



THE EXPECTATIONS, THE REALITY AND THE BURDEN OF DRUG DONATION



Ministry of Healthcare &
Nutrition



Faculty of Medicine
University of Colombo

THE EXPECTATIONS, THE REALITY AND THE BURDEN OF DRUG DONATIONS

Evidence for action

RESEARCH TEAM

PRINCIPAL INVESTIGATORS:

Dr BVSH Benaragama MBBS. MSc. Director, Medical Supplies Division,
Ministry of Health, Sri Lanka

Prof Rohini Fernandopulle MBBS. PhD. Professor, Dept of Pharmacology
Faculty of Medicine, University of Colombo

COMMITTEE:

Faculty of Medicine, University of Colombo
Dr Priyadarshini Gallappatthy MBBS, MD, MRCP, Dip Med Tox
Dr Nilesh Fernandopulle MBBS

Medical Supplies Division, Ministry of Health
Mr VLSS Liyanage
Mr KGSK Jayasekera
Mr MWR Shayaminda
Mr PHCS Perera

MANUSCRIPT BY:

Professor Rohini Fernandopulle

EDITED BY:

Dr BVSH Benaragama
Prof Rohini Fernandopulle
Dr Priyadarshini Gallappatthy
Beverley Snell

COVER DESIGN BY:

DD Lasika Malkanthi

ISBN:

ISBN- 955-9021-52-4

Printed by

**Thisara Printers
45, Maligakanda Road,
Colombo 10.**

ACKNOWLEDGEMENTS

It is a pleasure to thank our colleagues in the Department of Pharmacology, Faculty of Medicine, Colombo and Dr UA Mendis, Deputy Director General (Laboratory Services) of the Ministry of Health for the interest expressed and all the assistance given to us to carry out this study.

The authors acknowledge and thank in particular the following individuals who contributed to the development of the databases and analysis of the data.

BV Priyantha, PHCS Perera, S Rajkumar, N Shasikumar, ASM Izam, LCPT Liyanaarachchi, SMRS Semasinghe, Anusha Dulanthi, NK Karunaweera, BPT Warnasooriya of the Medical Supplies Division, Ministry of Health; Chula Edirisinge, Leslie Warakagoda, Parakrama Dharmadasa, Hemasiri Goonathilake and Arjuna Pathmaperuma of the Cosmetics Drugs and Devices Authority, Ministry of Health; and Uthpali Manamperuma and MUM Nisha of the Department of Pharmacology, Faculty of Medicine, Colombo.

The authors acknowledge the helpful comments and clarifications received from Dr Krisantha Weerasuriya, the former Professor and Head of the Department of Pharmacology, Faculty of Medicine, Colombo.

A very special thanks to Beverley Snell Senior Fellow, Essential Medicines and Community Health, Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne, Australia for editing the final version of the text.

Appreciation and thanks are extended to the Country Representative of the World Health Organisation for providing the necessary funds for data collection and publication of this document.

TABLE OF CONTENTS

Abbreviations and acronyms

List of Tables

List of Figures

List of Photographs

Executive Summary

CHAPTER 1: INTRODUCTION

1.1 Background

- 1.1.1 Sri Lanka
- 1.1.2. Literature review on pharmaceutical donations
- 1.1.3. Development of guidelines on drug donations
- 1.1.4 Emergency health kit

1.2 Objectives

1.3 Methodology

CHAPTER 2: RESULTS AND DISCUSSIONS

- 2.1 General information
- 2.2 Compliance with the WHO donation guidelines
- 2.3 Storage of donated drugs and storage capacity
- 2.4 Waste management
- 2.5 Costs
- 2.6 Safety issues
- 2.7 Problems faced by hospital pharmacists / stores managers
- 2.8 Perceptions of the end users (people affected by the tsunami)
- 2.9 Publicity seeking behavior of donors
- 2.10 Comparison with donations received by other tsunami affected countries.

CHAPTER 3: CONCLUSIONS AND RECOMMENDATIONS

- 3.1 Highlights of our study
- 3.2 Gaps identified in the donation process
- 3.3 Recommendations
 - 3.3.1 International Level
 - 3.3.2 The Local Level
 - 3.3.3 The Advocacy and Information Level
- 3.4 Conclusion

REFERENCES

LIST OF TABLES

- 1.1: Health status indicators of Sri Lanka as compared with selected developing and developed countries in the Asia – Pacific region
- 1.2: Comparison of country data on notifiable infective diseases pre and post tsunami
- 1.3: Problems associated with donated drugs as identified by the WHO
- 1.4: Summary of the WHO guideline on ‘Good Donation Practices’
- 2.1: Quantification of the pharmaceutical donations
- 2.2: List of drug substances amongst the expired medicines.

LIST OF FIGURES

- 1.1 Map of Sri Lanka depicting the areas affected by the tsunami with the corresponding number of reported deaths
- 1.2 The population structure of Sri Lanka as at 2001
- 2.1: Quantification of the different dosage forms of the medicines as a percentage of the total
- 2.2 Quantification of the ‘UDPs’ under the different ATC categories as a percentage of the total
- 2.3 Percentage of the ‘UDPs’ (n = 1646) included in the WHO - EML, MOH expressed list of needed medicines, HFL, and the WHO list of emergency medicines.
- 2.4 The percentage of donated pharmaceutical products / drug substances that were registered for use in Sri Lanka as at December 2004 and for which information was available in the March 2005 BNF
- 2.5 The remaining shelf life of the donated medicines at the time of arrival expressed as a Non-percentage of the total
- 2.6 Description of the different labeling languages of the medicines expressed as a percentage of the total
- 2.7 Information on the percentage of medicines that had the Product Information Leaflet, International Non-proprietary Name (generic name), batch number, expiry date, storage conditions, and were professional samples

LIST OF ANNEXES

- | | |
|----------|--|
| Annex 1 | Expressed list of medicines by the MOH compared with donations received. |
| Annex 2 | Explanation of ATC Classification |
| Annex 3. | List of ‘Drug Substances’ amongst the donations and their registration status with the CDDA of Sri Lanka |
| Annex 4 | Letter issued by The Director General of Health Services |
| Annex 5 | Adverse event that was reported in one of the Sri Lanka newspapers |
| Annex 6 | Questionnaire used in the field survey of pharmacists |

LIST OF PHOTOGRAPHS

- 2.1, 2.2, 2.3.2.4 Illustration of the problems caused by the donations with reference to storage
- 2.5 A replica of an almost life sized cheque with the price of donated medicines handed over to the MSD by a donor.

ABBREVIATIONS AND ACRONYMS

ATC	Anatomical – Therapeutic – Chemical classification
BH	Base Hospital
BNF	British National Formulary
CDDA	Cosmetic Devices and Drugs Authority
CMC	Christian Medical Commission
DH	District Hospital
DPI	Dry Powder Inhaler
EURO	European Union Currency
GDP	Gross Domestic Product
GH	General Hospital
HFL	Hospital Formulary List of medicines
INN	International Non-proprietary Name
MDI	Metered Dose Inhaler
MOH	Ministry of Health
MSD	Medical Supplies Division
MSF	Medecins sans Frontieres
NGOs	Non Governmental Organizations
PIL	Product Information Leaflet
SLR	Sri Lanka currency in Rupees
TH	Teaching Hospital
UDP	Unique drug product
USA	United States of America
USD	USA currency in dollars
WHO	World Health Organisation
WHO - EML	WHO Model Essential Medicines List

EXECUTIVE SUMMARY

BACKGROUND

On December 26th 2004 an earth-quake that measured 8.9 on the Richter Scale off the West Coast on Northern Sumatra led to a heavy death toll and destruction of property. The earth-quake also led to a tsunami that hit extensive areas along the coast-line of Sri Lanka. The wide publicity it received touched the hearts of the international community, led to empathy, and a desire to do something positive, which resulted in a massive outpouring of pharmaceuticals into the country.

Medicines are a critical element in health operations in an emergency situation and the expectations of the Ministry of Health was to receive pharmaceutical donations relevant to the emergency situation and to bridge the shortages of essential medicines prevailing at that moment of time. However, numerous examples over the last 20 years have demonstrated that most donations of medical supplies in emergency situations have not been based on precise assessment of actual medical needs and have done more harm than good. In this context, information on the pharmaceutical donations was important.

The objective of this study was to describe the profile of the donated medicines, and to determine appropriateness and the extent of compliance with the WHO guideline. The survey was carried out from March 2005 to July 2005 and included mainly donations received and handled by the Medical Supplies Division, Ministry of Health. The data was collected using a set of investigator administered questionnaires from the Medical Supplies Division, and from the administrators, pharmacists, stores managers in hospitals and refugees in camps from the tsunami affected areas. A product that had the same drug substance, in the same dosage form and in the same strength irrespective of their brand name and package size was classified as a 'Unique drug product' (UDP). To determine compliance with the World Health Organisation (WHO) Good Donation Practices guideline, the 2003 version of the WHO Essential Medicines List, the Ministry of Health expressed list of needed drugs and the Sri Lanka Hospital Formulary List of Medicines were used. Useless drugs included medicines irrelevant to the epidemiological context or unregistered drug substances. Unusable drugs comprised medicines already expired on arrival or expired within a month of arrival, and unidentifiable drugs (labelled in unknown foreign languages / no labels). Appropriateness was also checked by comparing items with the WHO list of essential medicines in emergency situations.

RESULTS

The majority of the UDPs ($\approx 80\%$) were unsolicited, and arrived unannounced and in unsorted boxes. Around 50% of the donations were inappropriate collections of unused drugs from private individuals collected at various centres and transported via international relief organizations. These donations were a mixture of many different products mixed with other relief items.

Fifty three percent of UDPs belonged to the 'non list' category (not listed in the MOH list, WHO – ML, HFL, WHO Emergency Medicines List) and 38% of the drug substances were never registered for use in the country. Hence, could be considered totally irrelevant useless and sometimes dangerous. Twenty eight metric tons (50.5% of the total donations) did not have expiry dates. Within those with the expiry date 6.5% had expired on arrival and only 67% complied with WHO guideline requirement that after arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year. A large proportion of non essential drugs were irrelevant to the emergency situation. Sixty two percent of the pharmaceutical products were labelled in languages not understood locally, 81% were without package inserts and 15% were without generic names. Stockpiling of unnecessary or expired drugs cluttered up storage depots, resulting in shortages of space for proper storage of essential medicines.

On the other hand, medicines purchased by local residents and organisations after consulting the Director MSD, and over 90% of the donations that were sent directly by Governments were on the MOH expressed list, had the required shelf life of over 1 year and were 100% utilized.

The monetary value of one donation as claimed by the donors was equivalent to approximately 50% of the public health drug budget. However all the tsunami donations reduced the total drug budget for the year 2005 by only 4%. The cost of destruction of some of the unwanted medicines was approximately SLR 2.5 million (1USD = SLR 102). Many agencies / individuals sought undue fanfare and publicity when handing over donations.

CONCLUSIONS

The great expectations of the Government of Sri Lanka were that the country would benefit both financially and materially from the donations. However the results of our study show the donations were more a burden than of benefit to the country. The study also highlights that although ‘Guidelines on Good Donation Practices’ (Christian Medical Commission, WHO and some country specific guidelines) have been in place and regularly updated on the available evidence since 1988 they have had very little impact on the quality of pharmaceutical donations in times of an acute emergency. This study has identified gaps in the process and proposed recommendations to reduce the negative and unintended consequences of drug donations in the future.

RECOMMENDATIONS

Recommendations for improving the quality and efficiency of drug medicine donations in emergency situations are detailed at three levels:

- International level: Implementation of international guidelines and regulations on Good Donation practices and international monitoring of drug donations by WHO, NGOs and donor countries
- Local level: MOH to include a national policy on pharmaceutical donations in the national drug policy and have operational guidelines on handling such donations
- Advocacy and Information level: dissemination of the study results, and organization of awareness raising and campaigning activities for good donation practices

It is strongly recommended that dumping of mixed unused medicines, expired drugs and radioactive products be strictly prohibited. It is further recommended that all donor countries consider adapting the legal framework of the European Union, which prohibits the collection and export of drugs that have been issued to patients and returned to pharmacies.

1. INTRODUCTION

December 26th 2004 remains etched in the minds and hearts of the global population as the day when an earth-quake that measured 8.9 on the Richter Scale off the West Coast on Northern Sumatra generated a tsunami that led to widespread catastrophe in Sri Lanka, India, Maldives, Indonesia and Thailand with damage also in Malaysia, Bangladesh, Somalia and Seychelles. The hardest hit with the largest number of deaths was Indonesia followed by Sri Lanka.

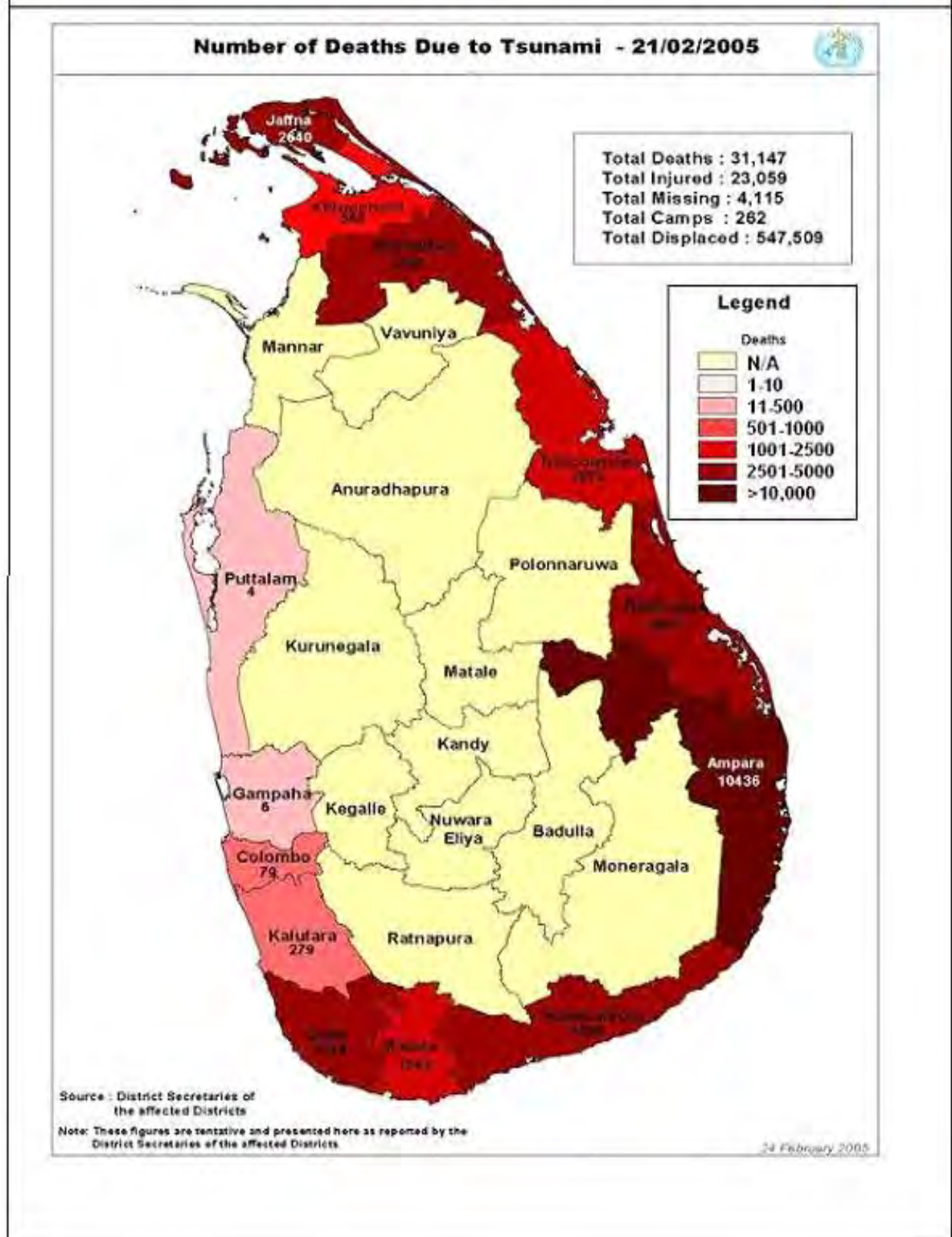
For us in Sri Lanka the disaster was totally unexpected, and the magnitude unimaginable. The data on the impact of the tsunami released in February 2005 indicated that 14 of the 28 districts were affected, 31,147 persons died, 4,115 were missing and 23,059 persons injured and that 547,509 persons were displaced in 262 welfare camps. The human and economic cost of this fateful ocean wave was most directly felt by the people of the north east, south and the southern part of the west living in close proximity to the coastline as seen in Figure 1.1. The Central Bank of Sri Lanka (1) estimates the total damage as USD one billion (4.9% of the GDP) and the cost of reconstruction as USD 1.8 billion (8.9% of the GDP).

Following the tsunami, the donor response to the government's request for immediate relief was overwhelmingly positive. Many bilateral donors and international agencies including Non Governmental Organizations (NGOs) provided immediate relief such as food, medicine, clothing, drinking water, temporary shelters as well as assistance in the form of services of medical personnel and rescue teams. As developed countries often perceive lack of medicines in developing countries such as ours to be a genuine problem, donations of medicines poured into the country and the Ministry of Health (MOH) was faced with a massive stock of medical supplies with inadequate human resources, storage space and transportation facilities to deal with it. Staff (assistant directors, pharmacists, store keepers, food and drug inspectors) attached to the Medical Supplies Division (MSD) and Cosmetic Devices and Drugs Authority (CDDA) were working round the clock to clear the donations. Numerous boxes were seen stockpiling in the open air at the MSD and the affected areas to be sorted and stored appropriately when trained human and financial resources were available.

Medicines are a critical element in health operations in emergency situations but numerous examples have demonstrated that donations of medical supplies are generally not based on

precise assessment of actual medical needs and do more harm than good (2 - 8). In this context, information on the pharmaceutical donations to Sri Lanka at the time of a major disaster was important to generate the evidence needed to decide on a pharmaceutical donation policy for the country.

