations that are being considered, prepared or actually under way.
11.	In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.
12.	Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

Source : WHO Department of Essential Drugs and Other Medicines, 1999

### **Box 1. WHO Guidelines for Drug Donations**

## 3.2. Content Analysis

### 3.2.1. Selection of Drugs

Overall, the meaning and purpose of each provision in 'Selection of drugs' section are clear and difficult to be misinterpreted. Every provision in this section is intended to ensure that all donations should benefit the recipient. It explicitly stated that every donation should be relevant to the recipient's needs and any form of medicines should be similar to the medicines that commonly used in the recipient country. Implicitly, it also gives 'authority' to the recipient to decline unwanted donations and intends to anticipate donations that are unknown or unfamiliar in the recipient country.

The 2nd provision of the guidelines recommends that donated medicines be limited to the medicines in the national essential medicines lists or WHO Model List of Essential Medicines (WHO-EML). This is specifically intended to ensure the cost-effectiveness, safety and efficacy of medicines in drug donations practice. On the other hand, this can be a disadvantage for those people or patients with unusual medical problems (Reich et al., 1999), since the NEML or WHO-EML does not include orphan medicines (medicine developed specifically to treat a rare medical condition). However, this can be disregarded in disasters considering it is uncommon to find rare disease in emergency situations. Certain medicines were donated by pharmaceutical companies seeking market authorisation for the same medicine moments after the disaster occurred (Benaragama, 2007).

On the other hand, to apply the 3rd provision of the guidelines is not easy. While it is mentioned 'as much as possible', in some countries the strength and formulation of certain medicines were unique in comparison to the rest of the world. For example, in Mexico and Brazil there is a branded medicine which consists of paracetamol 750mg (Janssen-Cilag, No date; International Vitamins, 2010), while in Sri Lanka, Indonesia and most other countries in the world, they only use paracetamol 500mg tablet (MoH RI, 2008; MoH SL, 2009; WHO, 2011). Another example is in Indonesia no medicine may contain phenylpropanolamine (PPA) more than 15mg (NADFC, 2001), while in Norway and Sweden the dosage form of PPA is 25mg (MEDA, No date; FASS, 2011).

### 3.2.2. Quality Assurance and Shelf Life

In general, the meaning and purpose of each provision in the 'Quality assurance and shelf life' section are clear and difficult to be misinterpreted.

Provisions in this section aimed to encourage donors to respect the needs and authority of the recipient, and also to prevent double standards in the quality of donated medicines. It explicitly stated that every donated medicine should be from a reliable source, meet the quality standard in both countries and have a minimum shelf life of one year after arrival in the recipient country. It also mentioned the need for supporting regulation that should be referred to. Implicitly, the provision intends to prevent the practice of 'drug dumping' that occurs when donors donate expired medicines or almost expired medicines to recipient countries instead of disposing those medicines.

### 3.2.3. Presentation, Packing and Labelling

Overall, the meaning and purpose of each provision in 'Presentation, packing and labelling' section are clear and some of them are difficult to be misinterpreted, except for the 8th provision. The provisions in this section emphasise that all donated medicines should be delivered in large quantity units and labelled in a language that easily understood in the recipient country. It also mentioned that detailed packing list should be accompanied by each donation and different type of medicines should not be put in the same carton. Each provision is applicable and feasible. However, in the 8th provision, the guideline should state the exact number of minimum quantity, because the term 'larger' can be relative and misinterpreted by some donors. Apart from facilitating the management of donated medicines, it can also prevent the donation of free sample medicines and donations from individual donors. In author's experience, most donated medicines from individual donors came in small quantities and are unsorted.

### 3.2.4. Information and Management

Overall, the meaning and purpose of each provision in 'Information and management' section are clear and difficult to be misinterpreted. The provisions in this section point out the importance of effective communication between donors and recipient in drug donations practices, but it does not explain how the lines of communication should be established. Furthermore, it mentioned that the

value of donated medicines should be based on its price in the recipient country. It also stated in detail that all costs of drug donations, from shipment to storing, should be borne by the donors. One area that needs urgent clarification is that of the disposal of unwanted medicines and the costs associated with it. The clause should include guidance on how these costs will be met and by whom.

