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**MEDICINES AND INTERNATIONAL
AID-
CASE STUDIES**

Diplomarbeit

zur Erlangung des akademischen Grades einer Magistra
an der Naturwissenschaftlichen Fakultät der Karl
Franzens-Universität Graz und der
School of Pharmacy, University of Otago, New Zealand

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Graz, Dunedin
2011

ABSTRACT

The aim of this project is to raise public awareness of the benefit and problems of drug donations, because the term “International Aid” involves significant issues that go far deeper than general public opinion. Therefore, it is important to have different perspectives on the topic and to be aware of the different types of donations. It will examine the systems and background of motives and problems, as well as the donor type and the general process of international drug donations.

At an approximate estimate, 5% to 40% of the drugs that are marketed in western European countries are not used. At first glance, donating these leftover drugs appears to be an appropriate and charitable option for countries that are desperately in need of essential medicines. By fighting many fatal diseases and eradicating others, drug producers have contributed to lowering mortality levels in many parts of the world. However drugs must be used carefully in order to ensure safety and efficacy. Skilled pharmaceutical personnel, labelling and strict regulations on drug usage can help prevent serious side effects and encourage appropriate use. In developing countries these criteria are difficult to fulfil. Consequently, inappropriate and expired drugs may cause more harm than good.

This report is outlined in four sections. The first chapter looks at the impact and significance of the World Health Organization and aims to question the accomplishments and importance of the WHO Guidelines for Drug Donations, established in 1996.

The second part of the study looks at structures and background information concerning humanitarian organizations that have specialized in providing and

distributing drugs. Therefore, the second part focuses on non-governmental organizations (NGOs), as well as international agencies active in humanitarian relief that have been established in order to alleviate poverty and health issues.

Donations can be provided as a support during natural disasters, in addition to donated medicines over the long term to fight an epidemic disease. The third section examines the treatment of common infectious diseases in specific regions that “International Aid” tries to fight, along with the donations made in response to emergency situations like the Tsunami in 2004. The worldwide coordination of national and international activities in order to fight infectious diseases such as AIDS, malaria, SARS, tuberculosis, and cholera represent a very significant task of the World Health Organization.

On the basis of particular case studies discussed in the fourth section, the project’s objective is to assess whether these tasks have been successfully accomplished or not. In disaster-struck areas, health workers first endeavour is to save lives and fight the outbreak of diseases. The study explores the problems that inappropriate drug donations have caused, by collecting publicly available information, including interviews given by local health professionals who were confronted with these issues. It is crucial to expand general public consciousness about global health topics in order to better accomplish small steps towards health equity and an acceptable global health status. The project is reviewing relevant information in order to improve public awareness of the problems often related to drug donations. The findings can be used as a practical introduction for people who have been unfamiliar with these issues in order to encourage them to start questioning aid, donations and donor companies.

KURZFASSUNG

Das Ziel dieser Diplomarbeit ist es, die Nutzen und Probleme von Arzneimittelspenden zu analysieren. Schätzungen zufolge werden 5% bis 40% der Medikamente, die von westeuropäischen Ländern in Verkehr gebracht werden, nicht verwendet. Auf den ersten Blick erscheint es als geeignete und karitative Option diese „Reste“ an Länder zu spenden, denen es an lebenswichtigen Arzneimitteln fehlt. Medikamente müssen allerdings mit Bedacht eingesetzt werden, um Sicherheit und Wirksamkeit zu gewährleisten. Qualifiziertes pharmazeutisches Personal, die korrekte Kennzeichnung und strenge Verordnungen über Medikamentenkonsum kann zur Vermeidung schwerer Nebenwirkungen erheblich beitragen. In Entwicklungsländern sind diese Kriterien jedoch schwer zu erfüllen.

Die Diplomarbeit ist in vier Abschnitte eingeteilt. Das erste Kapitel befasst sich mit der Weltgesundheitsorganisation (WHO), mit dem Ziel die Bedeutung der 1996 gegründeten „Richtlinien für Arzneimittelspenden“, zu hinterfragen.