Figure 1.1 Areas affected by the tsunami with the corresponding number of reported deaths



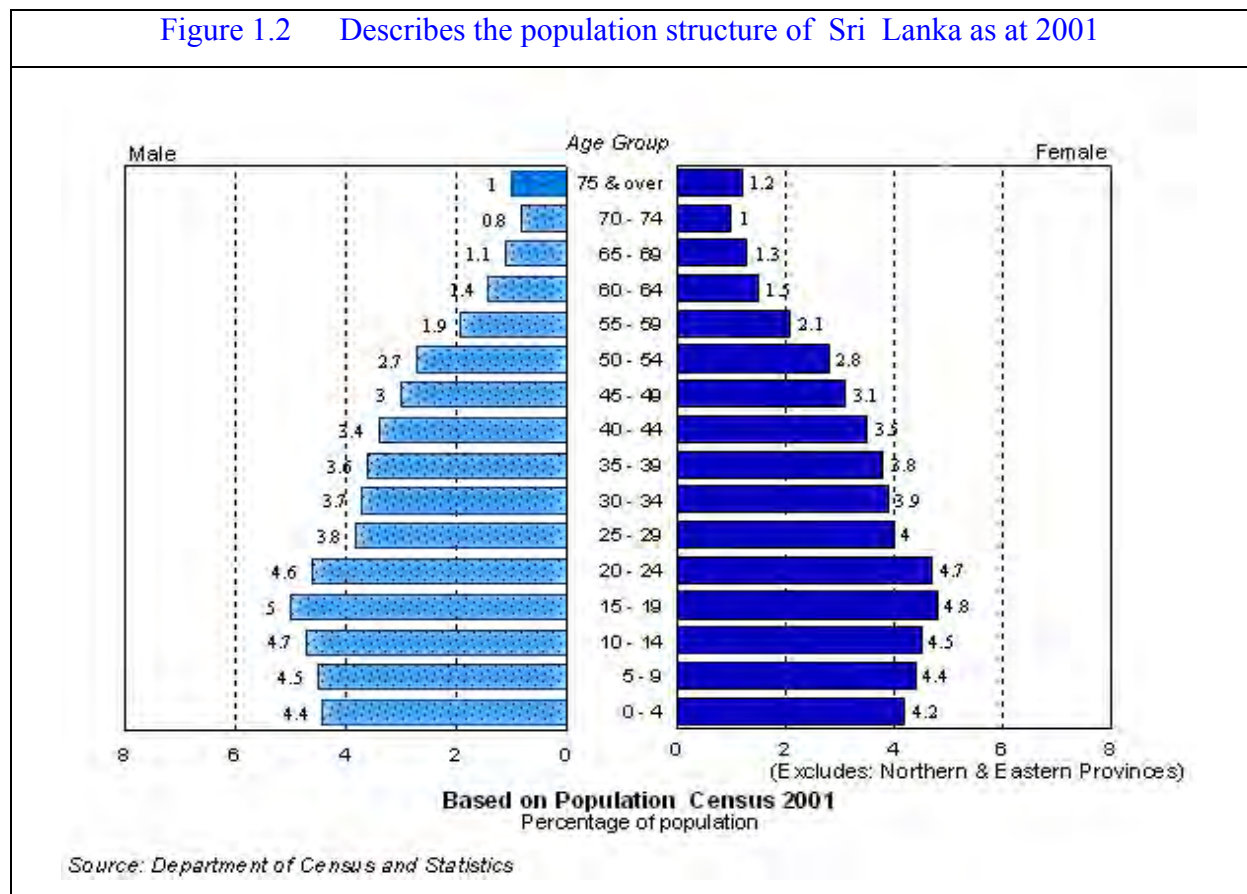
1.1 BACKGROUND INFORMATION

1.1.1 SRI LANKA

Country profile

Sri Lanka formerly 'Ceylon' is an island situated off the southern coast of India between northern latitudes $5^{\circ} 55'$ and $9^{\circ} 50'$ and eastern longitudes $79^{\circ} 42'$ and $81^{\circ} 53'$ and stretches through its greatest length of 432 km (270 miles) from Point Pedro in the north to Dondra Head in the south (1). Its greatest width is 224 km (140 miles) from Colombo in the west to Sankamankande in the east. The island is situated in the centre of the Indian Ocean separated from the southern part of the Indian subcontinent by a narrow strip of shallow water known as the Palk Strait and spans a land area of 65,608 square kilometers (25,000 sq miles). For administrative purposes it is divided into 28 districts. The population of Sri Lanka for the year 2004 was estimated to be 19.462 million with an average annual growth rate of 1.1% (1). A detailed age breakdown from the recent Census of Population and Housing, 2001 is given in Figure 1.2. The overall literacy rate (2003/04) was estimated to be 92.5% (1).

Figure 1.2 Describes the population structure of Sri Lanka as at 2001



The Health Care System

The government of Sri Lanka is committed to the provision of free health services to its citizens. The types of medicine practiced fall into two main types, Allopathic and Ayurvedic. Both are included in the public and private health services. Catering to the allopathic system are 598 government hospitals, 175 private hospitals and 375 government central dispensaries (9). The Ayurvedic Medical Services run 49 hospitals and 260 dispensaries. The average distance from any home in the country to a health care delivery point is 1.5 kilometers (9), while the median distance travelled to a western health facility in the state sector is three kilometers (9).

There are approximately 9,549 fully qualified medical doctors and 1276 registered medical practitioners (with three years of training) practicing allopathic medicine in the public sector. The private sector is serviced by about 800 practitioners of western medicine, mainly concentrated in urban areas but doctors in the public sector are allowed to practice privately after working hours. The total number of government ayurvedic practitioners is around 17,038. The overall doctor - patient ratio is 1: 2,224 (1).

In 2002, 2003, 2004 and 2005 the total government expenditure on health was SLR.19.7, 20.4, 28.5 and 34.4 billion respectively. The government funds the bulk of preventive health and inpatient expenditure. In 2003 and 2004 private consumption at current market prices was estimated to be SLR 47,907 and 57,072 million respectively (1). Out-of-pocket spending by households accounts for the largest share of private spending (43 per cent of national total). Employees and insurance expenditures account for less than 5 per cent of total national spending (1). Most private expenditure is for outpatient primary care services, and purchase of medicines from pharmacies. Each year, the MOH receives foreign aid in the form of money, materials, drugs, medical equipments and technical inputs. In 2002, the foreign aid component of the health expenditure was SLR 208.9 million (9).

In order to help the reader to understand the health status of Sri Lanka, Table 1.1 describes and compares the socio economic indicators which are used as tools of measurement of the health status of a country with those of some developing and developed countries (9 -11). The good health indices in Sri Lanka are often explained by pointing to the nature of the society, its educational levels, and its comprehensive social welfare and health system with free governmental health services including home visits by public health midwives serving pregnant women and nursing mothers (9).

Indicators	Sri Lanka	India	Australia	Singapore	Indonesia
Population '000	18,910	1,049,549	19,544	4,183	203,000
GNP per capita (USD)	810	440	20,640	30,170	640
Total health expenditure % of GDP	3.6	5.1	9.2	3.9	2.4
Literacy rate	92.5	65.38	87.6	94.6	86.3
Birth rate per '000	19.13	26.1	12.6	10.1	22.55
Death rate per ' 000	5.8	8.7	6.7	4.3	7.49
Life expectancy at birth for both sexes	70.3	61	80.4	79.6	66.4
Infant mortality rate per '000 live births	13.3	68	4.8	1.9	50
Physician density per 100,000 population	42.82	51.26	249.13	140	16.24

In the wake of the tsunami the MOH acted promptly and deployed epidemiologists as early as on the 27th of December to all affected districts including the war torn east and north. Doctors were also dispatched from unaffected areas to the affected areas a day after the disaster. The values of the emergency medications sent as on the 25th of January 2005, by the MOH to affected areas were as follows: North SLR 14,009,997, East SLR 48,178,454, and South SLR 33,121,248. The prompt action and preventive measures taken by the MOH contained the spread of infectious diseases in these areas. Post-tsunami the MOH reported only 135 cases of diarrhoea, and 579 cases of viral fever in the affected area which were below the baseline for epidemics and no major outbreaks of communicable diseases were reported to that date. A key reason for the low number of infectious diseases was that the affected areas were virtually free of such diseases before the tsunami. A summary of the relevant data pre tsunami and post tsunami (12, 13) are presented in Table 1.2.

Table 1.2: Comparison of country data on notifiable infective diseases pre and post tsunami				
Infectious disease	No of cases			
	2004	2005	January to March	
			2004	2005
Cholera	0	0	0	0
Dysentery	6289	7723	1303	1508
Enteric fever	2375	2298	727	697
Leptospirosis	1132	1504	286	401
Viral Hepatitis	1576	2214	552	402
Dengue haemorrhagic fever	15155	5608	1921	830
Encephalitis	107	62	29	17
Measles	78	45	16	21
Tuberculosis	8576	9601	1676	2513

Status of Pharmaceuticals

In Sri Lanka, regulation on pharmaceuticals was enacted in the year 1980 (14) and the registration of cosmetics, devices and drugs was started in year 1987. Compliance with these provisions is a prerequisite for importing and marketing pharmaceutical products in the country. As at November 2004, the total number of registered pharmaceutical products was 9345 for 884 drug substances: 87% single ingredients and 13% fixed-dose combinations (15). India supplies approximately 45% of the pharmaceuticals to Sri Lanka followed by Pakistan, UK, Switzerland, Malaysia Australia, Thailand and Cyprus. Local manufacture contributes to about 6% of the registered products.

The Cosmetic Devices and Drugs regulation of 1985 requires the container of every drug imported, manufactured, processed or packed locally or sold or exposed for sale to have a label bearing the non proprietary name, brand name, list of active ingredients and their weight, any special storage conditions, warnings and precautions, date of manufacture, date of expiry, the batch or lot number assigned by the manufacturer and the name and address of the manufacturer. The container of every drug specified in schedule 11 should in addition be accompanied by a printed product information leaflet.

Sri Lanka has an essential drugs list prepared by the MOH. It was first compiled in 1985. The last published list is the third version revised in 1999 and includes 231 drug substances. It is presently in the process of revision. It is based on the World Health Organisations Model Essential Medicines List (WHO - EML). WHO defines 'Essential Drugs' as those that satisfy the health needs of the majority of the population. The WHO - EML is revised every two years.

The MSD which comes under the jurisdiction of the MOH is the central point in deciding national requirements, storage and distribution of medical supplies. Medicines for the MSD are procured by the State Pharmaceutical Corporation. The MSD is headed by the Director who is assisted by assistant directors, pharmacists, planning officers, and store keepers. The main office of the MSD is located at Deans Road, Colombo 10, but the main drug store is scattered in four different places which makes administration difficult. In addition to pharmaceuticals the MSD deals with surgical items and devices.

Sri Lanka has been relatively free of massive natural disasters and influx of pharmaceutical donations until the tsunami struck. Donations received in the past were mainly at the request of the MOH for specific programmes. Hence there was no written policy nor a pre-determined list of medicines to be requested in the event of a major disaster. Immediately after the tsunami the MOH compiled an ad hoc list of drugs (Annex 1) which may have been needed for the country and it was updated daily.

1.1.2. LITERATURE REVIEW ON PHARMACEUTICAL DONATIONS

A Medline search was conducted from 1975 to 2005 for key words associated with pharmaceutical donations (developing countries, relief work, WHO, disaster, guidelines) and the bibliographies of articles published were critically examined. Most reports on inappropriate drug donations are stories based on actual experience and visual observations of facts.

1970s: In 1976 in Guatemala (2) two weeks after the earthquake had struck, 100 tons of unsorted medicines had been delivered (between 6,000 to 7,000 boxes) and huge volumes were still coming even though the acute emergency was over within 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.

1980s: In September 1983 eight tons of donated drugs were sent to Guinea Bissau (3); 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. A similar scenario was seen following the earthquake in Armenia in 1988 (4) and during the war of independence in Eritrea in 1989 (5). In Armenia 5,000 tons of drugs were sent and it took 50 people six months to gain a clear picture of the drugs received. Of these drugs, 8% had expired on arrival and 4% were destroyed by frost. Of the remainder only 30% were easy to identify and 42% were relevant for an emergency situation. Inappropriate donations included seven truck loads of expired aspirin tablets that took six months to burn.

1990s: The situation in Bosnia and Kosovo (2, 6) was no different. A study published in the *New England Journal of Medicine* (6) indicates that approximately half the drugs donated to Bosnia were of little or no use and the audit of the drug donations to Kosovo found that 65% of donated drugs were either due to expire in less than a year or had missing expiry dates. In Bosnia alone the cost to dispose of unneeded, unwanted, or expired drugs was estimated to be \$30m (£18.75m), or about \$2000 a ton.

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, partly due to their tax deductions, and a loss of USD 34 millions for recipients.

The same scenario was seen in war-devastated southern-Sudan (7). A large consignment of drugs was sent. 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. Of 50 boxes, only 12 contained drugs of some use. Closer to home was the situation in India. On the 1st of April 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 had 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 were non essential medicines (8).

The only study that found medicine donations to be satisfactory was the study done by the Harvard School of Public Health; ‘*An Assessment of US Pharmaceutical Donations: Players, Processes, and Products*’ in 1999 (16). However the settings were studied during non emergency situations. They noted that 50 -80% of drugs donated in three sample countries—Armenia, Haiti, and Tanzania—were on either the respective countries' essential drugs list or the WHO EML and that nearly 75% of the drug shipment items had a remaining time to expiration of greater than one year at the time of shipment. But, even in this study 289 of the 494 (59%) of the different pharmaceutical products arriving in the three researched countries were not on the country's essential drug list and issues such as generic name and language of labeling were not addressed in this study.

1.1.3. DEVELOPMENT OF GUIDELINES ON DRUG DONATIONS

The first guideline for drug donations was developed by the Christian Medical Commission (CMC) of the World Council of Churches to address the five main complaints associated with drug donations in the 1970s and 1980s; arrived after or near expiration dates, were inappropriate or unsuitable to the recipient country, sent without first asking the recipient about their needs and without prior notification or shipping documents, and were inadequately packaged or labeled with no prescriber or patient information. The Pharmaceutical Advisory group of the CMC convened a meeting in April 1988 and developed six guidelines which were published in April 1988 (17). However even in the mid nineties reports of ‘useless’ or ‘inappropriate’ drug donations continued, which prompted the WHO to re – look at the problem? The six main problems identified by the WHO were no different from those identified by the CMC in 1988 (Table 1.3).

Table 1.3: Problems associated with donated drugs as identified by the WHO:

1. Donated drugs are often not relevant for the emergency situation, for the disease pattern, or for the level of care that is available.
2. Many donated drugs arrive unsorted and labeled 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.

To re - address the problem a draft guideline was prepared by the WHO action program on Essential drugs and later ‘refined’ in collaboration with the WHO Division of Drug Management and Policies and the WHO Division of Emergency and Humanitarian Action but the final text was developed by the WHO with seven co – sponsoring organizations, after addressing the comments received from over 100 humanitarian organizations and individual experts. The final version represented the consensus of WHO, Churches' Action for Health of the World Council of Churches, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières,

the Office of the United Nations High Commissioner for Refugees, OXFAM and the United Nations Children's Fund. The WHO based its guideline on four core principles:

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

In 1996 the WHO (18) published the interagency guidelines for drug donations which provided 12 detailed guidelines on 'Good Donation Practices' (Table 1.4). The guideline aimed at maximising the positive impact of the donation: excludes the donation of unnecessary or dangerous drugs and drugs which are not specified for use in the country, excludes donor driven donations or donations which arrive unannounced and unwanted, prevents double standards and ensures a remaining shelf life of at least one year after the arrival into the country. The guideline also encouraged recipients to specify their needs. In the absence of such a list the guideline clearly states that all donated drugs should be on the national list of essential drugs of the recipient country or, if such a national list is not available, the donated drugs should be on the WHO Model List of Essential Drugs

In 1999 a further attempt was made to increase the donors who follow these guidelines by expanding the number of co-sponsors to include Caritas International, the International Pharmaceutical Federation, Pharmaciens Sans Frontières, UNAIDS, the United Nations Development Programme, the United Nations Population Fund and the World Bank. Born out of an expert committee seminar of the Medicines Crossing Borders project, further advice came in the form of a step by step guide called Good Drug Donation Practices (19). The objective was to inform an increasingly wide spectrum of donors from medical students and sympathetic tourists to NGOs, pharmacists, church groups and the pharmaceutical industry and is available in English, Dutch, French, German and Spanish. The updated guideline reads: 'The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible and that unsolicited drug donations are to be discouraged'. The guideline is in the form of a checklist to ensure the quality of donations prior to donation and or shipment. A few countries have adopted the WHO guideline to publish their own country guidelines, one such country is Australia (20).

However, the pharmaceutical companies participating in the development of the WHO inter-agency guidelines for drug donations created a strong lobby group, including some international relief agencies (mostly Americans), to counteract WHO and other relief agencies' willingness to tighten the guidelines recommendations. For example in a letter to WHO in March 1996, 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 (21). It should be noted that companies can also get tax deductions for consignments they donate.

1.1.4 Emergency Health Kit

The evidence that most medicines donations at the time of an acute disaster are of little or no use, and the need to respond quickly with drug supplies also led to the establishment of a guideline and a list of essential drugs for use in emergency situations by the WHO (22). At the same time, the New Emergency Health Kit was designed to meet the basic drug needs of a population of 10,000 people for a period of about 3 months. It was field tested in a range of settings and adjustments made as needed to ensure its relevance. A number of specialized kits were also developed by WHO (TB control, chronic disease management, mental health, reproductive health, and laboratory diagnosis), MSF (anesthesia) and the Norwegian Health Council (surgery). The design of these kits sought to take into account the known health needs of people, the character of the local health care system, and the professional knowledge of national staff. The WHO guideline (22) went beyond the identification of a list; it provided treatment protocols for primary health care workers, guidance to suppliers of the emergency kits on the specifications and labelling they should comply with and guidelines on procurement, handling, storage, and distribution of the kits. Backed by a sound quality assurance system the emergency kits were attractive to end users who did not have time to sort and assess less structured supplies. Most health institutions preferred the kits over mixed bulk supplies. Kits are an excellent means of ensuring an adequate supply of appropriate medicines at the onset of an emergency but they are not designed for long term use. Longer terms supplies need to be based on records of diseases patterns and accurate assessment of ongoing needs.