Although the 11th provision is appropriate to be applied in emergency situations, this provision is not really important for recipient countries since most of the donations in emergency situations were exempt from import tax. By using the price in donor countries or increasing the declared value, donors stand to benefit because they will get tax deductions through their participation in a charitable activity (Crooks, 1998; Pinheiro, 2008). They also often exploit the gaps in this provision, by donating expired or almost expired drugs, which is cheaper than to dispose of those medicines themselves. Donors sometimes take advantage of the practice of drug donations by inflating the declared value of donated medicines for publicity (Crooks, 1998). While the last provision is appropriate to be applied in emergency situations, it often abused by donors, which happened in Sri Lanka and Indonesia (Benaragama, 2007). Recipient usually 'forced' to spend effort and funds on clearance, local transport and storing of the donated medicines (WHO, 1999; Benaragama, 2007).

### 3.3. Context Analysis

#### 3.3.1. Selection of Drugs

The Indonesian Government has a national list of essential medicines since 1978, which is updated every 3 – 4 years (MoH RI, 2008; WHO, 2011). The national list is also available in English and published on the WHO website. But, the list that is published in the Indonesian Ministry of Health's website was only available in Bahasa Indonesia, the official language in Indonesia.

In Sri Lanka, they had a written/unwritten National Medicinal Drug Policy (NMDP) since the 1960s, the Ceylon Hospitals Formulary in early 1960s and the Cosmetics Devices and Drugs Act in 1980. The drug policy was 'written' as elements of a policy. However, there was no comprehensive document (WHO SEARO, 2007). Several attempts to develop NMDP in 1991 and 1996 did not get approval from the cabinet, although they were accepted by Sri Lankan Ministry of Health. By the time tsunami hit Sri Lanka in December 2004, although they still had NMDP, the country had an essential medicines list that was prepared by the Ministry of Health and was first compiled in 1985. The latest essential medicines list issued in 1999 contained 231 drug substances but were considered inappropriate for use at that time (Benaragama, 2007; Fernandopulle, 2011). They also had a Hospital Formulary List (HFL) that was published in 2004 (Benaragama, 2007). The presence of a national essential medicines list or expressed list of medicines during emergency situations may facilitate donors to learn about which medicines that were needed by the recipient. But it does not guarantee that the donors will comply or that the drug donations practice will work according to the guidelines, as in the two cases of Sri Lanka and Indonesia.

Donating medicines that are similar to the medicines commonly used in the recipient country is important since most of the health staff in recipient countries have been trained to use particular substances, formulations and dosage for certain illness. It will be very difficult for them if they are required to adjust to a new type of medicine or treatment (WHO, 1999).

#### 3.3.2. Quality Assurance and Shelf Life

In Sri Lanka, every drug substance has to be registered with the Cosmetic Devices and Drugs Authority (CDDA). During the 2004 tsunami, it was found that nearly one-third of the donated medicine substances received by the Medical Supply Division (MSD) were not registered in CDDA and among those drugs, one drug substance (dipyrrone) found banned by the CDDA (Benaragama, 2007).

Indonesia's National Agency of Drug and Food Control (NADFC) has a similar function to Sri Lanka's CDDA. They register drug substances that are approved to be traded in Indonesia and they publish it on their website (NADFC, 2011). But, there is no information available on the comprehensive list of donated medicines received by the Indonesian Ministry of Health for Aceh during the tsunami.

The existence of an official government agency that is responsible for regulation, standardization and certification of medicines in the recipient country, will aid the donors in finding information about which medicines or substances that legal to be distributed in the recipient country. In April

1998, the US/NGO Pharmaceutical Product Donation Steering Committee issued a “Statement of Principles on the Provision and Distribution of Donated Medicines and Medical Supplies for Disaster and Humanitarian Relief” (Asher, 2000). The Principles discouraged companies from donating free samples and returned medicines and recommended a minimum of six months shelf life on products when they are received by the NGOs (Reich, 1999). The latter was a difference in rule between the Principles and the WHO Guidelines for Drug Donations regarding the minimum shelf life, which can cause confusion among the donors and used by some pharmaceutical companies as a loophole to clear stagnant stocks of medicines.