Der zweite Teil der Studie befasst sich mit Strukturen und Hintergründen humanitärer Organisationen, die sich auf die Bereitstellung und Verteilung von Medikamenten spezialisiert haben. Daher konzentriert sich der zweite Teil auf nichtstaatliche Organisationen (NGOs), sowie internationale Agenturen. Weiters umfasst dieser Abschnitt die Entstehung und erste Schritte zur Einrichtung globaler Gesundheitsorganisationen, die zur Gründung von zahlreichen NGOs auf der ganzen Welt geführt haben. Programme wie "Aid for Aids" oder das "Carter Center Schistosomiasis Control Programme", konzentrieren sich auf bestimmte Krankheiten in bestimmten Gebieten, sowie auf die Versorgung armer und ländlicher Bevölkerungsgruppen mit entsprechenden internationalen Medikamentenspenden. Der vorliegende Bericht beschreibt die Arbeit anerkannter Spenderorganisationen

wie World Vision und "Ärzte ohne Grenzen" (auch als Medicines Sans Frontières, MSF bekannt), zusammen mit der Europäischen Kommission für humanitäre Hilfe und Katastrophenschutz (ECHO) als ihren wichtigsten Kooperationspartner.

Spenden können als Unterstützung bei Naturkatastrophen, oder langfristig zur Bekämpfung von Epidemien eingesetzt werden. Der dritte Abschnitt diskutiert die Behandlung von Infektionskrankheiten in bestimmten Regionen, die die "Internationale Hilfe" versucht hat zu bekämpfen, sowie Arzneimittelspenden, die infolge einer Notsituation wie dem Tsunami im Jahr 2004, bereitgestellt wurden. Die weltweite Koordination von nationalen und internationalen Aktivitäten im Kampf gegen Infektionskrankheiten wie Aids, Malaria, SARS, Tuberkulose, und Cholera stellt eine wesentliche Aufgabe der Weltgesundheitsorganisation dar. Anhand von Fallstudien im vierten Abschnitt wird diskutiert, ob diese Aufgaben erfolgreich bewältigt wurden oder nicht. In Katastrophengebieten gilt als erstes Bestreben, Leben zu retten und den Ausbruch von Krankheiten abzuwehren. Die Arbeit untersucht anhand öffentlich zugänglichen Informationen die Probleme, die unangemessene Arzneimittelspenden verursacht haben. Die Angaben in diesem Bericht stammen aus Sammlungen allgemeiner Debatten mit Empfängern inakzeptabler Spenden, sowie den örtlichen Gesundheitsbehörden.

Das Spenden lebenswichtiger Medikamente hat sich mittlerweile zu einem sehr wichtigen Bereich der internationalen Hilfe entwickelt. Arzneimittel haben schließlich wesentlich dazu beigetragen viele Krankheiten zu bekämpfen und die Lebensqualität in weiten Teilen der Welt zu verbessern. Ohne geregelte Abläufe sowie genauen Kontrollen, können unangemessene und abgelaufene Medikamente jedoch mehr Schaden anrichten als helfen. Grundlegende Ideen und Systeme bestehen bereits, und werden bei guter Ausführung mit Sicherheit Erfolge zeigen.

LIST OF ABBREVIATIONS

ARV	Antiretroviral (drugs/therapy/treatment)
BMS	Bristol Meyer Squibb
DAP	Drug Action Programme
DWB	Doctors Without Borders
EAR	Emergency Aid Reserve
ECHO	Humanitarian Aid department of the European Commission
E.U	European Union
GAVI	The Global Alliance for Vaccines and Immunisation
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GHI	Global Health Initiative
GMP	Global Malaria Programme/ Good Manufacturing Practice
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INGO	International Non-Governmental Organization
INN	International Non-proprietary Name
IRS	Internal Revenue Service
MDG	Millennium Development Goals
MEP	Malaria Eradication Programme
MSF	Médecins Sans Frontières
NGO	Non-Governmental Organization
PSFCI	Pharmaciens Sans Frontières Comite International
R&D	Research and Development
SSA	Sub-Saharan Africa
TB	Tuberculosis
UIA	Union of International Associations
U.N	United Nations
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHA	World Health Assembly
WHO	World Health Organization

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ACKNOWLEDGEMENT

This project was conducted at Otago University in Dunedin, New Zealand. It has been an honour to be part of the university, as I felt very comfortable and supported throughout my stay. It is my pleasure to thank all the people and staff at the School of Pharmacy, who made me feel very welcome as a visiting researcher. I am very grateful for all the hospitality extended to me. Therefore I would like to take this opportunity to show my gratitude to my supervisor Dr. Susan Heydon, who has made available her support in many ways. Her assistance and encouragement helped me to expand my view and knowledge during the completion of this thesis. Moreover, I would like to thank her for carefully correcting my grammar and mistakes as well as being very patient to teach me how to express my thoughts.