Table 1.4: WHO guideline for donated drugs (18)

1. Selection of drugs

- a) All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country.
- b) All donated drugs or their generic equivalents should be approved for use in the recipient country and appear in the national list of essential drugs.
- c) The presentation, strength and formulation of donated drugs should as much as possible be similar to those drugs commonly used in the recipient country.

2. Quality assurance and shelf life

- a) All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country.
- b) No drugs should be donated that have been issued to patients and then returned or were given to health professionals as free samples.
- c) After arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year. Exceptions to this rule have been accepted under specific conditions.

3. Presentation, packing and labeling

- a) All drugs should be labeled in a language that is easily understood by health professionals in the recipient country: the label on each container should contain at least the International Proprietary Name (INN or generic name) batch number, dosage form, strength, name of manufacturer quantity in the container, storage conditions, and expiry date.
- b) As much as possible, donated drugs should be presented in larger quantity units and hospital packs.
- c) 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 special storage conditions.

4. Information and management

- a) Recipients should be informed of all drug donations that are being considered, prepared or are underway.
- b) In the recipient country the value of the drug donation should be based upon the wholesale price of its generic equivalent in the recipient country.
- c) Costs of international and local transport, warehousing, port clearing and appropriate storage and handling should be paid by the donor agency.

1.2 OBJECTIVES

We have discussed numerous examples of unsolicited and inappropriate donations of medical supplies, generally not based on precise assessment of actual medical needs and requests for external assistance by the authorities of the stricken country, and the more harm than good it does. Such donations overwhelm the already fully stretched health facilities and use critical and often limited resources and created logistical nightmares with high handling, sorting, transport, storage and disposal costs, and very often at the expense of the recipient country.

This realization prompted us to undertake the study of pharmaceutical donations received by the Medical Supplies Division of the MOH following the tsunami in December 2004 as no such study has been undertaken in the country to date.

The MSD was chosen for the study as there was a MOH directive in February 2005 that all medicines donated henceforth to the country should be cleared, stocked and distributed by the MSD.

General objectives of the study

- 1.2.1 To describe the quantity, quality and appropriateness to the needs of the country of the pharmaceutical donations received by the MSD.
- 1.2.2 To analyse the extent of compliance with the WHO guideline with particular reference to selection of drugs, quality assurance, shelf life and labeling.
- 1.2.3 To generate the evidence to make recommendations for a national policy on pharmaceutical donations

Specific objectives

- a) To compile a database of all donated medicines received by the MSD
- b) To classify the products according to their International Non - Proprietary Name (INN), and Anatomical – Therapeutic – Chemical (ATC) classification
- c) To determine the percentage of donated medicines:
 - ✓ in the WHO model List of essential drugs (WHO – ML)
 - ✓ in the expressed needs of the MOH and Hospital Formulary List 2004
 - ✓ in the WHO / UNICEF emergency list
 - ✓ approved for the use in the country
 - ✓ in the British National Formulary (BNF) March 2005
 - ✓ as free medical samples / unused drugs from individuals.
 - ✓ having a remaining shelf life of over one year from the date of arrival in the country
 - ✓ labeled in a language that is easily understood by health professionals in the country
 - ✓ containing the International Proprietary Name (INN or generic name) batch number, storage conditions, and expiry date on the label.
- d) To determine the costs involved in destroying expired / useless donations.
- e) To describe the problems associated with the donations faced by hospital pharmacists, and stores managers in the tsunami affected districts
- f) To describe the perceptions of the end users (people affected by the tsunami) on medicines received by them within three months of the tsunami.
- g) To describe any donation associated adverse drug events

1.3 METHODOLOGY

The data was collected over a period of five months from March 2005 to July 2005. Tools were developed for collection of data at the MSD and for the field surveys.

1. A pre-tested questionnaire was developed to describe the pharmaceutical donation process and to analyse the pharmaceutical donations on selection and quality.
2. An investigator administered structured pre-tested questionnaire to describe the problems associated with the donations encountered by the hospital pharmacists, and stores managers in tsunami affected hospitals.
3. An interviewer administered pre-tested questionnaire to describe the perceptions of the end users (people affected by the tsunami) on the drugs given to them by foreign medical teams.

The data was collected and analysed by a multidisciplinary team consisting of the director MSD, two clinical pharmacologists, doctor, pharmacists, planning officers and development assistants attached to the Department of Pharmacology and MSD.

Definitions

In this study the term:

‘Pharmaceutical product’ includes all dosage forms, strengths and package sizes of branded and generic products of single / multiple ingredient medicines.

‘Unique drug product’ (UDP) is a product that has the same drug substance, in the same dosage form and in the same strength irrespective of their brand name and package size.

‘Drug substance’ includes any substance intended to modify or explore physiological systems or pathological states irrespective of brand name, dosage form and strength and package size.

Data collection

The main store of the MSD was selected as the central point to collect data on drug donations. To collect information on any direct donations that may have reached the tsunami affected hospitals via individual donors or non-governmental organizations (NGOs), the hospital pharmacists and stores managers in the tsunami affected provincial and district hospitals were interviewed using the interviewer administered structured questionnaire. The sites were as follows: Southern province: TH Karapitiya, GH Mahamodera, BH Balapitiya , GH Matara, BH Hambantota, Eastern Province: GH Ampara, GH Batticaloa, BH Kalmunai North and south, TH Trincomalee. In the Northern province TH Jaffna, DH Killinochchi that were accessible by surface transport were visited by the team. Regional medical supplies divisions of Matara, Galle, Hambantota, Kalutara, Kalmunai, Ampara, Trincomalee, Batticaloa, Jaffna and Killinochchi were visited also by the team.

All donated medicines were entered into a database maintained at the MSD. They were entered as the INN (when available) and / or brand name. If only the brand name was indicated the INN was searched either from *Martindale, The Complete Drug Reference* (23) or using Google search engine. Only a medicine for which the INN was known was included in our study. For each INN included in the study the following variables were entered: dosage form, strength, language of the label, name and address of manufacturer / donor expiry date, if storage conditions were mentioned, if Product Information Leaflet (PIL) was included and if included the language, quantity of each product received, whether they were free sample. The total weight of the donations is the sum of the weight of the individual products, obtained by multiplying the strength of the product by its quantity.

Products that fitted the definition of ‘unique drug product’ or ‘medicine’ were selected for the next component of the study which was determination of compliance with the WHO guideline and relevance. The same active ingredient, in the same dosage form and strength was counted as one unique product and each unique product was counted only once even if the same product was listed several times. Similarly a drug substance was counted only once even if the same substance was listed several times. UDPs were then categorized according to the ATC classification 2005 (24, Annex 2).

Determination of compliance with WHO Good Donation Practice Guidelines

The last published Sri Lankan essential medicine list is that of 1999 and hence was considered inappropriate for use at this moment of time by the authors. To determine potential relevance to local disease patterns the MSD pharmaceutical procurement lists for 2004 was used as the MSD is the sole supplier of drugs to the entire public sector, which caters for over 70% of health care in the country. This list is referred to as the Hospital Formulary List (HFL) in this study.

To determine compliance with the WHO Good Donation Practice guideline the 2003 version of the WHO Essential Medicines List (WHO – ML) which includes 312 individual medicines (25), the MOH expressed list of needed drugs (Annex 1) and the HFL was used. UDPs were classified as on the lists if the same active ingredient in the same dosage form was listed for the same indication regardless of the strength of the product. A donated drug that was stated as a substitute in the WHO – ML was classified as on the list. Drugs that were not in any of the three categories (MOH list, WHO – ML, HFL) were called non – list drugs. The drug substances were further analysed with respect to their registration status in the country and inclusion in the British National Formulary, September 2005 (26) as it is the widely used reference formulary in our country. Medicines which were in the non – list category and not registered for use in the country was considered ‘useless’. Medicines already expired on arrival or expired within a month of arrival, and unidentifiable drugs (labelled in unknown foreign languages / no labels) were categorised as ‘unusable drugs’. Appropriateness in an emergency situation was checked for by comparing with the WHO list of essential medicines in an emergency situation (22).

Field surveys

To collect information on the problems and difficulties encountered at the ground level selected hospitals were visited and the hospital directors, administrators, pharmacists and stores managers were interviewed using the interviewer administered structured questionnaire. To collect information on the perceptions of the refugees, six camps in the Galle district were visited and around 70 families were interviewed on the illnesses and treatment given by visiting foreign medical teams within the first 3 months of the tsunami.

2. RESULTS AND DISCUSSIONS

This study produced the following observations regarding the pharmaceutical donations received as humanitarian aid following the tsunami in December 2005.

2.1 GENERAL INFORMATION

MSD

At the time of the tsunami the MOH had no written policy on pharmaceutical donations. Immediately after the tsunami disaster, the country relied on stocks of drugs available in the MSD. Subsequently the MSD issued an expressed list of drugs (Annex 1) on the 27th of December 2004 which was updated weekly. The expressed list was prepared by the staff of the MSD after taking into consideration the expected morbidity following a major natural disaster and the out of stock pharmaceutical items at the MSD. The quantities on the lists were updated daily and published in the following sites.

- Health Ministry Website
- Mass Media
- President's Office Website
- Prime Minister's Office Website
- Commissioner of Essential Service Website

This list was also given to Non – Governmental Organisations (NGOs) and individual donors on request.

When the donations were pouring in there was an acute lack of storage space for drugs in the MSD. To accommodate the donations warehouses which were previously not used for storing drugs were used at first, but these too were insufficient and two others were hired in a hurry. These were and are still located in Colombo and its outskirts: Wellawatte, Angoda, Narahenpita and Colombo central (Vauxhall Street). The storage facilities were far from the expected standard specifications required for storing pharmaceuticals as shown in photographs 2.1, 2.2, 2.3, 2.4.

Donors

The MSD received donations from varying sources. Two hundred and seventy eight donors were identified which included 98 local organisations (NGOs, companies, national agencies, universities) and individuals, 150 international organisations (governmental and non

governmental organisations companies) and individuals and 30 foreign governments. Approximately 86% of the products were donated by individuals under an individual's name or donated to international centres which acted as focal points for collection or through the Sri Lanka High Commissions overseas. The balance was donated either by governments (8.4%) - Australia, Republics of Armenia, China, Korea, Macedonia, Moldova and Philippines, Kingdom of Jordan, and Moscow - or national or multinational pharmaceutical firms (5.6%).

Pharmaceutical donations

Table 2.1 quantifies the pharmaceutical units in the database of the MSD and their total weight, the 'UDPs' and the drug substances. Presuming that the donations were sent to meet the needs of the injured and displaced (total = 570,568) the number of products per person equals 434.65 units. In reality however it is much more than this as only a fraction of donated medicines was included in our study. Medicines donated directly to NGO's and to affected hospitals by individuals within a month of the disaster were not included as they were handled directly by the relevant organizations or individuals. This situation is clearly evident in the results presented later under the heading waste management where approximately 150 metric tons of medicines were destroyed by the MSD approximately six months after the tsunami. These substances included those sent by various health institutions and organisations to the MSD for destruction as they had expired, were not identifiable or were of inappropriate quality.

The list of drug substances received as donations is listed in Annex 3. Analysis of the UDPs with regards to the dosage form and the ATC classification is described in Figures 2.1 and 2.2. The top five ATC categories represented were anti-infectives for systemic use, followed by central nervous system, cardiovascular system, alimentary tract and metabolism and dermatological preparations.

Table 2.1: Quantification of the Pharmaceutical Donations	
Number of pharmaceutical products	8580
Total number of single units donated	248 million
Total weight of pharmaceutical products	55 metric tons
Number of 'unique drug products' (UDPs)	1646
Number of drug substances	769
Single ingredients	595
Fixed dose combinations	162
Herbals	12

Figure 2.1

Describes the dosage forms of the medicines received as a percentage of the total donations

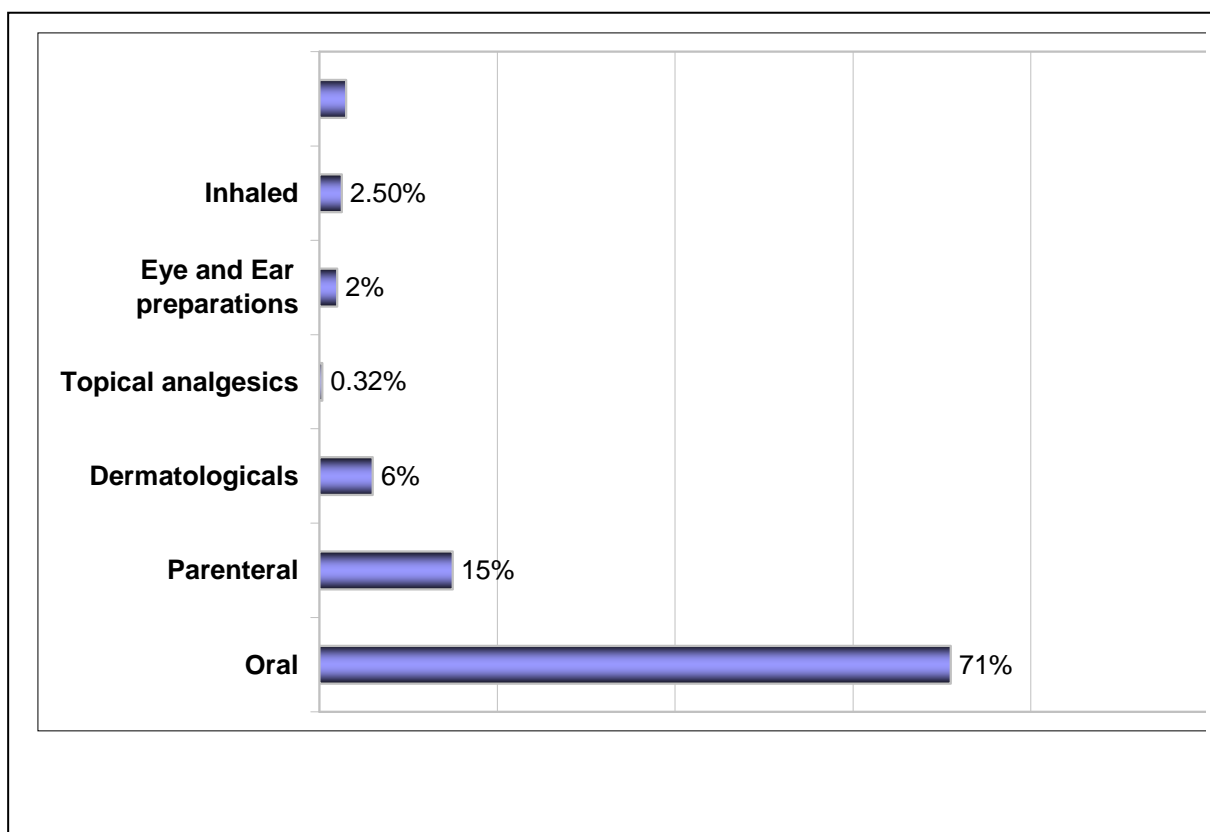
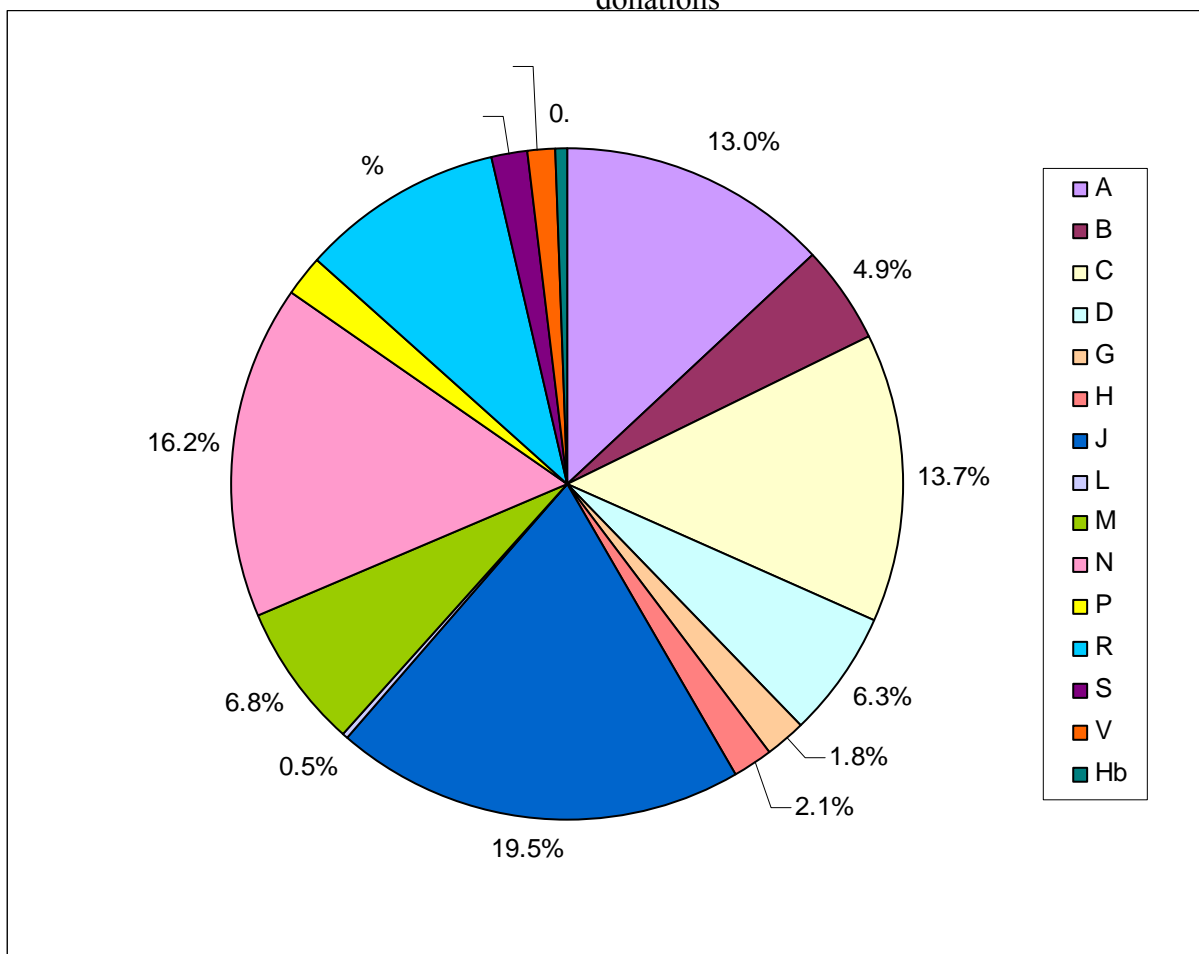


Figure 2.2

Describes the 'Unique Drug Products' under the different ATC categories as a percentage of the total donations



Level	Main Group	Level	Main Group
A	Alimentary tract & metabolism	L	Antineoplastic & immunomodulating agents
B	Blood & blood forming organs	M	Musculoskeletal system
C	Cardiovascular system	N	Nervous system
D	Dermatologicals	P	Antiparasitic agents
G	Genitourinary system & sex hormones	R	Respiratory system
H	Systemic hormonal preparations	S	Sensory organs
J	Anti-infectives for systemic use	V	Various

The top five ATC categories represented were anti-infectives for systemic use, nervous system, cardiovascular system, alimentary tract and metabolism and dermatological medicines.