### 3.3.3. Presentation, Packing and Labelling

Often donors forget about the core principles for drug donations, overreacted by media reports which seek urgent assistance and send whatever they had as quickly as possible (PAHO, 2009). Donors should not be hasty in preparing and sending the donated medicines in small quantities or mixed with other medicines in one box.

The presence of myths in emergency situations, such as “donating any drugs are better than none at all”, “any assistance received is useful whatever it is” and “it is better to have more than needed than less”, can hinder the realisation of some provisions’ purposes (Hechmann, 2007; PAHO, 2009). In reality, not all donations received were useful and unwanted donations can cause chaos (PAHO, 2009).

### 3.3.4. Information and Management

In some developed countries, such as United States of America (USA) and United Kingdom (UK), there is an act that grants a tax deduction for pharmaceutical companies or NGOs who participated in charitable activities including drug donations (Crooks, 1998, Bero, 2010). The presence of these acts may encourage donors to donate but on the other hand, it can also be a very convenient and cheap way for ‘clearing’ the stagnant stocks of medicine (Berckmans, 1997; Pinheiro, 2008). Some pharmaceutical companies also try to ‘take advantage’ to get tax exemption or tax deduction from their government (Crooks, 1998).

## 3.4. Process and Actors Analysis

### 3.4.1. Selection of Drugs

Although Aceh province in Indonesia was damaged heavily by the 2004 tsunami, Indonesian Ministry of Health never requested donors for medicines and declared that what they needed were blankets, food and shelter (Khaleej Times Online, 2006). However, donors still sent medicines to Aceh and there was an explicit example of unheeding this provision. An Australian medical specialist found a box of breast implants and expired medicines among the donations (ABC News, 2005).

In the case of 2004 tsunami drug donations in Sri Lanka, the Ministry of Health through the Medical Supply Division (MSD) published a comprehensive expressed list of medicines within three days of the disaster striking and it was updated weekly except for the quantities which were updated daily (Benaragama, 2007; Hechmann, 2007). The expressed list of medicines included the generic name of the medicine that they needed, the quantity and the dosage form, through the government’s official websites and mass media (Benaragama, 2007). The expressed list was also sent to the local WHO office, so they could provide information regarding the need for medicines (Fernandopulle, 2011). The MSD also sent the expressed list of medicines to Non-Governmental Organisations (NGOs) and individual donors on a request basis (Benaragama, 2007; Hechmann, 2007).

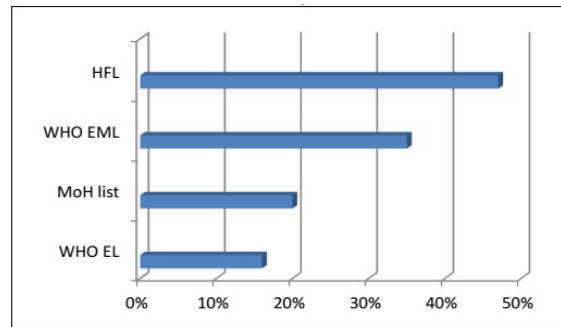
It is clear that the recipient already followed the WHO Guidelines for Drug Donations. But the process of implementation did not work as expected. According to a personal communication received (Fernandopulle, 2011), the expressed list of medicines was updated from time to time but there is no real time-based software to update it. However, the staffs at the MSD were fairly aware of the medicines situation to give a response when needed as this is a daily task for them.

The list might be updated daily, but within one day, many donors have looked at the list and sent the donated medicines according to the substance and quantity as a request in the list. This can cause the occurrence of multiple donations on the same medicine and the result is that one type of



medicine comes in a larger amount than requested. On the other hand, some medicines that were needed did not even reach the requested quantity.

Several donors might not have access to the expressed list of medicines prepared by the Sri Lankan Ministry of Health although it was published in some government's official websites (Benaragama, 2007). The findings showed that most of the donated medicines were not in the Ministry of Health's expressed list, WHO Model List of Essential Drugs or the Hospital Formulary List (Benaragama, 2007).