Also, I would like to express my thanks to my Austrian supervisor Ao.Univ.-Prof. Dr. Astrid Ortner, whose assistance in the completion of this project has been very helpful and important to me. I am particularly grateful for her support and efforts, as I would have been completely lost without her guidance.

Most of all I would like to show my deepest gratitude to my family and partner, who have enabled this great journey with their help and understanding. I am very fortunate to have a family who has always been an endless source of encouragement and support. I could not have done this without them!

Thank you!

INTRODUCTION

The term “International Aid” has many facets. In the popular mind it is often associated with in-kind donations for those in need and often referred to as “charity”, which has also become an expression frequently used in the media to “reveal” the genuine and well-intentioned side of large companies.¹ In fact, these terms involve significant issues that go far deeper than general public opinion. In order to understand the meaning of “International Aid” more fully, it is important to have different perspectives on the topic and to be aware of the different types of donations. In this regard, international drug* donations have become a very important sector of international aid. It is, however, important to draw a distinction between drug donations provided as a support during natural catastrophes as a response to a disaster related event, war, or other kind of emergency situations, and those that aim to improve and sustain global health status such as establishing vaccination initiatives to combat epidemic diseases over the long term.

The aim of this project is to raise public awareness of the benefit and problems of drug donations. It will examine the systems and background of motives and problems, as well as the donor type and the general process of international drug donations. It is crucial to expand general public consciousness about global health topics in order to better accomplish small steps towards health equity and an acceptable global health status. The project’s aim was to gather and review relevant information in order to improve public awareness of the problems often related to drug donations. The findings can be used as a practical introduction for people who have been unfamiliar with these issues in order to encourage them to start questioning aid, donations and donor companies.

* In the report, both terms Medicines and Drugs are used but do not refer to any illicit substances.

To achieve these goals, this project has referred to many articles from magazines, case studies, statistics and donors websites. The generally used search engines besides Google®, have been Pubmed and Google® scholar which allowed access to specific articles and information about research projects and case studies. Moreover, the Internet has contributed significantly to gathering key facts and numbers as well as sufficient information including considerable details about finances and payment transactions. In direct contrast to transparent donors homepages, which praise their humanitarian ventures, it is striking that academic articles about reliable case studies have overall been very negative.² Even though major organizations provide detailed insight into their finances, it appeared complicated to evaluate the reliability of these numbers.

At an approximate estimate, 5% to 40% of the drugs that are marketed in western European countries are not used.³ At first glance, donating these leftover drugs appears to be an appropriate and charitable option for countries that are desperately in need of essential medicines. By fighting many fatal diseases and eradicating others, drug producers have contributed to lowering mortality levels in many parts of the world.⁴ However drugs must be used carefully in order to ensure safety and efficacy. Skilled pharmaceutical personnel, labelling and strict regulations on drug usage can help prevent serious side effects and encourage appropriate use. In developing countries these criteria are difficult to fulfil. Consequently, inappropriate and expired drugs may cause more harm than good. The major aim of drug donations is to provide the medicines required to treat and prevent diseases, nevertheless they repeatedly cause problems. According to the World Health Organization (WHO), the most commonly reported problems related to drugs provided in an emergency situation are both a failure to meet the recipient country's

needs and the lack of skilled pharmaceutical personnel who are familiar with the proper usage of the provided drugs.⁵

This report is outlined in four sections. The first chapter looks at the impact and significance of the World Health Organization as a major international health institution on a global scale. The objective is to examine the structure, as well as the function and purpose of the World Health Organization in terms of drug donations and the support for the establishment of effective and economic healthcare systems in the developing world. The WHO's major endeavour has always been to improve the international public health status and to accomplish the containment of infectious diseases all over the world.⁶ The constitution stresses providing tools in order to reach these objectives for all people, consequently reducing health inequity. With reference to drug donations and improving the health of populations throughout the world, the first section aims to question the accomplishments and importance of the WHO Guidelines for Drug Donations, established in 1996.⁷ With 12 articles, these Guidelines are based on four core principles to ensure quality and compliance of donated drugs, received from a reliable source.⁵ Furthermore, they are designed to prevent a financial burden to the recipient country, as the costs of the correct disposal of excessive and inappropriate drugs, may lead the recipient country into more problems and appears less likely to meet the countries needs. This section includes a list of the most significant WHO guidelines and discusses problems and achievements.