2.2 COMPLIANCE WITH THE WHO DONATION GUIDELINES

Selection of drugs

To prevent unsolicited donations, and donations which arrive unannounced and unwanted, the WHO guideline states that all drug donations should be based on an expressed need, be relevant to the disease pattern in the recipient country, should be approved for use in the recipient country and appear in the national list of essential drugs. The presentation, strength and formulation of donated drugs should also as much as possible be similar to those drugs commonly used in the recipient country.

Figure 2.3 describes the analysis of the UDPs with respect to their status in the three lists: WHO – EML, expressed list of needed medicines by MOH, hospital formulary list of medicines (HFL) for 2004 and WHO emergency list. Although the UDPs requested by the MOH were among the donations received they accounted for only 20% of the total donated UDPs. Some were useless as they had expired on arrival. Annex 1 describes the medicines and quantities requested by the MOH and the approximate usable quantities donated.

Donors may not have access to the MOH list although it was on several web sites and our data indicates that only 35% of the UDPs were included even in the WHO – EML. If we consider the WHO Emergency Drug List designed to help donors at times of major disasters it accounted for only 16% of the UDPs and of this only 3.8% were of the strengths listed.

When the donations were compared with the HFL for 2004, 47% of the drug substances were listed, however, only a small proportion was usable as the majority of them had expired, or had an expiry less than 3 months.

Figure 2.4 presents data on the status of the drug substances in the donated medicines with respect to registration for use in the country (for details refer Annex 2) as at August 2005 and their status in the BNF March 2005. Thirty eight percent (single and fixed dose combination) were never registered for use in Sri Lanka which included 29%, 43%, 47%, 24% and 33% in the ATC category of anti- infective, nervous system, cardiovascular, alimentary tract and respiratory respectively. However it is important to highlight that several donated substances have recently been forwarded for marketing authorization in Sri Lanka. These include donepezil, nizatidine, clofoctol, oseltamivir, tizanidine, gabapentin, zopiclone, triotropium, lercanidipine, valsartan, telmisartan. Some of them have been donated by the company seeking market authorization for the same medicine a year after the tsunami; others are from

‘anonymous donors’. None of these medicines are particularly needed in Sri Lanka because there are other medicines from the same therapeutic group available. This occurrence arouses suspicion as to whether the opportunity was cynically exploited to introduce new medicines in the hope of future marketing advantages.

It is also important to highlight that donations included radiolabelled products such as Progesterone-Iodine 125, Serum ferritin IRMA (donated by a crown agent, with no date of expiry), cytotoxic drugs such as doxorubicin (no expiry date), etoposide, flutamide, exemestane and medicines withdrawn from use such as dipyrrone, cisapride, normifensine, dihydroergocristine, oral ampicillin, and hesperidine. None of the latter were requested by Sri Lanka. These medicines were in small quantities from individual donors overseas and were possibly left over medications.

Under *selection* the WHO guideline indicates that the presentation, strength and formulation of donated drugs should as much as possible be similar to those drugs commonly used in the recipient country. However this principle too was not adequately followed. A few examples of some commonly used medicines supplied in inappropriate formulations are capsules of amoxicillin 600 mg and 1000 mg, suspensions of amoxicillin and co – amoxiclav 500 mg / 5ml, paracetamol tablets of 750 mg and aspirin tablets of 200 mg and 500 mg. These products caused immense confusion amongst the health care personnel as their strengths had never been used in the country.

Although not relevant to an emergency situation a donation of voriconazole became useful during the outbreak of iatrogenic fungal meningitis in 2005. It was not registered for use in the country at that moment of time.

The WHO guideline also indicates that donation of vaccines is not appropriate because of the logistical problems associated with transport and storage. The donations received included hepatitis A, B and influenza vaccines and tetanus toxoid. Although Influenza vaccine was not registered for use in the country a NGO had got it cleared by the customs without proper documentation. It had also been brought to the notice of the Epidemiological Unit that several foreign medical teams had obtained clearance for stocks of vaccine which they had administered to persons in refugee camps without the knowledge of any of the local health authorities, which compelled the Director General of Health Services to issue a circular to health professionals in the affected areas (Annex 4).

Figure 2.3

Describes the percentage of the total UDPs (n = 1646) included in the WHO –EML, MOH expressed list of medicines, HFL 2004 and the WHO Emergency Medicines List

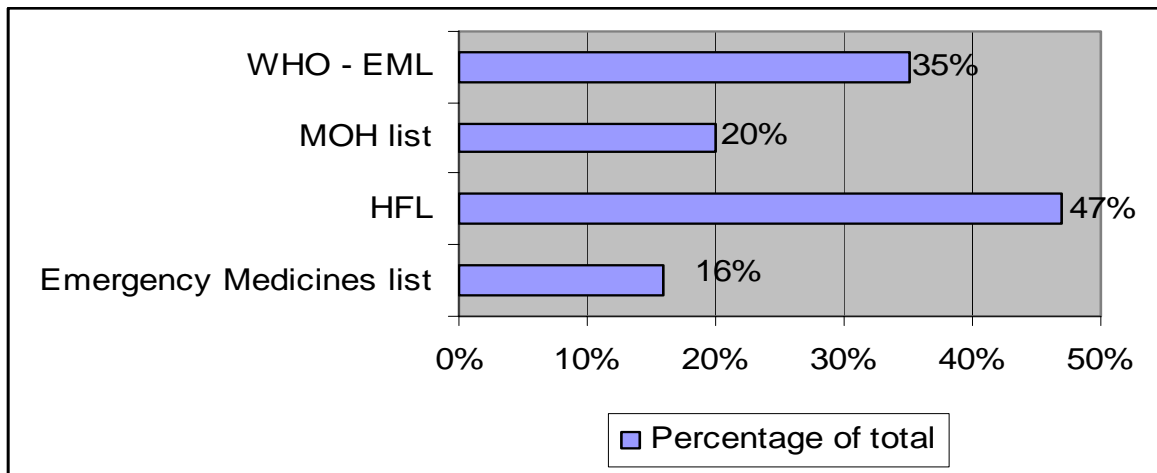
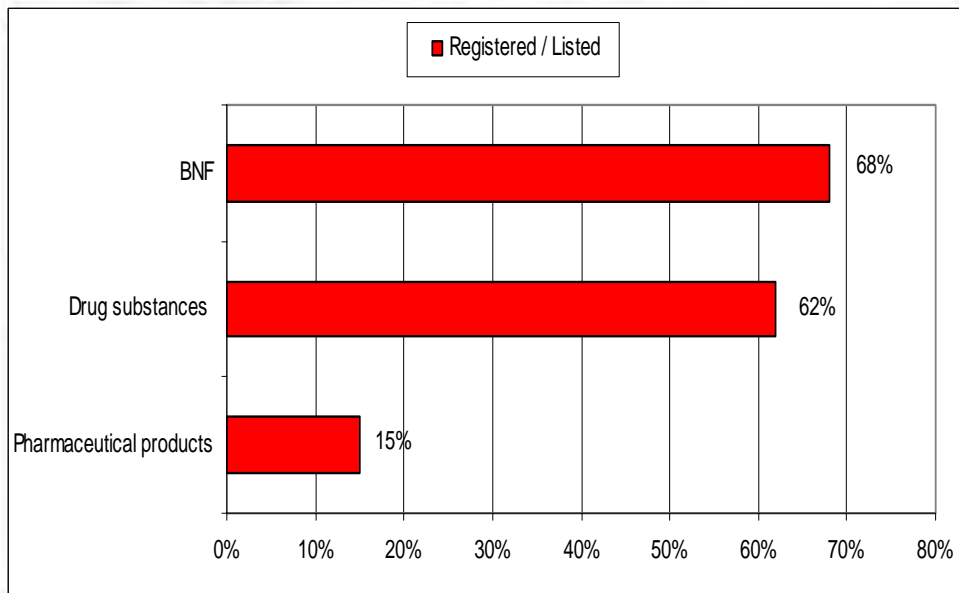


Figure 2.4

Indicates the percentage of donated pharmaceutical products (N = 8580) and drug substances (N = 772) that were registered for use in Sri Lanka as at December 2004 and the percentage of drug substances for which information was available in the March 2005 BNF



85% of the pharmaceuticals and 38% of the drug substances (single and combinations) were never registered for use in Sri Lanka and probably 32% were not registered for use in UK either as they were not listed in the BNF

Quality assurance and shelf life

The WHO guideline states that no drugs should be donated that have been issued to patients and then returned or were given to health professionals as free samples. In our study around 2% of the donations received were labeled as free professional samples, but the majority of the unsorted medicines (> 50%) were left over's of medicines issued to patients or returned to pharmacies. The majority were inappropriate and unusable.

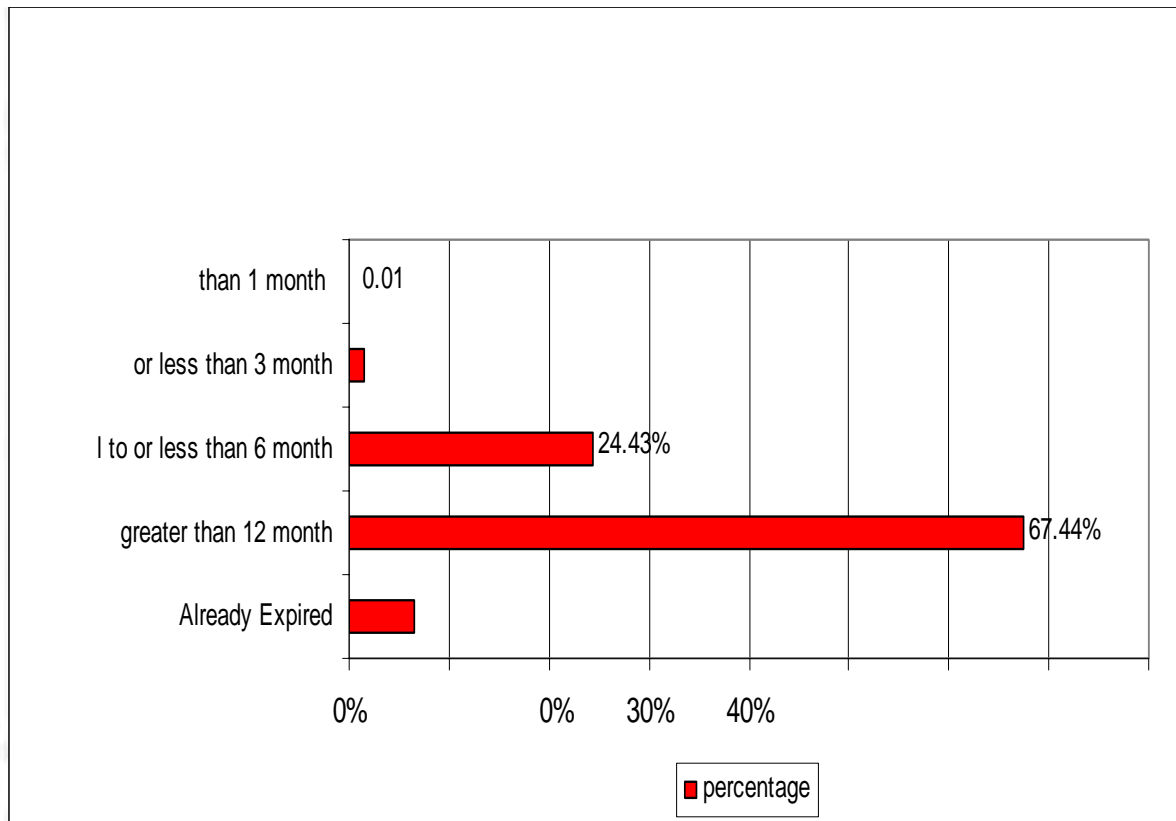
The next guideline concerning quality assurance reads that after arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year. Figure 2.5 describes in more detail the status of the donated drugs with respect to their expiration dates on arrival in the country. Of the total donations, 50.5% by weight (28 metric tons) did not have the expiry date. Of the balance, 6.5% (0.5 metric tons) of the products were expired or expired within a few days of arrival. Around 67% had one year or more remaining to expiry from the time of arrival. Hence 57% of the total weight was unusable right from the start.

More than 80% of the products that had expired or expired within a few days were from overseas: from individual donors delivered personally or collected by organizations and sent. Expired drugs sent by one local and one Middle East pharmaceutical company as well as a government of a country that had previously documented receiving outdated donations, were identified. Expired drugs were also included amongst donations collected and sent through Red Cross International. It was sad to note that even Sri Lankan people (including doctors) who had left the country years ago to greener pastures thought it appropriate to donate their outdated / non- dated / half used medicines to the less fortunate people in their homeland. These examples mainly originated from USA, France and Germany. The medicines that were expired on arrival were typically those medicines readily available in the country or inappropriate or delisted medicines as indicated below.

acetylcysteine	desonide	olmesartan
adenosine triphosphate	domperidone	hesperidine
allopurinol	doxazosin	methylcholine
amoxicillin	elodipine	paracetamol
amoxicillin – clavulanic acid,	fluticasone DPI	paroxetine
acetylcysteine	gabapentin	phloroglucinol hydrate
beclometasone DPI,	irbesartan	pimecrolimus
benazepril	salmeterol MDI,	pioglitazone
brompheniramine	fluticasone MDI,	prednisolone
budesonide DPI	hydralazine	ranitidine
candesartan	josamycine	racecadotril
carbamazepine	levalbuterol	ramipril
cefaclor	levocetirizine	rimexolone
cefalexin	loperamide	rofecoxib
cefixime	metronidazole	salbutamol
cefoxitin	montelukast	<i>saccharomyces boulardii</i> ,
cefprozil	moxonidine	tegaserod
cefotaxime	naratriptan	telmisartan – hydrochlorthiazide
clonazepam	nifedipine	thiocolchicoside
cloxacillin	nifuroxazide	quinapril
colesevelam	nimesulide	
diclofenac	nisoldipine	
digoxin	normiflumate	

An important finding which needs highlighting was that donations purchased by local residents and organisations after consulting the Director MSD though small in quantity, had the required shelf life of over one year, were appropriate to the needs of the time and hence 100% utilized. Also worth noting was that over 90% of the donations that were sent directly by Governments were on the MOH expressed list and had the required shelf life of over one year.

Figure 2.5



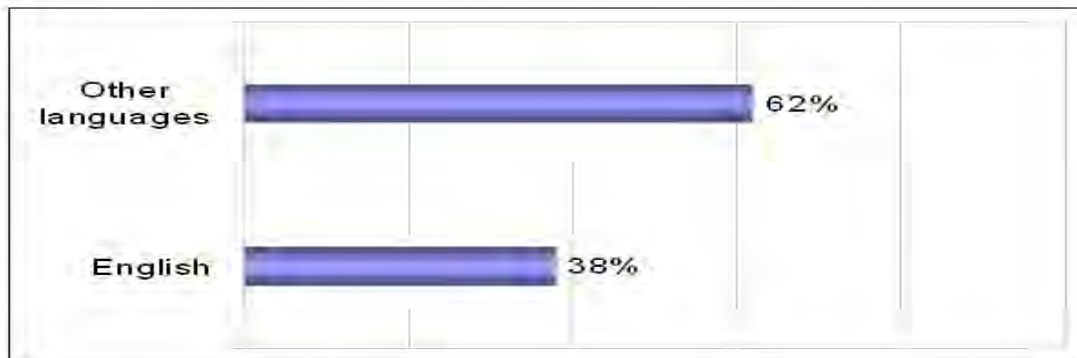
Presentation, packing and labeling

The WHO guideline states that all drugs should be labelled in a language that is easily understood by health professionals in the recipient country and that the label on each container should contain at least the International Non-proprietary Name (INN or generic name) batch number, dosage form, and strength, name of manufacturer quantity in the container, storage conditions, and expiry date. Figure 2.6 and 2.7 describes in detail the compliance of the donations with regards to this guideline.

This guideline further states that as much as possible, donated drugs should be presented in larger quantity units and hospital packs. However a fair proportion of the drugs ($\approx 50\%$) were patient packs and in small quantities (≤ 50 units) and were often unsorted (many different drugs were mixed in the same box, or were mixed with non pharmaceutical items).