Source: Benaragama, 2007

**Fig. 2.** Percentage of medicines included in the Sri Lankan Ministry of Health's expressed list, WHO Model List of Essential Drugs and Hospital Formulary List.

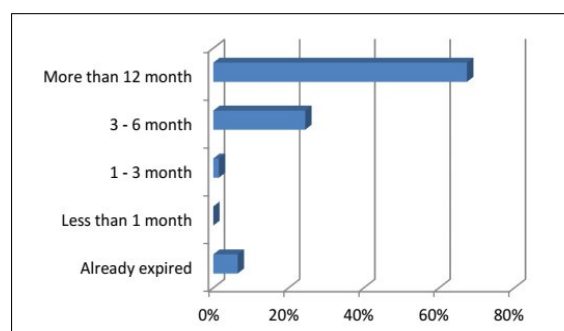
There was an interesting case in Sri Lanka about the donation of 2,500 doses of influenza vaccine, which was not registered for use in the country, but got a clearance by the Sri Lankan Customs without proper documentation (Benaragama, 2007). Based on Sri Lankan experience, this provision was not adequately followed. Some medicines had never been used and its formulation was considered unfamiliar by the health staff in Sri Lanka. This condition created confusion among the health staff in providing treatments.

Another example from Aceh, Indonesia was the case of Pantozol injection, a drug for used to treat gastritis, which becomes a waste due to local health staffs having never seen it before. To treat gastritis in Indonesia, most doctors usually use tablets (Khaleej Times Online, 2006).

### 3.4.2. Quality Assurance and Shelf Life

About 2% of the donated medicines received by the Sri Lanka MSD were labelled as free professional samples and most of the unsorted medicines were identified as medicines issued to patients or returned to pharmacies (Benaragama, 2007). However, there was no detailed information available about the free samples

and unsorted medicines in drug donations received by Aceh. In Sri Lanka, the number of medicines that were found expired or due to expire within a few days of arrival was around 0.5 tons or about 6.5% of the total donated medicines (Benaragama, 2007). On the other hand, 67% of the medicines met the shelf life requirement of the WHO Guidelines for Drug Donations which had one year or more remaining to expiry from the time of arrival.



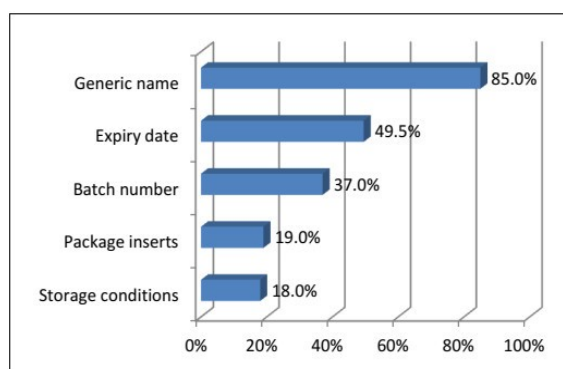
Source: Benaragama, 2007

**Fig. 3.** Status of donated medicines to their expiration dates on arrival in Sri Lanka.

While in Indonesia, around 25% of the donated medicines - equal to 1,000 tons - had inadequate expiry dates, such as already expired on arrival, expire within 6 months from the date of donation and no expiry date (PSF-CI, 2005). Learning from the two examples, some donors might not understand the concept of the Guidelines for Drug Donations, which are to maximise the positive impact of the donation. This excludes the donation of unnecessary or dangerous medicines, and medicines which are not specified for use in the recipient country (WHO, 1999; APAC, 2001).