The second part of the study looks at structures and background information concerning humanitarian organizations that have specialized in providing and distributing drugs. Therefore, the second section focuses on non-governmental organizations (NGOs), as well as international agencies active in humanitarian relief,

that have been established in order to alleviate poverty and health issues. Understanding global aims and endeavours is a key element to assessing the purposes and quality of the kind of aid NGOs are providing.

The section outlines concerns about the power and influence of international health organizations such as the WHO, in order to objectively estimate the actual feasibility of improving global health status. It discusses coordination and funding of non-governmental organizations. The fact that Non- governmental Organizations mostly receive money from government sources, raises questions about their ability to act in a non-governmental and independent manner.

Additionally, this section includes the emergence and first steps towards the establishment of global health organizations, beginning with the development of ideas to relieve suffering, which led to the foundation of thousands of non-governmental organizations across the globe. Many different types and classifications of NGOs can be found. Programmes like “Aid for Aids” or the “Carter Center Schistosomiasis Control Programme”, concentrate on specific diseases in certain areas, to supply the poor and underprivileged, rural and marginalized populations with appropriate drug donations. Focusing on international drug donations and international aid this report outlines the work of well-known and approved donor organizations such as World Vision and the Nobel-Prize winning programme “Doctors Without Borders” (also known as Medicines Sans Frontières, MSF), along with the European Commission- Humanitarian Aid and Civil Protection (ECHO) as their most important cooperation partner.

Donations can be provided as a support during natural disasters, in addition to donated medicines over the long term to fight an epidemic disease. The third section examines the treatment of common infectious diseases in specific regions that

“International Aid” tries to fight, along with the donations made in response to emergency situations like the Tsunami in 2004. The worldwide coordination of national and international activities in order to fight infectious diseases such as AIDS, malaria, SARS, tuberculosis, and cholera represent a very significant task of the World Health Organization.

On the basis of particular case studies discussed in the fourth section, the project’s objective is to assess whether these tasks have been successfully accomplished or not. In disaster-struck areas, health workers first endeavour is to save lives and fight the outbreak of diseases. The study explores the problems that inappropriate drug donations have caused, by collecting publicly available information, including interviews given by local health professionals who were confronted with these issues. The report draws on statements of former staff in pharmaceutical businesses, and gathered information provided by websites of non-governmental organizations and international health organizations including the WHO and aid workers in recipient countries. Referring throughout this study to many articles that have been found on the Internet, the general experience with discussions about international aid, has been that health workers are worried about debating openly about these issues, because they fear that donations might stop. Several cases occurred, when authorities both turned down and ignored complaints and reports about problems linked to unsolicited drug donations². Furthermore, those who had enough courage to discuss the issues of unacceptable donations had to face adverse consequences by their governments. Subsequently, authors of articles quoted in this study have protected their references and did not publish any names. Furthermore, spokesmen of various pharmaceutical companies have been very reluctant to give interviews about individual cases. Therefore the information gathered in this report had to be collected from these general discussions with the

recipients of unacceptable donations, as well as local health workers and government ministers.

CHAPTER 1

THE WORLD HEALTH ORGANIZATION AND DONATING MEDICINES

“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.⁸

WHO definition of health

The World Health Organization (WHO) was founded in New York on April 7, 1948, as a specialized unit of the United Nations. Its main aim is on improving international public health status as well as accomplishing both the containment and eradication of infectious diseases throughout the world.⁶ The constitution demands to provide tools in order to reach these objectives for all people, consequently reducing health inequity. To achieve its aims the WHO has established numerous international programmes and activities in order to fight infectious diseases, such as AIDS and malaria through supporting efforts to eradicate and control global diseases that kill millions of people in the developing world. Additionally, the WHO sponsors the development and donation of vaccines and medicines.⁹

1.1 The World Health Organization - Introduction

In 1945 the United Nations declared that health was “fundamental to the attainment of peace and security”.¹⁰ The foundation of an international health organization to “consider the scope of, and the appropriate machinery for, international action in the field of public health and proposals for the establishment of a single international health organization of the United Nations”¹¹ led into the establishment of a global

health organization that connected world politics and world health, in order to coordinate global health issues.⁹