Figure 2.6

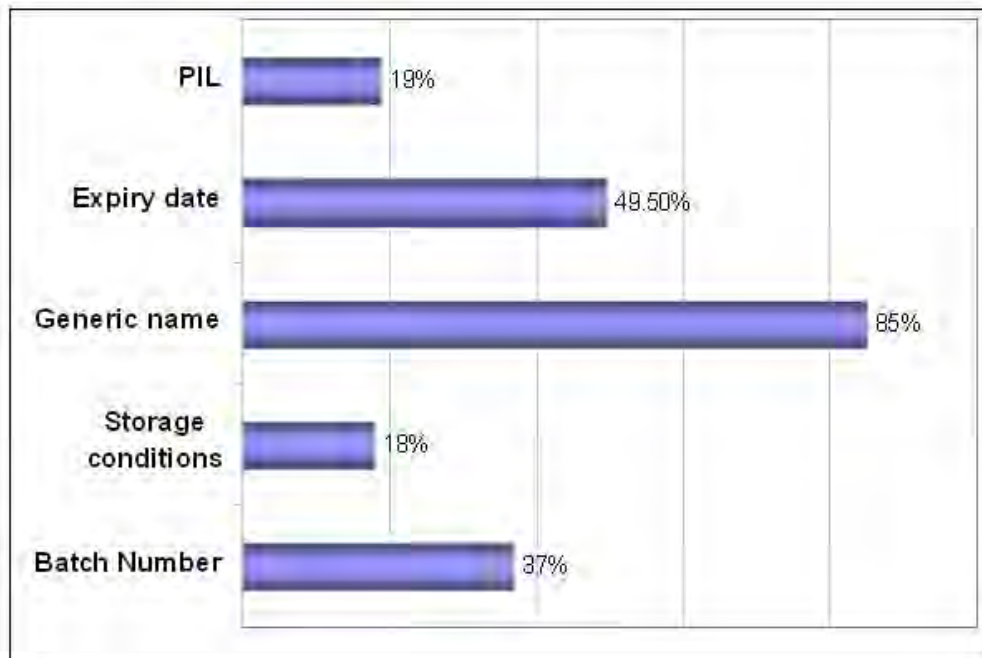
Describes the labelling language of the donated medicines (N = 8580)



Approximately 62% of the drugs were labelled in a language that could not have been read and understood by the majority of Sri Lankans. The other languages included Arabic, Chinese, Danish, French, German, Korean, Spanish, Irish, Italian, Turkish, and some unknown languages.

Figure 2.7

Provides information on the percentage of medicines (N = 8580) that had the Product Information Leaflets (PIL), International Proprietary Name (INN), Batch number, Expiry date, and Storage conditions.



2.3 STORAGE OF DONATED DRUGS AND STORAGE CAPACITY

During the field visits the donated medicines were found to be stacked at varying sites as the tsunami had badly damaged or destroyed 86 medical facilities (excluding private pharmacies and other medical related facilities) and two regional drug stores (Matara and Kalmunai).

Sites included

- Hospitals corridors
- Primary health care centres, refugee camps, temples, churches, schools in the tsunami affected provinces
- NGO warehouses

These sites were over-crowded with unsorted boxes with very little space between for staff to move to sort the medicines. As indicated in the background information the health infrastructure of Sri Lanka had limited storage capacity for even the essential medicines. The damage caused by the tsunami further reduced this capacity in terms of buildings and equipment.

At the MSD, stockpiles of unnecessary or expired drugs cluttered storage depots, resulting in shortage of space for essential medicines. It is estimated that approximately 20 – 30 metric tons were not appropriately stored. Medicines were stored in the courtyard or in sheds exposed to the atmosphere. The MOH acquired four warehouses in the District of Colombo but was still unable to adequately cope with the problem as illustrated in Photographs 2.1, 2.2, 2.3, and 2.4.

2.4 WASTE MANAGEMENT

The MOH has no incinerators for disposal of drugs. All expired drugs were disposed in consultation with the WHO in a private cement kiln (Holcim Private Lanka Ltd). The destroyed medicines included those without expiry dates, drugs already expired at the time of arrival, drugs due to expire in one month from the date of arrival and those labeled in an unknown language. Approximately 150 metric tons were destroyed within the first six months.

2.5 COSTS

It was difficult to accurately cost the donations. However, the authors would like to highlight certain aspects relative to costs. Photograph 2.5 depicts a life size certificate presented by a donor to the MSD with the cost supposedly incurred by them. The cost printed on the certificate amounted to USD 26 million three hundred thousand and sixty four and twenty three cents, which is approximately SLR 2.6 billion (1USD = 99.85 as on the date of donation). However, when their purchase order was costed by the authors, based on government procurement prices, the value of the donations totaled only USD 373,291.90 (SLR 37,329,190/-). This scrutiny indicated that the donor had paid as much as 87 times the local purchasing cost. In the year 2004 and 2005 the total government allocation for drugs was approximately Rs.5 billion and 6 billion respectively. Consequently, in monetary value the donation was presented as being equivalent to approximately 50% of the public health drug budget and should have had the purchasing power to supply 50% of the medicines on the Sri Lanka hospital formulary. In fact, according to the MSD, the sum of all the tsunami donations reduced the total drug budget for the year 2005 by only 4%.

Furthermore, contrary to the requirement in the WHO guideline, that costs of international and local transport, warehousing, port clearing and appropriate storage and handling should be paid by the donor agency, all local costs of handling, transport storage were borne by the MOH Sri Lanka.

The costs incurred by international organizations to transport medicines collected at collecting centres overseas is also considered a total waste as most (> 90%) of these donations were in the unusable category.

The cost incurred by the MOH to destroy the unusable 150 metric tons of donations alone was approximately SLR 2.6 million (1USD = SLR 99.85):

- Holcim Private limited SLR 12,000 per metric ton, total cost for 150 = SLR 1.8 million
- Transport and human resources cost = SLR 0.8 million

The authors support the suggestion of Professor Michael Reich (Director of the Harvard study) who, considering the 1999 updated WHO guideline, recognized that ‘that new guidelines, while helpful, are not enough’ and that ‘No donation should be allowed without disposal insurance’.

2.6 SAFETY ISSUES

No serious adverse effects associated with the use of donated drugs were reported to the national centre monitoring Adverse Drug Reaction (ADR). But this may not mean that no ADRs occurred as reporting rates are low in our country. There were occasional reports of adverse effects reported in the local newspaper (Annex 4) and anecdotal stories of children and adults receiving three different antibiotics within 24 hours from foreign teams who visited refugee camps. However, the main concern of the MOH was indirect safety issues due to improper storage of the stock items and usable donations due to the lack of adequate storage facilities in the stores of the MSD. This issue became a reality in July 2005 when seven cases of nosocomial meningitis including three deaths were reported in post natal mothers who had received spinal anaesthesia for caesarian section. Post mortem examination implicated *Aspergillus sp* as the infectious agent. A total of ten injection devices from three different manufacturers grew *Aspergillus fumigatus*. The syringes included stock items from the MSD, tsunami donations and direct donations by NGOs to the maternity hospital (Kavax brand whose country of origin was unknown and another brand from China). To highlight the problem the authors quote from the report of the investigating team from the WHO: **‘two warehouses contained disorganized stocks with many open boxes of medical devices and miscellaneous items that came from tsunami – related donations’**. As to whether these were the sources of infection remains unconfirmed, nevertheless it was a concern.

2.7 PROBLEMS FACED BY HOSPITAL PHARMACISTS / STORES MANAGERS

Thirty two pharmacists responded to the administered questionnaire (annex 6) Seven of them had received between 25 and 50% of expired drugs as donations and around 11 of them indicated that between 20 and 70% of the donated medicines had short expiry dates. The majority of pharmacists (mode 100%) were in agreement that they did not have adequate storage space for the donated drugs and that the drugs were in unsorted boxes lying in open corridors. When questioned on what percentage of the donations were relevant for use in their hospitals the mode was 25% (range 10 – 50%). One in four pharmacists said that they were unable to maintain an inventory of the donations as they did not have adequate

resources. With regard to percentage of drugs never used in the public sector the majority estimated it to be around 20% (range 5% – 40%).

2.8 PERCEPTIONS OF THE END USERS (PEOPLE AFFECTED BY THE TSUNAMI)

About 70 families living in tsunami camps were interviewed. Regarding the spectrum of illnesses noted, none of them or family members reported that they had suffered any serious illnesses as a result of the tsunami. A few had minor illnesses such as respiratory tract illnesses, body aches, headaches and rashes. Some had chronic illnesses such as diabetes, asthma, hypertension and psychiatric illnesses for which they had been taking long term treatment.

Various voluntary medical groups visiting the camps had given treatment for both the acute and chronic illnesses reported by the families. Some patients had the prescriptions for the medicines issued, other patients had noted down the medicines given in a book or sheet of paper as it is the routine practice in Sri Lanka (patients have personal exercise books in which their long term medications are entered in by the hospital / clinic doctors) . People had doubts about taking medicines offered by foreigners, mainly because they could not communicate with them properly. Some who were taking long term treatment were reluctant to take medicines as the medicines they were given were different from the usual tablets they obtained through the hospital.

Most people interviewed had access to medical help and medicines were available for their ailments. However there was wide variation noted. People in one camp with 8 families that was located a fair distance from a health facility said they did not even have paracetamol for pain relief.

The drugs provided to the families interviewed included analgesics such as paracetamol, diclofenac sodium, ibuprofen; antibiotics such as amoxicillin, erythromycin, azithromycin, furazolidine, cloxacillin; antacid formulations and antiulcer therapy such as cimetidine, ranitidine; antiasthmatic drugs such as salbutamol; antihistamines such as chlorpheniramine and cetirizine and nutrients such as multivitamin and iron preparations.

It was reported that most often the medicines had been given by a doctor or a pharmacist and people had been given advice on how to use them. Medicines had been issued only for a few days. There was mixed opinion about satisfaction regarding the medicines given.

2.9 PUBLICITY SEEKING BEHAVIOR OF DONORS

Many donors requested publicity for their donations and been photographed when handing over the donations indicating that this would be beneficial for seeking more aid from their country. One donor brought a replica of an almost life sized cheque (photograph 2.5) with the price of the donated medicines (similar to that handed over to the winners in One Day International Cricket) and wanted a photograph with the Director of Medical Supplies Division. Sadly however the same drugs could have been purchased in Sri Lanka for a fraction of the price on the cheque. Many Directors of the tsunami affected recipient hospitals shared similar experiences. For example one Director had provided transport to the donors immediately after the disaster as traveling to the area was a problem. However, after photographs, free transport and refreshments the boxes when opened subsequently contained mostly expired and useless drugs.

2.10 COMPARISON WITH DONATIONS RECEIVED BY OTHER TSUNAMI AFFECTED COUNTRIES

Other countries affected by the December 26th 2005 tsunami included, India, Maldives, Indonesia and Thailand with damage to a lesser extent in Malaysia, Bangladesh, Somalia and Seychelles. The hardest hit with the largest number of deaths was Indonesia followed by Sri Lanka.

The findings of studies of the quality of pharmaceutical donations to the province of Banda-Aceh in Indonesia (27, 28) were similar to the findings in this study: 4000 tons of drugs were received for a population of 2 million people, 60% were not on the national list of essential drugs, 70% were labeled in a foreign language, 25% had inadequate shelf lives and their disposal cost was EUR 2,400,000.

India and Thailand were also affected by the Tsunami but escaped the problem by not accepting donations following lessons learned in the past (8). However it maybe argued that they had made that bold decision because they are self sufficient in pharmaceuticals unlike Sri Lanka which is almost totally dependent on imported pharmaceuticals as local manufacture is negligible.

3. CONCLUSIONS

The great expectations of the tsunami affected countries were that they would benefit both financially and materially from the donations. But the reality supported the position that the quality of humanitarian aid with respect to drug donations in acute emergency situations is more a burden than of benefit.

The wide publicity the tsunami received in both the local and international media which touched the hearts of the international community resulting in a massive outpouring of aid is appreciated. Unfortunately, in the pharmaceuticals area, this outpouring was unfocused and swamped the system with irrelevant medicines. The very drugs which were meant to be a part of the solution became part of the problem. In a disaster of such a magnitude it would be unrealistic to expect perfect donations, and good logistics. Some imperfections waste and duplication would be expected but the almost total chaos caused by donations did more harm than good. It is also suspected that the opportunity was cynically exploited by some to dump unwanted medicines, and introduce new medicines in the hope of future marketing advantages.

The study also confirms the findings in Aceh in Indonesia that in spite of the experience gained over the years current donation practices show that lessons are not being learned. Guidelines have been in place for about 20 years and were developed to improve the quality and efficiency of drug donations but the quality of humanitarian aid with respect to drug donations in acute emergency situations has improved very little to date as shown in this study and the study from Banda Aceh (28). It seems that the general public and most non governmental organisations in donor countries are unaware of the common problems associated with drug donations and the inside situation of the recipient countries when contemplating donating medicines.

3.1 HIGHLIGHTS

- Majority of the UDPs (>> 80%) were unsolicited, came unannounced and in unsorted boxes. Around 50% of the donations were non-discriminatory collections of unused medicines from individuals collected on an *ad hoc* basis and transported via international relief organizations including the International Red Cross Federation. These donations were a mixture of many different brands and mixed with other relief items.

- 53% of UDPs belonged to the ‘non list’ category (not listed in the MOH list, WHO – EML, HFL, Emergency Medicines List) and 38% of the drug substances were never registered for use in the country. Therefore they could be considered totally irrelevant, useless and sometimes dangerous.
- A large proportion of non essential medicines (80%) were irrelevant to the emergency situation.
- 28 metric tons (50.5%) did not have the expiry dates. Of the remaining products 6.5% had expired on arrival and only 67% complied with WHO guideline requirement that after arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year. Hence 57% were unusable right from the start.
- 62% of the pharmaceutical products were labelled in languages not understood locally, 81% were without package inserts and 15% were without generic names.
- Donations were not cost free for the country, the main costs incurred have yet to be computed such as import duties, in country transport costs, storage costs and last but not the least important the human costs to handle these donations. The cost of destruction of some of the unwanted medicines was approximately SLR 2.6 million (1USD = SLR 99.85).
- Stockpiling of unusable and useless medicines cluttered storage areas, resulting in a shortage of space for proper storage of essential medicines.
- Many agencies / individuals sought undue fanfare and publicity when handing over donations.
- The monetary value of one donation as claimed by the donors was equivalent to approximately 50% of the public health drug budget and should have had the purchasing power to supply 50% of the medicines on the Sri Lanka hospital formulary. However all the tsunami donations reduced the total drug budget for the year 2005 by only 4%.
- Medicines purchased by local residents and organisations after consulting the Director MSD and over 90% of the donations that were sent directly by Governments were on the MOH expressed list, had the required shelf life of over one year and were 100% utilizable.

3.2 GAPS IDENTIFIED IN THE DONATION PROCESS

- ✓ Non availability of updated National Essential Drug List or a National Guideline on Donation Practices at the time of the tsunami as guidance for the international community.
- ✓ Lack of awareness of the WHO guideline/ country specific guideline on drug donation practices (for example Australian guidelines for the Australians) by international organisations and people in the donating country.
- ✓ Lack of a national disaster management plan for pharmaceutical donations, and insufficient coordination of plans on needed medicines at the country level.
- ✓ Inadequate guidance on media reporting at times of a disaster in order to maximize the positive impact of donations. The tsunami was adequately projected across all borders of the world by both the local and international media. Repeated showing of only destruction seems to have touched the hearts of the international community leading to empathy, and ‘wanting to do something positive’ resulting in a massive outpouring of medical assistance without much guidance on the priority needs.
- ✓ Absence of clinically experienced health care professionals, clinical pharmacologists and pharmacists in the local emergency response planning for medicines donations
- ✓ Inadequate knowledge of the logistics involved in pharmaceutical donations and appreciation of the complexity of the medicines donations amongst the stakeholders.
- ✓ Lack of initiative and courage by the government of Sri Lanka to refuse unsolicited donations in spite of the evolving knowledge that most of the donations were inappropriate

3.3 RECOMMENDATIONS

Recommendations are made at three levels:

3.3.1 The international level

3.3.2 The local level

3.3.3 The advocacy and information level

3.3.1 INTERNATIONAL LEVEL

It is recommended that

- Feedback be provided to donors informing them of the findings of this study to prevent similar recurrences in the future.
- All organisations that act as collecting centres be informed that donations of left over medicines from individuals must not be accepted. Donations of mixed unused medicines, however well-intentioned, should never be encouraged and accepted. This requirement should be strictly implemented and monitored by aid collecting centres.
- Governments, pharmaceutical companies and NGOs be urged to adopt drug donation policies and mechanisms which strictly comply with the WHO inter-agency guidelines for drug donations.
- Donors collaborate in the establishment of a coordinating body in emergency situations in line with the WHO guideline recommendation. The coordinating body should determine the needs, priorities, storage, logistics and distribution, and act as the central international contact point in discussion with the government authorities of the recipient country. To act as a central contact point in the recipient country, a similar coordinating body presided over by a **'lead donor'** will be established at headquarters level in **that** country to ensure that appropriate donation policies and processes are followed. This body will act as the central contact point in all discussions **between potential international donors and the recipient government.**
- In line with the recommendation of Michael Reich that 'No donation should be allowed without disposal insurance,' should be included in international Good Donation Practices Guideline' and adhered to by international donors

- For all donor countries to consider adapting the legal framework in the European Union, which prohibits the collection and export of drugs that have been issued to patients and returned to pharmacies.