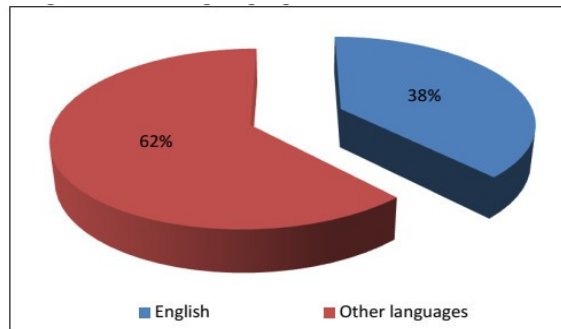
### 3.4.3. Presentation, Packing and Labelling

Improper labelling such as inadequate information was creating confusion among the health staff in Sri Lanka. Many drugs were found without package inserts, inadequate information regarding the substance and use of the medicine, and were labelled in a language which not spoken in recipient country, such as Arabic, Chinese, Danish, French, German, Korean, Spanish, Irish, Turkish and some unknown languages (Benaragama, 2007; Hechmann, 2007; Bero, 2010).



Source: Benaragama, 2007

**Fig. 4.** Donated medicines which accompanied by their storage conditions, package inserts, batch number, expiry date or generic name.



Source: Benaragama, 2007

**Fig. 5.** Labelling language of the donated medicines.

Contrary to the seventh provision of WHO Guidelines for Drug Donations, 70% of donated medicines that received in Aceh, Indonesia were labelled in a language other than English or Indonesian language. Mostly they were labelled in Arabic, Chinese, Hindi, Japanese, Korean, Polish, Russian and Spanish (PSF-CI, 2005; Khaleej Times Online, 2006). In Sri Lanka, the MSD found that around 50% of the medicines were in patient packs, small quantities or less than 50 units per package, and often found unsorted and mixed with another kind of medicines in the same box (Benaragama, 2007). There was no detailed information available about quantity and the kind of packaging of inappropriate drug donations for Aceh, Indonesia.

### 3.4.4. Information and Management

In the initial stages of the emergency situation, the donations were received and distributed by several organisations. To minimise the confusion and turmoil in communication and coordination, the Sri Lankan Government decided to take over the process of receiving and distribution of donated medicines through the MSD (Benaragama, 2007; Hechmann, 2007). Due to major destruction in

Aceh, the Indonesian Ministry of Health requested for assistance from WHO and Pharmaciens Sans Frontières Comité International (PSF-CI) to assess the pharmaceutical situation in the affected region (BRR, 2005). In the 2002 Bali bombings, most of the donors did not contact the recipient before they sent the donated medicines. There were 182 donors who donated medicines and medical supplies but only 32 donors (17.5%) who made a contact via telephone to the recipient before sending their donations (Maryetty, 2007).

The MSD learned that a donor claimed that the value of their donated medicines with the selling price in the donor's country which was more expensive than in Sri Lanka. The claimed value was approximately USD 26 million, while based on the Sri Lankan Government procurement price, the value was only USD 373,291.90 (Benaragama, 2007). It means that the donor paid 87 times more than the local purchasing cost. However, there was no detailed information about the total value of the donated medicines in Aceh, Indonesia. In Sri Lanka tsunami drug donations practice, contrary to the WHO guideline, the recipient was burdened by the cost of local handling, transport and storage (Benaragama, 2007). It was difficult to calculate accurately the cost that was burdened to the Government of Sri Lanka for local handling, transporting and storing the donations. For disposing of the 150 tons of unusable medicines, the Sri Lanka Ministry of Health had to spend approximately USD 26,039 (Benaragama, 2007; Bero, 2010). A similar case also happened in Aceh, Indonesia. The Indonesian Ministry of Health was burdened by the cost of disposing the inappropriate donated medicines, such as those with no expiry date and already expired medicines, which reached 00 tons. The average cost of disposal was about EUR 2,400,000 or equal to USD 3,420,000 (PSF-CI, 2005; Bero, 2010).

#### 4. Discussion

The WHO has been working steadily to develop guidelines for drug donations even though they have no power or mandate to enforce the implementation of those guidelines at the country level. This leads to the inadequate adherence to the WHO Guidelines for Drug Donations' provisions in most of the drug donations practices. In general, the content of WHO Guidelines for Drug Donations is clear. However, during emergency situations, such as the 2004 tsunami, there were several provisions which were difficult to implement or could be misinterpreted either by donors or recipients.