Soon after its foundation as a specialized unit of the U.N in 1948, the WHO was confronted with several problems related to decentralization and membership. Additionally, the organization's Malaria Eradication programme (MEP) of the 1950s and 1960s turned out to be the WHO's greatest failure. The rise and fall of this initiative will be discussed in the following chapter. In contrast, in 1980, the WHO announced its major accomplishment by declaring that smallpox had been eradicated, after more than 20 years of fighting the disease, when the World Health Assembly announced that the "smallpox eradication had been achieved throughout the world"¹² in May 1980.

The World Health Organization now has 193 member states; its headquarters are in Geneva, Switzerland.⁶ Membership of the WHO is at the discretion of every state.

1.2 Governance and Financing

The financial affairs of the World Health Organization are regulated by its key elements, the World Health Assembly (WHA), the Executive Board and the Secretariat.

- The World Health Assembly represents the decision-making body, where all members of the WHO gather every year to discuss financial and organizational affairs as well as future programmes and activities. Dr. Margaret Chan was elected by the WHA after nomination by the Executive Board to be General-Director on the 9th of November 2006.
- The Executive Board consists of 34 health care experts, elected for a period of

3 years at the World Health Assembly. The major task of the Board is to supervise the assembly's guidelines and decisions.

- The WHO's Secretariat functions under the supervision of the Director-General, who is the chief technical and administrative officer of the Organization. The headquarters is in Geneva with six regional offices in Brazzaville (Africa), Washington D.C (America), New-Delhi (South-East Asia), Copenhagen (Europe), Kairo (Eastern Mediterranean) and Manila (Western Pacific). Each regional committee enjoys notable autonomy to implement and realize the organizations activities.⁹

In 2006-2007, US\$ 915 million of the programme budget (in total US\$ 3313 million) adopted by the WHA were provided as membership dues, whereas 72% had to be financed by voluntary contributions of the member states. In 2008-2009 the budget was raised to US\$ 4.227 million, with the financial solvency of each state determines the amount of contribution. The voluntary payment was predominately given by the United States, the United Kingdom, Canada, Norway, Sweden and the Netherlands. The remaining amount originated in voluntary contributions from other international organizations, charity several services provided by the World Health Organization.¹³

Projects today are often funded by Public Private Partnership, such as the Global Alliance for Vaccines and Immunization (GAVI), that obtained about 75 % (US\$ 750 million) of its financial resources from the Bill and Melinda Gates Foundation ¹⁴, and the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), which was established in 2002 at the G8 meeting in Okinawa. The WHO (along with UNAIDS and the World Bank) is a non-voting member of the GFATM Board and has allocated over US\$ 11,4 billion for vaccination programmes.¹⁵

1.3 Accomplishments

There here have been many efforts to eradicate several diseases dominant in developing countries, such as yellow fever, bilharzia, malaria and poliomyelitis.

The “**Global strategy for All by the Year 2000**” which was been issued by the WHO in 1981, has had a significant influence on health policies over the past three decades. In the 1980s, numerous international agencies targeted the immunization of children against a group of vaccine-avoidable conditions such as polio, tuberculosis, diphtheria, tetanus and measles. This project was successful in raising the proportion of the world’s immunised children from 20% (in 1984) to 75% (1990).^{16 (page 59)} In 1997 it was reported that 88% of the infants in third world countries were vaccinated against tuberculosis and 79% against measles. However 2 million children died from vaccine-preventable diseases in the late 1990’s. This situation led to the foundation of the **Global Alliance for Vaccines and Immunisations (GAVI)**, which is mainly funded by the Bill and Belinda Gates Foundation in order to enlarge access to safe vaccines. It is also intended to invest in research for new vaccines against malaria and AIDS.^{16 (page 59)}