3.3.2 THE LOCAL LEVEL

It is recommended that

- Ministry of Health be urged to design national guidelines for medicines donation based on the WHO guideline, and to update the National Essential Medicines List as quickly as possible and make these documents available on their website.
- The MOH clearly inform donors on the needs and priorities when requesting foreign assistance.
- Ministry of Health be proactive at times of disaster and lay down the administrative procedures to maximize the potential benefit and minimize the negative aspects of drug donations. Persons in the medicine supply system should be involved in these decisions. Important questions to be addressed include:
 - ✓ Who is responsible for defining the needs, and who will prioritize them?
 - ✓ Development of the national coordination body as described in 3.3.1
 - ✓ Who coordinates management of all drug donations, including **receipt storage and distribution?**
 - ✓ Which procedure is to be used when donations do not follow the guidelines?
 - ✓ The criteria for accepting / rejecting a donation and who makes the final decision?
 - ✓ How inappropriate donations would be disposed of?
- To be courageous and prohibit bad donation practices in the future, and report cases of inappropriate donations to the relevant authorities.
- To maintain strong communication links with customs officials and provide guidelines and educational workshops to customs officials at the points of entry into the country on what to and what not to allow as pharmaceutical donations into the country in the event of a major disaster.
- To conduct workshops to inform all stakeholders (health professionals, customs officers at the ports of entry, NGOs, pharmaceutical companies, international health organizations, religious organizations and diplomatic missions) the findings

of this study. To prevent future recurrences by drawing attention to abuses and problems caused by unsolicited drug donations, and to disseminate and promote adherence to Sri Lanka's Guidelines (newly developed) for drug donations and the WHO's inter-agency guidelines for drug donations.

- To provide foreign missions in Sri Lanka and Sri Lankan missions in other countries with the necessary information and guidelines for appropriate donations for dissemination through media and organisations
- To explain that cash donations are much more helpful than donations in kind because they can be used for purchase of needed supplies locally or close to hand at a fraction of the cost of transporting supplies from other countries. In addition cash can be used for local capacity building and reconstruction.

3.3.3 THE ADVOCACY AND INFORMATION LEVEL

It is important that the government of the recipient and donor countries transmit the right message at times of public appeal in the event of a disaster. Governments should 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. Using the resources developed by the MOH and described above, the media should raise awareness among the general public, both nationally and internationally about good donor practices and the negative impacts of collecting and donating unused drugs, unsold surpluses, expired drugs and pharmaceutical samples.

In the event of an appeal for help, an information release should be issued to all foreign missions in Sri Lanka and to Sri Lankan missions in other countries to provide them with the resources to inform the public and all interested bodies about procedures to follow.

3.4 CONCLUSION

It is disappointing that lessons have not still been learnt from earlier episodes associated with donations of inappropriate medicines. It is important that Sri Lanka and other countries learn from the results of this study and use the evidence to institute policy on receiving pharmaceutical donations. This policy should be widely disseminated as explained in the recommendations above.

India and Thailand made a strong stand, having learnt from the lessons of the past. Sri Lanka should follow their example in the future and not accept unsolicited international help.

Also, opportunistic use of the media should be made to curb unwanted donations. For example, repeatedly broadcasting of the list of wanted medicines and showing the international community some positive aspects on Sri Lanka such as our good health infrastructure.

REFERENCES

1. Central Bank of Sri Lanka. Annual Report of the Monetary Board of the Honorable Minister of Finance for the year 2004. Sri Lanka: Central Bank; 2005.
2. de Ville de Goyet C., del Cid E., Romero A., Jeannée E. and Lechat M., Earthquake in Guatemala: epidemiologic evaluation of the relief effort. PAHO Bulletin 1976; X (2):95-109.
3. Berckmans P, Dawans V, Schmets G, Vandenberg D, Autier P, Matthys F. Drug donation practices in Bosnia and Herzegovina 1996 – 1997. Report of a study supported by a grant from Médecins Sans Frontières – Belgium; 1997: 31
4. Autier P, Ferir MC, Hairapetien A, et al. Drug supply in the aftermath of the 1988 Armenian earthquake. Lancet 1990; 335: 1388 – 90.
5. Woldeyesus K, Snell B. Eritrea's policy on donations. Lancet 1994; ii: 879.
6. Nerckmans P, Dawans V, Schmets G, Vandenberg D, Autier P. Inappropriate drug – donation practices in Bosnia and Herzegovina, 1992 – 1996. N Eng J Med 1997: 337:1842 – 45.
7. Susan Cohen, Drug donations to Sudan. Lancet 1990; 336:745
8. Community Development Medicinal Unit (CDMU), *HHI Airlift of donated medicines to Calcutta as received on 01.04.1996*, Press release on 8 April 1996, India
9. Ministry of Health Sri Lanka. Annual Health Bulletin. Sri Lanka: Ministry of Health; 2002.
10. World Health Organisation. World Health Report. Geneva: World Health Organisation ; 2003
11. World Health Organisation. World Health Statistics. Geneva: World Health Organisation, 2005
12. Epidemiological Unit, Ministry of Health Sri Lanka. Weekly Epidemiological Report 2006; 33(1): 3 – 4.
13. Epidemiological Bulletin, 4th Quarter. Sri Lanka: Epidemiological Unit, Ministry of Health; 2005
14. Cosmetic Devices and Drugs Act No 27 of 1980. The Gazette of the Democratic Socialist Republic of Sri Lanka 2nd December 1985. No 378/3
15. Abdulla AA, Fernandopulle BMR. Drug registration in Sri Lanka: does it add to the confusion? The Ceylon Medical Journal 2005: Supplement (1):38
16. Reich MR, Editor. An Assessment of US Pharmaceutical Donations: Players, Process, and Products. Boston: Harvard School of Public Health; 1999
17. Christian Medical Commission of the World Council of Churches. Guidelines for donors and recipients of pharmaceutical donations. Geneva: Christian Medical Commission of the World Council of Churches; 1990.
18. World Health Organization. Guidelines for Drug Donations. Geneva: WHO; 1996
19. World Health Organization. Interagency Guidelines for Drug Donations, Published on behalf of agencies by the World Health Organization; 1999

20. Australian Pharmaceutical Advisory Council. Australian guidelines for donations to developing countries. Australian: Government Publishing Service, Canberra, Australia: 2000
21. Drug Issues at the 49th World Health Assembly-May 1996, HAI-Europe, 12 June 1996.
22. World Health Organisation. The New Emergency Kit 98. 2nd ed. Geneva: World Health Organisation; 1998. WHO/DAP/98.10
23. Parfitt K, editor. Martindale The Complete Drug Reference. 32nd ed. London (UK): The Pharmaceutical Press; 1999.
24. Norwegian Institute of Public Health. Guidelines for ATC classification and DDD assignment: 10th edition. Oslo, Norway: WHO Collaborating Centre for Drug Statistics Methodology. 2003
25. World Health Organization. Essential Medicines, WHO Model List, 14th ed. Geneva: WHO; 2003
26. British Medical Association. British National Formulary, 43rd ed. UK: British Medical Association and the Royal Pharmaceutical Society of Great Britain; 2004
27. Mason P. Tsunami relief: same mistakes repeated. The Pharmaceutical Journal 2005; 274: 178
28. Pharmaciens Sans Frontières Comité International. A study of drug donation in the province of Aceh, Indonesia; 2005.

Annex 1 Expressed list of medicines by the MOH compared with donations received.

	Name of Item	Quantity requested	Dosage form	Donation received
1	Adrenaline Tartrate 0.1% 0.5ml	5,000	Inj.	7,856
6	Aminophylline 250mg/10ml	2,000	Inj.	5492
7	Amoxicillin (soluble) 125mg	100,000	Tab.	128605
8	Amoxicillin 250mg	10,000,000	Cap.	765560
9	Amoxicillin125mg/5ml,100ml	10,000	Syrup	5,937
10	Ampicillin 250mg Vial	100,000	Inj.	1600
11	Aspirin 300mg	5,000	Tab.	97274
12	Atropine sulphate 600mcg/1ml	50,000	Inj.	268
25	Ceftazidime 1g	25,000	Inj.	87925
26	Ceftazidime 500mg	5,000	Inj.	13926
95	Cefuroxime 750mg	100,000	Inj.	100380
27	Cefuroxime tablet 250mg	100,000	Tab.	0
158	Cephalexin 125mg/5ml,100ml	10,000	Sy.	0
30	Cephalexin 250mg	100,000	Sy.	0
31	Chloramphenicol 500mg Vial	20,000	Inj.	10050
32	Chlorhexidine+Cetrimide	500	Solu.	0
33	Chlorpheniramine maleate 4mg	100,000	Tab.	2016500
34	Ciprofloxacin 200mg/100ml	2,000	Inj.	6447
174	Ciprofloxacin 250mg	100,000	Tab.	2577656
35	Clarithromycin IV infus.500mg	1,000	Inj.	4018
36	Clarithromycin Tablet 250mg	2,000	Inj.	7603
37	Cloxacillin 125mg/5ml,100ml	10,000	Sy.	26107
38	Cloxacillin 250 mg	100,000	Inj.	200400
39	Cloxacillin 250mg	100,000	Cap.	5663325
40	Co-Amoxiclav syrup 100ml bottle	10,000	Sy.	10574
41	Co-amoxycrav 1000/200mg	5,000	Inj.	10000
42	Co-amoxycrav 375mg	50,000	Tab.	61040
44	Compound sodium lactate 500ml	5,000	Inj.	5000
47	Dexamethasone 0.5 mg	100,000	Tab.	309554
48	Dexamethasone 8mg/2ml	5,000	Inj.	10000
49	Dextrose 25% , 25ml	20,000	Inj.	20360
50	Dextrose 5%, 500ml	10,000	Inj.	156184
51	Dextrose 50% ,50ml	20,000	Inj.	20095
52	Diazepam 10mg/2ml	10,000	Inj.	10200
53	Diclofenac sodium 12.5mg	5,000	Supp.	6225
54	Diclofenac Sodium 25 mg	500,000	Tab.	10897202
55	Diclofenac sodium 50mg	5,000	Supp.	6603
56	Dobutamine 250mg/20ml	1,000	Inj.	507
57	Domperidone 10mg	10,000	Tab.	264140
58	Dopamine 200mg/5ml	1,000	Inj.	0
70	Erythromycin 125 mg/5	10,000	Sy.	18556
71	Erythromycin 250mg	100,000	Tab.	1154733
73	Famotidine 20mg	5,000	Tab.	1044292
74	Frusemide 20mg/2ml	20,000	Inj.	100
75	Frusemide 40 mg	50,000	Tab.	1000
76	Furazolidone 100mg	100,000	Tab.	238448
81	Gentamicin Sulphate 80mg/2ml	10,000	Inj.	12197
83	Heparin 25,000 I.U/5ml	3,000	Inj.	0
84	Hydrocortisone hemisucci. 100mg	5,000	Inj.	30900
85	Hydrogen peroxide 450ml	1,000	Solu.	4010
92	Ibuprofen 200mg	100,000	Tab.	1264176
97	Isosorbide dinitrate 10mg	100,000	Tab.	0
98	Ketamine HCl 200mg/20ml	2,000	Inj.	1300

	Name of Item	Quantity requested	Dosage form	Donation received
99	Ketamine HCl 500mg/10ml	2,000	Inj.	2000
102	Lignocaine 2%with Adrenalin30ml	2,000	Inj.	0
103	Lignocaine plain 2%/20ml	2,000	Inj.	120
105	Mannitol 20% I.V., 250 ml	5,000	Infusion	0
175	Metoclopramide 10mg	1,000	Tab.	103101
106	Metoclopramide 10mg/2ml	5,000	Inj.	10
176	Metronidazole 200mg	100,000	Tab.	215982
96	Metronidazole 500mg /100ml	25,000	Inj.	147632
107	Midazolam 5mg/1ml Amp	2,000	Inj.	0
108	Morphine sulphate 15mgInj.	1,000	Inj.	1000
109	Naloxone 400mcg/1ml	500	Inj.	380
112	New Emergency Medical kits	400		0
113	Nifedipine S.R. 20mg	50,000	Tab.	84600
177	Nitrofurantoin 50mg	100,000	Tab.	114
114	Omeprasole 20mg	200,000	Cap.	4579082
115	Oral Rehydration	500,000		0
116	Paracetamol 500mg	10,000,000	Tab.	86486386
117	Paracetamol120mg/5ml, 100ml	50,000	Sy.	91461
118	Pethidine HCl 75mg	2,000	Inj.	2000
119	Phenobarbitone 200mg/1ml	5,000	Inj.	0
120	Phenoxymethyl penicillin	100,000	Tab.	125881
121	Phenytoin sodium 100 mg	10,000	Tab.	0
126	Povidone iodine Soln.10%,500ml	5,000	Solu.	24052
127	Prednisolone 5mg	100,000	Tab.	579742
128	Promethazine HCl 25mg	10,000	Tab.	1416300
129	Promethazine HCl 25mg/1ml	5,000	Inj.	10400
130	Propofol injection 20ml Ampoule	1,000	Inj.	5
131	Propofol injection 50ml Ampoule	1,000	Inj.	50
132	Ranitidine HCl 50mg/2ml Amp.	5,000	Inj.	5000
135	Salbutamol 2mg/5ml, 100ml	5,000	Sy.	11657
136	Salbutamol 4mg	100,000	Tab.	2323600
137	Salbutamol respi.solu.0.5%,10ml	5,000	Solu.	5076
141	Soda lime	1,000		0
142	Sodi.chlo 0.18% & Dext	5,000	Inj.	0
143	Sodi.chlo 0.45% & Dext	5,000	Inj.	532
144	Sodium bicarbonate 8.4% 50ml	1,000	Inj.	200
145	Sodium chloride 0.9% ,500ml	20,000	Inj.	5540
146	Solvent Ether, 500ml	500		0
148	Spirit surgical	5,000		0
178	Tetanus toxoide Vaccine 0.5ml	50,000	Inj.	100000
179	Theophylline SR 125mg	100,000	Tab.	2000000
180	Theophylline Table 125mg	100,000	Tab.	2000000
186	Tramadol 100mg/2ml Amp.	5,000	Inj.	5000
187	Tramadol 50mg	200,000	Cap.	73300
188	Tropical chlorinated lime	10,000		0
191	Water for Injection 10ml	500,000	Inj.	505240

Anatomical Therapeutic Chemical (ATC) Classification System

In the ATC classification system, drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified into groups at 5 different levels.

- **1st level** - At the broadest level, drugs are divided into one of the following fourteen anatomical groups. The first level of the code is based on a letter e.g. 'B' for Blood and blood forming organs:

Level	Main Group	Level	Main Group
A	Alimentary tract & metabolism	L	Antineoplastic & immunomodulating agents
B	Blood & blood forming organs	M	Musculo-skeletal system
C	Cardiovascular system	N	Nervous system
D	Dermatologicals	P	Antiparasitic agents
G	Genito urinary system & sex hormones	R	Respiratory system
H	Systemic hormonal preparations	S	Sensory organs
J	Antiinfectives for systemic use	V	Various

- **2nd level** - is either a pharmacological or therapeutic subgroup (e.g., 'B03' for Antianemic preparations).
- **3rd level** - is a chemical or therapeutic or pharmacological subgroup (e.g., 'B03A' for Iron Preparations).
- **4th level** - is a chemical or therapeutic or pharmacological subgroup. **5th level** - is the subgroup for the chemical substance (e.g., 'B03AA07' Ferrous sulphate).

In the ATC system all DINs (drug identification numbers) with the generic name 'ferrous sulphate' would be assigned the code B03A A07. In other words, an ATC code has five levels that are described by seven digits.