##### 4.1. Selection, Quality and Presentation of Drugs

The WHO Guidelines for Drug Donations emphasise that donated medicines should be similar to the medicines commonly used in the recipient country. As explained in Chapter Three, these some provisions in the guidelines are difficult to apply in the field. However, during the 2001 Gujarat earthquake in India, most of the donated medicines were reported as compliant with the WHO Guidelines for Drug Donations in terms of drug selection, quality assurance and shelf life, presentation, packaging and labelling, and information and management (Autier, 2002; Bero, 2010). More than 95% of the donated medicines, equal to 1,308 tons, were appropriate and had the remaining shelf life at least one year from the time of arrival in India.

This could be attributed that to the fact that most of the donors, including overseas donors that consist of 30 – 40% of total donors, purchased the medicines in India (Autier, 2002). The donors distributed the donated medicines to areas that affected by the earthquake. Since the medicines were purchased from Indian pharmaceutical companies, where companies must follow the quality standards of the country, most of the medicines were appropriate. It was also supported by the existence of good disaster management system including an essential medicines list, organisation scheme for managing drug donations and availability of local buffer supply of essential medicines for immediate aid (Bero, 2010). During the 1999 East Timor war, it was reported that only less than 10% of the donated medicines were inappropriate during the emergency situation (Autier, 2002). The NGOs that were active in East Timor seemed aware of the needs and mostly they imported New Emergency Health Kit (NEHK) which was the first supplies that arrived in East Timor. The NEHK is assembled by WHO in 1998 which includes medicines, disposables and instruments, sufficient to support 10,000 people during a three months period (WHO EMRO, 2011). It consists of a Basic unit and a Supplementary unit. NEHK were specially designed for the early stage of emergency situations.

Although the NEHK and cash donation already mentioned in the WHO Guidelines for Drug Donations, but they were not considered to be the main issues, as they were written in the chapter “Other ways donors can help” instead of in the chapter “Guidelines for drug donations” (WHO, 1999). Donations in form of NEHK and cash become more relevant in emergency situations based on the previous drug donations practices. The first provision of the WHO Guidelines for Drug Donations implicitly gives the recipient authority to decline unwanted donations (WHO, 1999). However, this provision is not easily applied in some Asian regions. From the author’s experiences, in Asian cultures including Indonesia, it is considered impolite to refuse any assistance offered. This leads to the hesitation of the recipient to decline any assistance offered, even if they did not need it or felt that the assist was not as expected. In this case, it might be better if the provision stated clearly and explicitly that the recipient can decline any unwanted donations. It is also important to state in the provision that any unwanted medicines or inappropriate donations can be returned to the donor and the cost should be borne by the donor.

#### 4.2. Information and Management

The establishment of information and communication between donors and recipients is essential in order to ensure the drug donations practices progress in accordance with the WHO Guidelines for Drug Donations. The previous drug donations practices indicate that inadequate information and communication plays a big role in inappropriate drug donations practice. The establishment of information and communication between donors and recipient is essential in order to ensure the drug donations practices progress is in accordance with the WHO Guidelines for Drug Donations.

The WHO Guidelines for Drug Donations emphasises the importance of communication between donors and recipient (WHO, 1999). However, the WHO Guidelines for Drug Donations do not give clear guidance on how the communication should be maintained. It only states that there should be communication between donors and recipient before they send any donation. But, it does not give suggested protocols or activities for donors and recipients, on how the communication should be established and maintained. In order to improve effective communication between donors and recipient, it is considered that existence of Information and Communication Centre (ICC) in recipient country is crucial. It should be run by local government and functioning as a coordination centre which controls the quality and flow of information on medicines. Unfortunately, the WHO Guidelines for Drug Donations do not mention the ICC approach.

Every notification from local and international donors about donated medicines that were prepared or underway should go through the ICC. The staffs in ICC have the responsibility to receive, record and update information regarding drug donations from donors. They should also be accountable for providing information that is needed or requested by the donors, such as the needs of medicines including type and quantity.