1.3.1 WHO Smallpox Eradication Programme

The eradication of smallpox was the most significant accomplishment of the World Health Organization. The WHO campaign was initiated in 1967, at the time at which 10 million cases of smallpox were reported in 33 countries, concerning over 1.2 billion persons (approximately half in India). These countries included many of the poorest countries in the world. As a result of the efforts of many people the disease was progressively eradicated by a scheme based on supervision and containment rather than focusing on mass vaccination. The last case of smallpox was reported

only ten years after the beginning of the eradication campaign, in Somalia in 1977. Two years later, the WHO's Global Commission for the Certification of Smallpox eradication declared that the disease had been successfully eradicated .^{16 (page 57);17 (page 129)} In May 1980 the World Health Assembly concluded that the "smallpox eradication had been achieved throughout the world".¹²

1.3.2 WHO Malaria Eradication Programme (MEP)

In contrast to the effective smallpox eradication efforts, the WHO's Malaria Eradication programme (MEP) has not been successful. The programme was established by the World Health Organization in 1955 as an attempt to fight a disease that caused 2.5 million deaths each year.^{9 (page 126)} Malaria elimination represented the first eradication programme that needed the participation of dozens of countries. After the structural issues of the WHO had been resolved, health experts believed that eliminating malaria was mainly a technical issue. It was publicly acknowledged as the greatest and most remarkable undertaking in the history of global health collaboration for numerous reasons as it was the first mass eradication initiative conducted by an international health organization. However, this goal was too unrealistic and costly to succeed. Despite early success in the 1960s, the MEP was mostly ineffective due to many factors such as the development of resistance of the mosquitoes and the limited financial support by the donors.^{9 (page 26)} Furthermore, the misconception of eradicating this global menace led donors and activists to lose sight of efficient efforts. For example, Venezuela was the first country to announce that malaria has been eradicated in 1961, but had a major malaria crisis in 1985. The continuing epidemic reappearance of epidemic malaria raised questions about whether WHO activities against the disease had been appropriate or had failed due

to political and non-technical motives. The MEP was more a paradigm of the rising importance of the WHO in contrast to its predecessor associations in order to prove the organization's power as an "executing agency".^{9 (page 26)}

The rise and fall of the MEP had a more significant impact on the WHO's health philosophy and strategy than any other mass initiative. It offered a chance to analyse a campaign that started with vast support, to understand and learn from mistakes as distinct from later and previous global health missions. Consequently the MEP was re-evaluated in 1969 and replaced the initial elimination objectives with a "Malaria **Control**" programme. Furthermore, an "eradication" programme needed to be financed for a short period of time only, whereas a "control" programme required financial support over the long term. Fortunately, international aid money became available to provide assistance in such campaigns with the result that the programme was able to decrease the annual death rate over the past two decades.^{9 (page 137)}

The current Global Malaria Programme (GMP) is now focusing on malaria supervision, control and evaluation, guidelines formulation, technological support, and organization of WHO's global efforts to battle malaria. To date the WHO has established numerous programmes, which are active in malaria vaccine development, diagnosis and treatment.¹⁸ However, eradicating malaria completely still is an intangible goal.

1.4 Programmes and Projects

Apart from coordinating national and international activities in order to fight and control infectious diseases such as AIDS, malaria, SARS, tuberculosis, cholera and influenza, the World Health organization is also responsible for the surveillance of many other programmes. The WHO aims to encourage the development and supply

of safe and efficient vaccines and medicines and has established a large number of humanitarian programmes and projects. The WHO's website (<http://www.who.int/entity/en/>) provides a detailed list of health-related programmes that have been issued striving for an adequate global health status, including extensive information and resources.¹⁵

1.4.1 UN Development Millennium Goals

In 2000, eight Millennium Development Goals (MDGs) were established as part of the United Nations Millennium Declaration. The 191 United Nation member states are intended to achieve these goals dedicated to fight poverty, hunger, disease, illiteracy, environmental degradation and gender discrimination by 2015.¹⁹ Three of the eight MDGs are directly related to health. These are: to decrease child mortality; to improve maternal health; and to fight HIV/AIDS, malaria and tuberculosis. In 2010 the World Health Organization published an article about “20 ways that the World Health Organization helps countries reach the Millennium Development Goals“²⁰ including access to medicines that have been approved for the treatment of HIV/AIDS, tuberculosis (TB), malaria, reproductive health and other pervasive health issues in the third world. In addition the prevention of a financial burden in terms of health care for individuals, training of educated health workers, availability and surveillance of needed information and the continuation of vaccination programmes are crucial to WHO efforts.