Annex 3

List of 'Drug Substances' amongst the donations and their registration status with the CDDA of Sri Lanka

Drug Substances	ATC code	Registration status
Dipyrrone	N	Banned
2-hydroxyethylsalicylate	M	No
Acebutolol	C07A B04	No
Acemetacine	M01A B11	No
Acetylcysteine	R05CB01	No
Acetylcysteine + Betacarotene	V+B9	No
Acetylcysteine + Tuaminoheptane	R01AB08	No
Acetyl-dl-leucine	N07CA04	No
Acetylsalicylic acid + Aluminium hydroxide	N02BA51	No
Alcana tinctoria extract	HERBAL	No
Alfa Amylase oral preparation	A	No
Almagate	A02A D03	No
Aloe vera + Emu oil + Silymarin	HERBAL	No
Alverine + Simethicone	A03A X58	No
Amlodipine + Atorvastatin	C10A A55	No
Ammonia + chlorine	V07AV	No
Ammonium chloride	G04BA01	No
Ammonium fluoride + Vitamin A	A01AD11	No
Amodiaquine	P01BA06	No
Amoxicillin + Paracetamol	N02BE51	No
Aniracetam	N06B X11	No
Anti prolactin-Iodine 12	V07AZ	No
Apronal	N05CM12	No
Aprotinin	B02AB01	No
Artemether	P01B E02	No
Artesunate	P01B E03	No
Azulene + natural oils	R	No
Bacampicillin	J01CA06	No
Bacillus cereus oral preparation	A	No
Balsamum Indicum	Herbal	No
Barbexaclone	N03AA04	No
Baume de perou,Huile de	HC05AW	No
Benazepril	C09AA07	No
Benazepril + Hydrochlorothiazide	C09BA07	No
Bendroflumethiazide	C03AA01	No
Benzydamine	A01AD02	No
Betametasone + Dexchlorphenamine	R06AB54	No
Bethanechol	N07A B02	No
Bifonazole	D01A C10	No
Biperiden	N04A A02	No
Bismuth subcarbonate	A	No
Bismuth subnitrate	A02B X12	No
Brompheniramine	R06AB01	No
Brompheniramine + Phenylephrine	R06AB51	No
Brompheniramine + Pseudoephedrine	R06AB51	No

Bufexamac	M02AA09	No
Butamirate	R05D B13	No
Caffeine	N06BC01	No
Calcitonin	H05BA03	No
Calcium ascorbate	A11GB01	No
Captopril + Carvedilol	C	No
Carbinoxamine	R06A A08	No
Carbinoxamine + Pseudoephedrine	R01BA52	No
Caroverine	A03A X11	No
Cefadroxil	J01DB05	No
Cefamandole	J01DC03	No
Cefdinir	J01DD15	No
Cefditoren	J01DD	No
Cefprozil	J01DC10	No
Celiprolol	C07AB08	No
Charcoal + Sorbitol	A07BA51	No
Charcoal active + Simethicone	A07BA01	No
Chiniofon	P01AX01	No
Chloropyramine	R06AC03	No
Chlorothalidone + Reserpine	C02LA01	No
Chlorprothixene	N05AF03	No
Chlorquinaldol + promestriene	G01AC03	No
Chlortetracycline	J01AA03	No
Chondroitine Sulfate + Glucosamine	M 01B	No
Clofoctol	J01X X03	No
Clopamide + Dihydroergocristine	C04AE54	No
Clorazepate	N	No
Codeine + Ephedrine	N02AA59	No
Codeine + Sulfogunaicol	N02AA59	No
Colesevelam	C10A C04	No
Dexamethasone + Tromazoline	D07CB04	No
Dexamethazone + Chloramphenicol	S01CA01	No
Dexibuprofen	M01AE14	No
Dextropropoxyphene + Paracetamol	N02AC54	No
Dibekacin	J01GB09	No
Dibrompropamidine	D08AC01	No
Diclofenac + Misoprostol	M01AB55	No
Dicycloverine	A03AA07	No
Digitoxin	C01AA04	No
Dihydroergocristine+ Rutin	C04A E54	No
Dimetindene	R06AB03	No
Diosmectite	A07BC05	No
Diosmin	C05CA03	No
Diosmin + Hesperidone	C05CA53	No
Dipyridamole + Acetylsalicylic acid	B	No
Donepezil	N06DA02	No
Doxazosin	C02CA04	No
Drotaverine	A03AD02	No
Ebastine	R06A X22	No
Enalapril + Hydrochlorothiazide	C09BA02	No
Enoxacin	J01MA04	No
Entacapone	N04BX02	No
Eprazinone	R05CB04	No
Eprosatan + Hydrochlorothiazide	C09DA02	No
Erythromycin ethyl succinate + Sulphafurazole	J	No

Ethacridine	B05CA08	No
Etofenamate	M02AA06	No
Etoricoxib	M01AH05	No
Famciclovir	J05AB09	No
Famotidine + Magnesium hydroxide	A02BA53	No
Felodipine+ Ramipril	C09BB05	No
Fenoterol	R03AC04	No
Fenspiride	R03BX01	No
Fexofenadine + Pseudoephedrine	R01BA52	No
Fluindione	B	No
Flupirtine	N02BG07	No
Fosfomycin	J01X X01	No
Fosinopril + Hydrochlorothiazide	C09BA09	No
Fraxiparin	B	No
Furosemide + Amiloride	C03E B01	No
Gabapentin	N03A X12	No
Gallamine	M03A C02	No
Guaifenesin	R05CA03	No
Helicidine	R	No
Heptaminol	C01DX08	No
Hesperidine + Rutin	B	No
Hesperidine + Vitamin C	B	No
Hydrochlorothiazide + Triamterene	C03DB02	No
Ibuprofen + Paracetamol	M01AE51	No
Ibuprofen + Pseudoephedrine	M01AE51	No
Influenza vaccine (inactivated)	J07BB01	No
Inositol hexaphosphate + Calcium gluconate + Vitamin D2	A11JB	No
Irbesartan	C09CA04	No
Irbesartan + Hydrochlorothiazide	C09DA04	No
Josamycin	J01FA07	No
Kanamycin	J01GB04	No
Lactated Ringers + Dextrose	B05BB02	No
Lactitol	A06AD12	No
Lactobacillus acidophilus	A	No
Lercanidipine	C08CA13	No
Lisinopril + Hydrochlorothiazide	C09BA03	No
Loperamide + Simethicone	A07D A53	No
Loratadine + Pseudoephedrine	R01BA52	No
Losarten + Hydrochlorothiazide	C09DA01	No
Macrogol + Electrolyte	A06AD65	No
Magnesium pidolate	A12CC08	No
Magnesium pyridoxal 5 phosphate glutamate	C10AX07	No
Manidipine	C08CA11	No
Mebhydrolin	R06AX15	No
Mecetronium	D	No
Meclofenamic acid	M01AG04	No
Melperone	N05AD03	No
Mephenesin	M03BX06	No
Mesalazine	A07EC02	No
Metamizole	N02BB02	No
Metergoline	G02CB05	No
Methocarbamol	M03BA03	No
Methotrimeprazine	N	No
Methylcysteine	R	No
Methylergometrine	G02AB01	No

Metopimazine	A04AD05	No
Mezlocillin	J01CA10	No
Miocamycin	J01FA11	No
Molsidomine	C01DX12	No
Montmorillonite	A	No
Morinamide	J04AK04	No
Morniflumate	M01AX22	No
Naftidrofuryl	C04AX21	No
Naratriptan	N02CC02	No
Nefopam	N02BG06	No
Nicergoline	C04AE02	No
Niflumic acid	M01AX02	No
Nifuroxazide	A07AX03	No
Nilvadipine	C08CA10	No
Nimesulide	M01AX17	No
Nisoldipine	C08CA07	No
Nitrendipine	C08CA08	No
Nizatidine	A02BA04	No
Nomifensine	N06AX04	No
Nopoxamine + Diethylamine	M	No
Noscapine	R05DA07	No
Olafur	A01AA03	No
Olmesartan	C09CA08	No
Ornidazole	J01XD03	No
Orphenadrine citrate	M03BC01	No
Orphenadrine + Aspirin + Caffeine	M03BC51	No
Oseltamivir	J05AH02	No
Otilonium bromide	A03AB06	No
Oxacillin	J01CF04	No
Oxatomide	R06AE06	No
Oxazepam	N05BA04	No
Oxetacaine	C05AD06	No
Papaverine + Activated charcoal	G04BE52	No
Paracetamol + Acetyl salicylic acid	N02B E51	No
Paracetamol + Caffeine	N02BE71	No
Paracetamol + Dextropropoxyphene	N02BE71	No
Paracetamol + Diphenhydramine	N02B E51	No
Paracetamol + Methionine	N02B E51	No
Paracetamol + Phenylephrine	N02B E51	No
Paracetamol + phenylephrine + chlorphenamine	N02BE71	No
Paracetamol+Aspirin +Caffeine	N02B E 71	No
Parecoxib	M01AH04	No
Paromomycin	A07A A06	No
Pectine+Cellulose microcrystalline	A07B C01	No
Pefloxacin	J01MA03	No
Pentoxyverine	R05DB05	No
Pentoxyverine + Pseudoephedrine	R01BA52	No
Phenazone	N02BB01	No
Phloroglucinol	A03AX12	No
Pimecrolimus	D11AX15	No
Pinaverium	A03AX04	No
Piperazine	PO2CB01	No
Piracetam	N06B X03	No
Polyethylene glycol	A	No
Potassium + Magnesium	A12BA30	No

Prazepam	N05BA11	No
Praziquantel	P02BA01	No
Prednicarbate	D07AC18	No
Prednisone	H02AB07	No
Pristinamycin	J01FG01	No
Procyclidine	N04AA04	No
Progesterone-Iodine 125	V04CX	No
Pygeum africanum hook	G04CX01	No
Racecadotril	A07XA04	No
Ramipril + Piretanide	C09BA05	No
Rifaximin	A07AA11	No
Rimexolone	H02A B12	No
Risedronic acid	M05BA07	No
Rizatriptan	N02CC04	No
Rosiglitazone + Metformin	A10BD03	No
Saccharomyces boulardii	A07F A02	No
Salbutamol + Ipratropium	R03AK04	No
Serenoa repens	G04CX02	No
Serrariopeptidase	A09AA03	No
Serum ferritin IRMA	V04CX	No
Simethicone + Phloroglucinol	A03AX12	No
Sodium acetate	B05XA08	No
Sodium cellulose phosphate	V03AG01	No
Sodium chloride (blader irrigation)	G	No
Sodium chloride hypertonic	S01XA03	No
Sodium Dichloroisocyanurate	V07AB	No
Sotalol	C07A A07	No
Spiramycin	J01FA02	No
Spiramycin + Metronidazole	J01RA04	No
St John's wort	HN06AW	No
Sulbutiamine	A11D A02	No
Sulpiride	N05A L01	No
Suramin	P01C X02	No
Tebonin	Herbal	No
Tegaserod	A03A E02	No
Telithromycin	J01F A15	No
Telmisartan	C09C A07	No
Telmisarten + Hydrochlorothiazide	C09DA07	No
Tetrazepam	M03B X07	No
Tetryzoline	S01GA02	No
Tetryzoline	R01AA06	No
Tetryzoline combination	S01GA52	No
Theobromine + Garlic + Choline	C03BD01	No
Thiamazole	H03B B02	No
Thiocolchicoside	M03B X05	No
Tiabendazole	P02CA02	No
Tiapride	N05A L03	No
Tiaprofenic Acid	M01A E11	No
Tilbroquinol	P01AA05	No
Tilidine	NO2AX01	No
Tiropamide	A03A C05	No
Tixocortol + Bacitracin	R01A D57	No
Tizanidine	M03B X02	No
Tolperisone	M03BX04	No
Tolterodine	G04B D07	No

Torsemide	C03C A04	No
Tramadol + Paracetamol	N02A X52	No
Triflusal	B01AC18	No
Trihexyphenidyl	N04A A01	No
Trimebutine	A03AA05	No
Trimetazidine	C01EB15	No
Trimipramine	N06A A06	No
Triticum vulgare+2-fenos	A06AC07	No
Trolamine	D	No
Tropium	G04BD09	No
Troxerutin	C05C A04	No
Troxerutin + Heptaminol	C05C A54	No
Trypsin	B06AA07	No
Turpentine + Diprophylline	R	No
Tyrothricin	D06A X08	No
Ubibadecarenone	C01E B09	No
Urapidil	C02CA06	No
Valdecoxib	N01A H03	No
Valerian	N05CM09	No
Valsarten + hydrochlorothiazide	C09DA03	No
Vigabatrin	N03AG04	No
Vitamin B Co	A11EA	No
Vitamin H	A11HA05	No
Voriconazole	J02AC03	No
Xipamide	C03BA10	No
Zidovudine + Abacavir	J05AF30	No
Zopiclone	N05C F01	No
Cisapride	A03FA02	Withdrawn
Acetylcysteine	V03AB23	Yes
Algenate de sodium + Sodium bicarbonate	A02AH	Yes
Butylscopolamine	A03BB01	Yes
Chlorpropamide	A10BB02	Yes
Dexpanthenol	D03AX03	Yes
Diphenhydramine + Phenylephrine	R06A A52	Yes
Diphenhydramine + Pseudoephedrine	R06AA52	Yes
Ephedrine	R03CA02	Yes
Nicotinamide	A11HA01	Yes
Nortriptyline	N06AA10	Yes
Ramipril + Hydrochlorothiazide	C09BA05	Yes
Acarbose	A10B F01	Yes
Aceclofenac	M01A B16	Yes
Acetylsalicylic acid	N02BA01	Yes
Acetylsalicylic acid	B01AC06	Yes
Acetylsalicylic acid + Codeine	N02BA71	Yes
Aciclovir	J05A B01	Yes
Adenosine	C01EB10	Yes
Albendazole	P02C A03	Yes
Albumin	B05A A01	Yes
Alendronate	M05B A04	Yes
Alfacalcidol	A11C C03	Yes
Allopurinol	M04A A01	Yes
Alprazolam	N05BA12	Yes
Aluminium Hydroxide + Magnesium hydroxide	A02AD01	Yes
Aluminium Hydroxide	A02A B01	Yes
Aluminium phosphate	A02AB03	Yes

Ambroxol	R05C B06	Yes
Amikacin	J01GB06	Yes
Amiloride	C03DB01	Yes
Aminophylline	R03D A05	Yes
Aminosalicylic acid	J04A A01	Yes
Amiodarone	C01B D01	Yes
Amitriptyline	N06AA09	Yes
Amlodipine	C08CA01	Yes
Amoxicillin	J01CA04	Yes
Amoxicillin + clavulanic acid	J01CR02	Yes
Amphetamine	N06BA01	Yes
Amphotericine B	J02AA01	Yes
Ampicillin	J01CA01	Yes
Ampicillin + Sulbactam	J01CR01	Yes
Anti D (rh) immunoglobulin	J06BB01	Yes
Apomorphine	N04BC07	Yes
Astemizole	R06AX11	Yes
Atenolol	C07A B03	Yes
Atorvastatin	C10AA05	Yes
Atropine	A03B A01	Yes
Attapulgit	A07B C04	Yes
Azathioprine	L04AX01	Yes
Azithromycin	J01F A10	Yes
Bacitracin	D06A X05	Yes
Bacitracin + Neomycin	D06C	Yes
Bacitracin + Polymyxin B	D06C	Yes
Baclofen	M03BX01	Yes
Beclomethasone	R03BA01	Yes
Benzathine penicillin	J01CE08	Yes
Benzoic acid + Salicylic acid	D	Yes
Benzyl benzoate	P03A X01	Yes
Benzylpenicillin	J01C E01	Yes
Betahistine	N07C A01	Yes
Betametasone	H02AB01	Yes
Betametasone + Salicylic acid	D07XC01	Yes
Betamethasone + Gentamicin	D07CC01	Yes
Betamethasone + Neomycin	D07CC01	Yes
Bezafibrate	C10AB02	Yes
Bisacodyl	A06A B02	Yes
Bismuth subsalicylate	A	Yes
Bisoprolol	C07AB07	Yes
Boric Acid	S02AA03	Yes
Bromazepam	N05BA08	Yes
Bromhexine	R05C B02	Yes
Budesonide	R03BA02	Yes
Bupirone	N05BE01	Yes
Calamine + Zinc Oxide + Glycerin	D	Yes
Calcifediol	A11CC06	Yes
Calcitriol	A11CC04	Yes
Calcium carbonate	A12A A04	Yes
Calcium carbonate + Colecalciferol	A11CC20	Yes
Calcium carbonate + Magnesium carbonate	A12CX	Yes
Calcium folinate	V03A F03	Yes
Calcium gluconate	A12A A03	Yes
Candasarten	C09CA06	Yes

Candesartan + Hydrochlorothiazide	C09DA06	Yes
Captopril + Hydrochlorothiazide	C09BA01	Yes
Captopril	C09A A01	Yes
Carbamazepine	N03A F01	Yes
Carbimazole	H03BB01	Yes
Carbocisteine	R05CB03	Yes
Carvedilol	C07AG02	Yes
Cefaclor	J01DC04	Yes
Cefalexin	J01DB01	Yes
Cefazolin	J01DB04	Yes
Cefixime	J01DD08	Yes
Cefotaxime	J01DD01	Yes
Cefpodoxime	J01D D13	Yes
Cefradine	J01DB09	Yes
Ceftazidime	J01DD02	Yes
Ceftriaxone	J01DD04	Yes
Cefuroxime	J01DC02	Yes
Celecoxib	M01AH01	Yes
Cetirizine	R06A E07	Yes
Cetrimide	D11AC01	Yes
Charcoal activated	A07BA01	Yes
Chloramphenicol	J01BA01	Yes
Chloramphenicol	S01AA01	Yes
Chlordiazepoxide	N05BA02	Yes
Chlorhexidine	D08AC02	Yes
Chlorhexidine + Cetrimide	D08A C52	Yes
Chlorine	V07AV	Yes
Chloroquine	P01BA01	Yes
Chlorphenamine	R06AB04	Yes
Chlorphenamine + Pseudoephedrine	R06AB54	Yes
Chlorphenamine + Ephedrine	R06AB54	Yes
Chlorpromazine	N05A A01	Yes
Chlortalidone	C03BA04	Yes
Cholecalciferol + Calcium	A12AA08	Yes
Choline theophyllinate	R03DA02	Yes
Ciclopiroxolamine	D01AE14	Yes
Cimetidine	A02BA01	Yes
Cinnarizine	N07C A02	Yes
Ciprofloxacin	J01MA02	Yes
Citalopram	N06AB04	Yes
Clarithromycin	J01FA09	Yes
Clindamycin	J01FF01	Yes
Clobazam	N05BA09	Yes
Clobetasol	D07AD01	Yes
Clobetasone	D07AB01	Yes
Clomifene	G03GB02	Yes
Clomipramine	N06AA04	Yes
Clonazepam	N03AE01	Yes
Clonidine	C02AC01	Yes
Clotrimazole	G01AF02	Yes
Cloxacillin	J01AF02	Yes
Clozapine	N05AH02	Yes
Codeine	R05DA04	Yes
Colchicine	M04AC01	Yes
Cromoglycate	R01AC01	Yes

Crotamiton	D	Yes
Cyanocobalamin	B03BA01	Yes
Dalteparin	B01AB04	Yes
Deferoxamine	V03AC01	Yes
Dequalinium	R02AA02	Yes
Desloratadine	R06AX27	Yes
Desonide	D07AB08	Yes
Dexamethasone	H02AB02	Yes
Dexamethasone + Neomycin	S01CA01	Yes
Dexamethasone + Tobramycin	D07CB04	Yes
Dexchlorphenamine	R06AB02	Yes
Dextran	B05AA05	Yes
Dextromethophan	R05DA09	Yes
Dextromethorphan	R05DA09	Yes
Dextrose	B05CX01	Yes
Dextrose + Sodium Chloride	C05BB56	Yes
Diazepam	N05BA01	Yes
Diclofenac	M01AB05	Yes
Diflucortolone	D07AC06	Yes
Digoxin	C01AA05	Yes
Dihydroergotamine	N02CA01	Yes
Diltiazem	C08DB01	Yes
Diphenhydramine	R06AA02	Yes
Diphenoxylate + Atropine	A07DA01	Yes
Disopyramide	C01BA03	Yes
Domperidone	A03FA03	Yes
Dopamine	C01CA04	Yes
Doxepin	N06AA12	Yes
Doxorubicin	L01DB01	Yes
Doxycycline	J01AA02	Yes
Enalapril	C09A A02	Yes
Enoxaparin	B01A B05	Yes
Epinephrine	C01CA24	Yes
Eprosartan	C09CA02	Yes
Erythromycin	J01FA01	Yes
Erythropoietin	B03XA01	Yes
Ethambutol	J04AK02	Yes
Ethinylestradiol + Levonorgestrol	G03AA07	Yes
Ethyl chloride	N01BX01	Yes
Etodolac	M01AB08	Yes
Etofilline + Theophylline	R03DA54	Yes
Etoposide	L01CB01	Yes
Exemestane	L02BG06	Yes
Famotidine	A02BA03	Yes
Felodipine	C08CA02	Yes
Fenofibrate	C10AB05	Yes
Ferric sodium gluconate complex	B03AC07	Yes
Ferrous fumarate	B03AA02	Yes
Ferrous gluconate	B03AA03	Yes
Ferrous glycine sulfate	B03AA01	Yes
Ferrous sulfate	B03AA07	Yes
Ferrous sulfate + Folic acid	B03AD03	Yes
Fexofenadine	R06AX26	Yes
Flecainide	C01BC04	Yes
Flucloxacillin	J01CF05	Yes