Some experiences of drug donation practices indicate the importance of the ICC. In the 1999 East Timor war, there was no disaster preparedness plan and system including drug donations, and no government transitory or ad interim (Autier, 2002). All situations, including drug donation administration, were managed by the United Nations Transitional Administration in East Timor (UNTAET). Conversely, in the 2001 Gujarat earthquake, the Indian Ministry of Health was fully functional and had a disaster preparedness system including a policy about drug donations (Autier, 2002). Commissioner’s Office in Gandhinagar was established as a 24 hours control room for management of health sector activities including medical supplies.

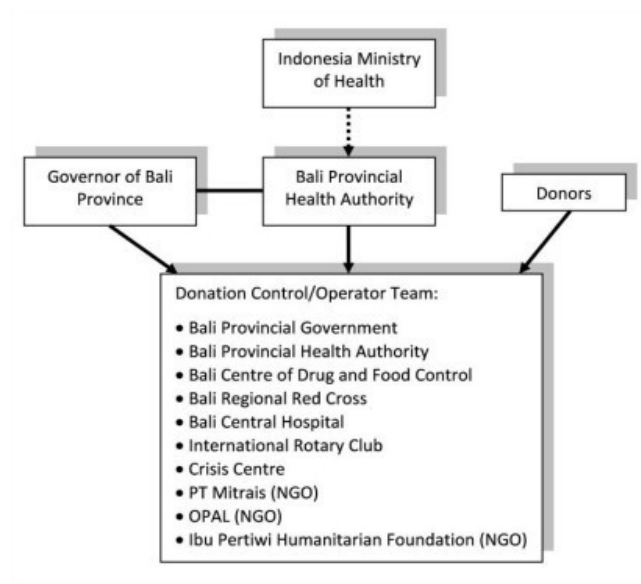
The medicines demand list was published through the mass media (Autier, 2002). In the beginning, the mass media put more emphasis on illustrating the damage and suffering. Later, the mass media were used by the Indian Government as a channel to inform the needs of affected populations to agencies and public. One of the possible ways to facilitate and maintain the communication between donors and recipient is to set up one ICC in the recipient country that responsible for providing any information regarding the needs of the affected population, including the need of medicines. Unfortunately, the WHO Guidelines for Drug Donations did not mention about the ICC which is crucial especially during the early phase of emergency situations.

Donors who wished to donate medicines or other assistance should contact the ICC in advance. The ICC should act as a guide for donors in understanding the needs of the recipient and should not be driven by the donors. The ICC should also have the authority to confirm or decline the donations.

The ICC also needs to work together with the customs in terms of receiving the donated medicines, especially for medicines from abroad. Every donation that arrives in any port of entry in recipient country should be checked by customs. Donations without proper documentation or without consent from the ICC should not be cleared by the customs of the recipient country.

From the experience of drug donations in 2002 Bali bombings, while not exactly in form of ICC, the local government showed an effort towards establishing an ICC. The effort resulted in the establishment of a control/operator team for Bali bombings drug donations (Maryetty, 2007). Bali Provincial Health Authorities (PHA) appointed by the Ministry of Health as its representative in the disaster management. The PHA in collaboration with the provincial government of Bali established a donation control/operator team based on the Bali Governor's Decree (Maryetty, 2007). The team consisted of representatives from Bali provincial government, Bali PHA, Bali Centre of Drug and Food Control, Bali regional Red Cross, Bali Central Hospital staff, International Rotary Club, director of Crisis Centre and three local NGOs.

There were 182 donors who donated medicines and medical supplies but only 32 donors (17.5%) who made verbal communication via telephone to the team before sending their donations (Maryetty, 2007). Maryetty (2007) reported that the number could be less than the actual number because each donor communicated with different team members. This system with multiple team members communicating with donors caused turmoil in the communications system and led to the drug donation process becoming complicated and disorganized. When several members communicate with donors, there should be a proper process with record keeping and handover. The organisational structure of the team as stated in the Bali Governor's Decree is shown below.



Source: Maryetty, 2007

**Fig. 6.** Organizational structure of 2002 Bali bombings drug donations.

About 89% of the donors sent donated medicines directly to the Bali Central Hospital, where the bomb victims were treated. The other 11% of the donors sent their donations to a warehouse lent by PT Mitrais, one of the three local NGOs in the team, and none of the donors sent their donations through government institutions (Maryetty, 2007). It is understandable because donors intended for efficiency in the transportation of donated medicines. This does not need to be a problem if the donation control/operator team acts as an agency and has authority to controls wherever the medicines arrive.

#### 4.3. The Other Guidelines/external Obstacle

It is not unusual for each pharmaceutical company or donor to have their own regulations or guidelines about how they donate medicines in certain situations. But, the existence of guidelines that do not comply with or those that set lower standards than the WHO Guidelines for Drug Donations' provisions can reduce the possibility of achieving the best practice of drug donations.

WHO needs to approach the association of pharmaceutical companies and NGOs, and persuade them to adopt WHO Guidelines for Drug Donations in their guidelines and regulations. There should be only one guideline for drug donations practice that should be used by donors and recipient, which is the WHO Guidelines for Drug Donations. It is also necessary for the WHO to encourage each country, especially those that are prone to disasters, to build their own regulations about drug donations based on the WHO Guidelines for Drug Donations (WHO, 1999; Asher, 2000; Bero, 2010).

#### **4.4. Example of Adapted WHO Guideline in Country Level**

The Australian Government through the Australian Pharmaceutical Advisory Council (APAC) has endorsed Australian Guidelines for Drug Donations to Developing Countries in November 1996 and revised 4 years later in November 2000 (APAC, 2000). It was built based on the WHO Guidelines for Drug Donations with some adjustments. But, the Australian guideline was created only as a guide for donors from Australia to donate the medicines to other countries and not for receiving donations from foreign countries. While the first section of both, the WHO guidelines and the Australian guidelines were similar, the latter has a clearer statement.

The provision clearly excludes the possibility of donor-driven donations. It also encourages the recipients to specify what they need and empower them to reject unwanted donated medicines. The Australian guidelines also emphasise the importance of communication and coordination between donors and recipients

There is an additional section about Federal Permits in the Australian guideline. It is stated that every Australian donor must have a written permission from the Commonwealth Department of Health and Family Services in order to export or donate certain medicines, such as psychotropic substances. It is a supporting act for good drug donations practice which can be followed by other countries in developing their own drug donations guidelines or regulations. It is understandable that guidelines have no power to enforce donors and recipient to comply with it. The Australian example shows that the guidelines can be strengthened at the country level.

### **5. Recommendation and Conclusion**

The WHO should consider augmenting of some provisions of the WHO Guidelines for Drug Donations.

- NEHK should be mentioned in the provision and stated that in emergency situations, NEHK is preferable for donations.
- Cash donations should also be mentioned as another preferable donation in the provision of the WHO Guidelines for Drug Donations or in the provision's explanation.

The WHO should encourage countries to build their own regulations or guidelines for drug donations and give technical assistance in formulating the country's guidelines or regulations.

#### **5.1. Recommendations for Donor**

The donors should seek out and consult local level or national level regulations or guidelines for drug donations in recipient countries before making donations. If such regulations do not exist in the recipient country, donors should refer to WHO Guidelines for Drug Donations in order to make donations.

#### **5.2. Recommendations for Recipient**

The recipient country should have a centre that able to communicate about the need of medicines. This centre can be operated by the government of recipient country.

#### **5.3. Recommendations for Those Who Interested in Drug Donations Topic**

Experts and those interested in drug donations need to conduct specific research on the obstacles faced in drug donation practices, especially from the perspective of donors. We need to know what hinders donors in complying with the WHO Guidelines for Drug Donations.

Effective communication between donors and recipient is very important especially in early phase emergency situations. Thus, establishing an Information and Communication Centre (ICC) in

the recipient country is crucial for maintaining effective communication. The WHO should list the necessity of ICC in the WHO Guidelines for Drug Donations. It is important that all guidelines or regulations on drug donation practices should be built based on the WHO Guidelines for Drug Donations. The Australian Guidelines for Drug Donations to Developing Countries shows that the guidelines can be strengthened at country level and adjusted to follow regulations in the countries, as long as it does not conflict with the WHO Guidelines for Drug Donations.

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