Fluconazole	J02AC01	Yes
Fluocinolone	D07AC04	Yes
Fluorometholone	D07AB06	Yes
Fluoxetine	N06AB03	Yes
Fluphenazine	N05AB02	Yes
Flurbiprofen	M01AE09	Yes
Flutamide	L02BB01	Yes
Fluticasone	R03BA05	Yes
Fluticasone + Salmeterol	R03AK06	Yes
Fluvastatin	C10AA04	Yes
Fluvoxamine	N06AB08	Yes
Folic Acid	B03BB01	Yes
Formoterol	R03AC13	Yes
Framycetin	D09AA01	Yes
Furazolidone	G01AX06	Yes
Furosemide	C03CA01	Yes
Fusafungine	R02AB03	Yes
Fusidic acid	D06AX01	Yes
Fusidic acid	J01XC01	Yes
Gatifloxacin	J01MA16	Yes
Gelofusine	B05AA06	Yes
Gemfibrozil	C10AB04	Yes
Gentamicin	D06AX07	Yes
Gentamicin	J01GB03	Yes
Gentian violet	D	Yes
Ginkgo biloba	N06DX02	Yes
Glibenclamide	A10BB01	Yes
Gliclazide	A10BB09	Yes
Glimepiride	A10BB12	Yes
Glutaraldehyde	V	Yes
Glycerine	A06AX01	Yes
Glyceryl trinitrate	C01DA02	Yes
Glycine irrigation	B05CX03	Yes
Griseofulvin	D01AA08	Yes
Haloperidol	N05AD01	Yes
Hamamelis + Zinc oxide	HC05AW	Yes
Heparin	B01AB01	Yes
Hepatitis A vaccine	J07BC02	Yes
Hepatitis B vaccine	J07BC01	Yes
Human Anti Tetanus Immunoglobulin	J06BB02	Yes
Hyaluronic acid	M09AX01	Yes
Hydroxychloroquine	P01BA02	Yes
Hydralazine	CO2DB02	Yes
Hydrochlorothiazide	C03AA03	Yes
Hydrochlorothiazide+Amiloride	C03EA01	Yes
Hydrocortisone	D07AA02	Yes
Hydrogen peroxide	D08AX01	Yes
Hydroxyzine	N05BB01	Yes
Hyoscine butylbromide	A03BA03	Yes
Ibuprofen	M01AE01	Yes
Imipenem + Ciliastatin	J01DH51	Yes
Indapamide	C03BA11	Yes
Indometacin	M01AB01	Yes
Insulin human (fast)	A10AB01	Yes
Iodine	D08AG03	Yes

Ipratropium	R01AX03	Yes
Isosorbide dinitrate	C01DA08	Yes
Isosorbide mononitrate	C01DA14	Yes
Ispaghula	A06AC01	Yes
Ispaghula	A06AC01	Yes
Itraconazole	J02AC02	Yes
Ketamine	N01AX03	Yes
Ketoconazole	J02AB02	Yes
Ketoprofen	M01AE03	Yes
Ketorolac	M01AB15	Yes
Ketotifen	R06AX17	Yes
Labetolol	C07AG01	Yes
Lactated Ringer	B05BB01	Yes
Lactulose	A06AD11	Yes
Lamivudine	J05AF05	Yes
Lamotrigine	N03AX09	Yes
Lansoprazole	A02BC03	Yes
Levamisole	P02CE01	Yes
Levocetirizine	R06AE09	Yes
Levodopa + Benserazide	N04BA02	Yes
Levofloxacin	J01MA12	Yes
Levonogestrel	G03AC03	Yes
Levothyroxine	H03AA01	Yes
Lidocaine	N01BB02	Yes
Lidocaine + Adrenaline	N01BB52	Yes
Lidocaine + Prilocaine	N01BB52	Yes
Lincomycin	J01FF02	Yes
Lindane	P03AB02	Yes
Liquid paraffin	A06AA01	Yes
Lisinopril	C09AA03	Yes
Lithium carbonate	N05AN01	Yes
Loperamide	A07DA03	Yes
Loratadine	R06AX13	Yes
Lorazepam	N05BA06	Yes
Losartan	C09CA01	Yes
Lovastatin	C10AA02	Yes
Macrogol	A06AD15	Yes
Magnesium hydroxide	A02AA04	Yes
Magnesium hydroxide + Magnesium sulphate	A12CC30	Yes
Magnesium sulphate	B05XA05	Yes
Magnesium trihydrate + Magnesium hydroxide	A12CC30	Yes
Magnesium trisilicate	A02AA05	Yes
Mannitol	B05CX04	Yes
Maprotiline	N06AA21	Yes
Mebendazole	P02CA01	Yes
Mebeverine	A03AA04	Yes
Mecillinam	J01CA11	Yes
Mefenamic Acid	M01AG01	Yes
Mefloquine	P01BC02	Yes
Meloxicam	M01AC06	Yes
Menthol+ Eucalyptus oil	M02AC	Yes
Meropenem	J01DH02	Yes
Metformin	A10BA02	Yes
Methyldopa	C02AB01	Yes
Methylphenidate	N06BA04	Yes

Methylprednisolone	D07AA01	Yes
Methylpredrednisolone sodium succinate	H02BX01	Yes
Methylsalicylate + Menthol	M02AC	Yes
Metildigoxin	C01AA08	Yes
Metoclopramide	A03FA01	Yes
Metoprolol	C07AB02	Yes
Metronidazole	J01XD01	Yes
Miconazole	D01AC02	Yes
Midazolam	N05CD08	Yes
Mirtazapine	N06AX11	Yes
Moclobemide	N06AG02	Yes
Mometasome	D07AC13	Yes
Montelukast	R03DC03	Yes
Morphine	N02AA01	Yes
Moxifloxacin	J01MA14	Yes
Moxonidine	C02AC05	Yes
Mucilar+Psyllium+Oatbran	A06AC51	Yes
Mulitivitamin + Mineral	A11AA03	Yes
Multi Vitamin	A11BA	Yes
Mupirocin	D06AX09	Yes
Nabumetone	M01AX01	Yes
Nalidixic Acid	J01MB02	Yes
Naloxone	V03AB15	Yes
Naproxen	M01AE02	Yes
Neomycin	D06AX04	Yes
Neomycin + Bacitracin		Yes
Neomycin + Polymycine B	D06C	Yes
Neomycin + Polymyxin + G	D06C	Yes
Nicorandil	C01DX16	Yes
Nicotinic acid	C04AC01	Yes
Nifedipine	C08CA05	Yes
Nimodipine	C08CA06	Yes
Nitrofurantoin	J01XE01	Yes
Norethisterone	G03AC01	Yes
Norfloxacin	J01MA06	Yes
Norgestrel + Ethinyl estradiol	G03AA06	Yes
Nystatin	A07AA02	Yes
Nystatin+ Triamcinolone	G01AA51	Yes
Ofloxacin	J01MA01	Yes
Olanzapine	N05AH03	Yes
Omega 3 triglycerides	C10AX06	Yes
Omeprazole	A02BC01	Yes
Ondansetron	A04AA01	Yes
Oral rehydration salt	A07CA	Yes
Orciprenaline	R03CB03	Yes
Oxymetazoline	R01AA05	Yes
Oxytetracycline	D06AA03	Yes
Oxytocin	H01BB02	Yes
Pamidronic acid	M05BA03	Yes
Pancreatic enzyme	V04CK02	Yes
Pantaprazole	A02BC02	Yes
Paracetamol	N02B E01	Yes
Paracetamol+ Codeine	N02BE71	Yes
Paraldehyde	N05CC05	Yes
Paroxetine	N06AB05	Yes

Pentazocine	N02AD01	Yes
Pentoxyfilline	C04AD03	Yes
Permethrin	P03AC04	Yes
Pethidine	N02AB02	Yes
Pheniramine	R06AB05	Yes
Phenobarbitone	N03AA02	Yes
Phenoxymethylpenicillin	J01CE02	Yes
Phenytoin	N03AB02	Yes
Pholcodeine	R05DA08	Yes
Phytomenadione	B02BA01	Yes
Pilocarpine	S01EB01	Yes
Pioglitazone	A10BG03	Yes
Piperacilin	J01CA12	Yes
Piperacillin + Tazabactam	J01CR05	Yes
Piroxicam	M01AC01	Yes
Pivampicillin	J01CA02	Yes
Pivmecillinam	J01CA08	Yes
Potassium chloride	A12BA01	Yes
Potassium permanganate	D08AX06	Yes
Povidone Iodine	D08AG02	Yes
Pravastatin	C10AA03	Yes
Prednisolone	H02AB06	Yes
Prednisolone	S01BA04	Yes
Primaquine	P01BA03	Yes
Procaine Benzylpenicillin	J01CE09	Yes
Procaine penicillin (fortified)	J01CE09	Yes
Prochlorperazine	N05AB04	Yes
Proflavine	D08AA	Yes
Proguanil	P01BB01	Yes
Promazine	N05AA03	Yes
Promethazine	R06AD02	Yes
Promethazine + Ammonium chloride	R06AD52	Yes
Propantheline	A03AB05	Yes
Propofol	N01A X10	Yes
Propranolol	C07A A05	Yes
Pseudoephedrine	R01BA02	Yes
Pseudoephedrine + Chlorphenamine	R01B A52	Yes
Pyrantal	P02CC01	Yes
Pyridoxine	A11HA02	Yes
Quetiapine	N05AH04	Yes
Quinapril	C09A A06	Yes
Quinine	P01BC01	Yes
Ramipril	C09A A05	Yes
Ranitidine	A02B A02	Yes
Ribaverin	J05AB04	Yes
Rifampicin	J04A B02	Yes
Rifampicin + isoniazid + pyranzinamide	J04AM06	Yes
Risperidone	N05AX08	Yes
Rosiglitazone	A10BG02	Yes
Rosuvastatin	C10A A07	Yes
Roxithromycin	J01F A06	Yes
Salbutamol	R03AC02	Yes
Salmeterol	R03AC12	Yes
Selenium sulfide	D01A E13	Yes
Senna glycosides	A06A B06	Yes

Sertraline	N06A B06	Yes
Silver sulphadiazine	D06B A01	Yes
Simvastatin	C10A A01	Yes
Sodium bicarbonate	B05CB04	Yes
Sodium chloride	B05C B01	Yes
Sodium hypochloride	D08AX07	Yes
Sodium phosphate	B05XA09	Yes
Spirolactone	C03D A01	Yes
Streptomycin	J01GA01	Yes
Sulfacetamide	S01A B04	Yes
Sulfamethoxazole + Trimethoprim	J01E E01	Yes
Sulfasalazine	A07EC01	Yes
Sulfur	D10AB02	Yes
Sulfur + salicylic acid	D11AC08	Yes
Sulindac	M01AB02	Yes
Sulphadoxine+ Pyrimethamine	P01BD51	Yes
Sultamicillin	J01C R04	Yes
Sumatripan	N02CC01	Yes
Tenoxicam	M01A C02	Yes
Terbinafine	D01BA02	Yes
Terbutaline	R03A C03	Yes
Tetanus toxoid	J07AM01	Yes
Tetracycline	J01AA07	Yes
Theophylline	R03D A04	Yes
Thiopental	N01A F03	Yes
Timolol	S01E D01	Yes
Tinidazole	J01X D02	Yes
Tioconazole	G01AF08	Yes
Tiotropium	R03B B04	Yes
Tobramycin	J01GB01	Yes
Tolfenamic acid	M01A G02	Yes
Tolnaftate	D01A E18	Yes
Tramadol	N02A X02	Yes
Tranexamic acid	B02AA02	Yes
Triamcinolone	H02AB08	Yes
Trimethoprim	J01E A01	Yes
Tripolidine	R06A X07	Yes
Tripolidine + Pseudoephedrine	R01BA52	Yes
Trypsin + Chymotrypsin	M09A B52	Yes
Typhoid vaccine	J07AP02	Yes
Valproic Acid	N03A G01	Yes
Valsartan	C09C A03	Yes
Vancomycin	J01XA01	Yes
Vaseline	D	Yes
Venlafaxine	N06A X16	Yes
Verapamil	C08D A01	Yes
Vitamin A	A11CA01	Yes
Vitamin A + D	A11CB	Yes
Vitamin B	A11DA	Yes
Vitamin B complex	A11EA	Yes
Vitamin B1	A11DA01	Yes
Vitamin B12	B03BA53	Yes
Vitamin B6	A11HA02	Yes
Vitamin C	A11GA01	Yes
Vitamin D	A11CC01	Yes

Vitamin E	A11HA03	Yes
White soft paraffin	D02CA	Yes
Xylometazoline	R01AA07	Yes
Zinc oxide	D02AB	Yes
Ziprasidone	N05AE04	Yes
Zolpidem	N05C F02	Yes
Zuclopenthixol	N05A F05	Yes
Rofecoxib	M01A H02	Yes

Epidemiological Unit
Ministry of Healthcare, Nutrition & Uva Wellassa Development
231, de Saram Place, Colombo 01000, Sri Lanka
Telephone: (+94-1-)2695112, (+94-1-)2681548, Fax: (+94-1-)2696583, E-mail: epidemi@slinet.lk and
chcpidi@slinet.lk

My No.: EPI/77/2004
18th January 2005.

Secretary,
Drug Advisory Sub-Committee,
Ministry of Healthcare,
Colombo 10.

USE OF DONATED STOCK OF INFLUENZA VACCINE FOR TSUNAMI VICTIMS, UNRESTRICTED FREE FLOW OF DONATED VACCINES INTO THE COUNTRY

2,500 doses of Influenza vaccine, "Surface Antigen Inactivated" produced by CHIRON vaccines Italy has been brought to Sri Lanka and it is now stored in the cold rooms of the Epidemiological Unit. This particular NGO has informed that this vaccine is intended for use in the North East provinces.

Apart from the product insert (a copy is attached for your reference) no other documents accompanied the vaccine stocks.

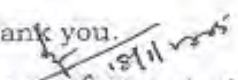
Sri Lankan Customs has cleared this particular stock of vaccines to the NGO without the usual clearance. In an earlier instance also another stock of vaccines was cleared by the Customs without proper documentation and is now lying in the Epidemiological Unit cold stores.

It also came to be known that several foreign medical teams were able to get clearance for some stocks of vaccine which they have used in some of the refugee camps without knowledge of any of the local health authorities.

I would be thankful if you could lay down the procedure and inform the concerned authorities regarding the import of such biological products into the country as donations.

Also I would like to have your advice as to whether the stock of influenza vaccine mentioned above could be allowed use by the NGO concerned.

Thank you.


Dr M R N Abeysinghe
Epidemiologist.

c.c.- 1. Addl. Secretary
2. D.G.H.S.
3. DDG (PHS)
4. D (MSD)
5. D (M.S.& T)

} Ministry of Healthcare

pi/:

Annex 5

TSUNAMI DOCTORS MEDICINE BURNS BOY'S THROAT

A three-year old boy who was given a dose of 'syrup' by a team of doctors who arrived at the tsunami - hit areas has been admitted to the Karapitiya hospital with a history of his throat being burnt.

It is also said that this syrup was given by a group of a doctors from the Karapitiya hospital.

Although the bottle carried the label 'Chlorpheniranine - maleate syrup', the content of bottle was meant to clean wound.

The mother of the boy has complained to the Dodanduwa police and Galle Human Rights Commission.

In her complaint to HRC, she has said that that when they were displaced due to the tsunami, her son had a fever and a group of doctors from the Karapitiya hospital who visited gave her two bottles with seals intact and gave instructions as to how it should be administered.

By that time she had already taken treatment from another doctor and hence kept the two syrup bottles safely. When her son fell sick again, under the advice of their family doctor, the seals were broken and half a teaspoonful was given to her son and his throat burnt.

The victim is Hashin Dushan Weerasuriya, the son of K.W.Dushani of Dodanduwa

By : Vineetha Gamage

Source: Daily Mirror 22nd march 2005

Annex 6

Questionnaire for field survey of pharmacists working in tsunami affected areas

Did you encounter any one of the following problems regarding the drugs donated from other countries and indicate to what extent (as a percentage) it was a problem

Problem	Percentage									
	10	20	30	40	50	60	70	80	90	100
1. Unable to read language										
2. Drugs not used in Sri Lanka										
3. Dosage form not used in Sri Lanka										
4. Dosage strength not used in Sri Lanka										
5. Combination not used in Sri Lanka										
6. Already expired drug										
7. Short expiry dates										
8. Unable to adhere to recommended storage conditions										
9. Storage conditions not indicated										
10. Space for storage inadequate										
11. Unable to maintain inventory										
12. Drugs not relevant for use in your Hospital										

PHOTOGRAPHS

PHOTOGRAPH - 2:1



PHOTOGRAPH - 2:2



PHOTOGRAPH - 2:3



PHOTOGRAPH - 2:4



PHOTOGRAPH - 2:5



ISBN 955-902152-4



9 789559 021520