1.5 Essential medicines

Essential medicines are “those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence

on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford".²¹ They are the focal point of global medicines policies of the World Health Organization. Almost one-third of the world's population lacks regular access to essential medicines, and this figure is thought to be as high as one half in developing countries.²¹ This lack of access to essential medicines shows great variation within the regions in developing countries. It reflects failures in health and distribution systems, and also indicates broader problems of organization, finance and delivery of health services.²²

The initial concept was first presented in 1977 and confirmed at the International Conference on Primary Health Care in the ten articles of the Alma Ata Declaration in 1978.²³ The list was meant to serve as a guide for the establishment of national essential medicines lists for developing countries. The WHO's Expert Committee for the Selection and Use of Essential Medicines has revised the list every two years. At present, the 16th edition, issued in 2009, is in force, including 350 medicines for the treatment of priority diseases. In 2007 the WHO also issued a Model List of Essential Medicines for Children.²⁴

The list is comprised of both a core list and a complementary list. The core list provides a list of necessary medicines to maintain a basic health-care system, showing the most effective, safe and economic drugs for priority diseases. The complementary list shows medicines for conditions, for which specific diagnostic or controlling services, or professional medical care and training are required.²⁵

It can be consulted as a national list of essential medicines for guidance in terms of donating, producing, purchasing and providing drugs. Drugs need to be selected carefully in compliance with local disease patterns, cost-effectiveness as well as required efficacy and safety standards. Essential medicines should be accessible in functioning health systems in sufficient quantity, in correct dosage forms, with proved quality, and at reasonable costs. Establishing a list of required essential medicines for the population can assist countries in terms of obtaining and providing drugs, to lower the expenses on health care. The WHO Model List suggests treatments for major diseases like malaria, AIDS, tuberculosis, and also chronic diseases. Essential medicines are ordered by their International Non-proprietary Name (INN) or generic name.

The WHO List has also been used to establish global lists for special circumstances. Many non-governmental organizations as well as several humanitarian programmes such as The Interagency Emergency Health Kit (2006), the United Nations Children Fund (UNICEF) and the Interagency Pharmaceutical Coordination, have implemented the WHO concept and built their drug supply system on the Model List.²⁴ The list is available from:

http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf²⁵

It is important that donors accept these policies and restrictions in order to ensure safe drug quality and assistance as well as to avoid excess and consequential expensive drug disposal. Unfortunately, donors may also have other agendas, and implement their own standards for their personal interests and benefit. This report will discuss various case studies to illustrate compliance with the WHO guidelines in Section 4 “case studies”.

1.6 WHO Guidelines for Drug Donations

International aid in terms of drug donations appears to be appropriate and charitable assistance for countries that are desperately in need of essential medicines. However, improper and expired drugs can cause more damage than good. Health-related goals fail to be achieved due to many problems linked to drug donations such as poorly educated health-workers, missing communication, greed, political instability and increasing reliance on external sources for health in war-torn and third world countries.¹⁶ Drug donations repeatedly cause problems. The most frequently reported problem relating to drugs provided in an emergency situation, is the failure to meet a country's needs or interests.⁵ Furthermore, in order to prevent a financial burden to the recipient, it is crucial to avoid excess of inappropriate donations. The costs of the disposal may lead the recipient country into more problems and appears less likely to provide assistance in an emergency situation. Drugs must be used carefully in order to assure safety and efficacy. Skilled pharmaceutical personnel, labelling and strict regulations on drug usage could prevent tremendous side effects. In developing countries these criteria are difficult to meet.

Medicines are an important factor in relieving suffering, and international humanitarian programmes can significantly benefit from donations of needed drugs. Very often the assessment of medical assistance is performed without regards to the priority needs. Many examples of unsolicited drug donations have occurred.² In order to achieve an equalized health status the World Health Organization established international *Guidelines for Drug Donations*, aiming at reducing the problems that are related to drug donations.²⁶ According to the WHO, the most common problems are outlined in the below:

1. Numerous donated drugs do not meet the recipient's needs or interest in emergency situations. They are often unknown to regional health workers and patients, and inappropriate for the local disease pattern. Most of the donated medicines do not comply with local drug policies and could cause more harm than good.
2. Donated drugs are often unsorted and labelled in a foreign language and do not provide the required information about their origin, generic name, or manufacturer.
3. Weak control leads to drugs that do not comply with the required quality standards. Donated drugs may have already expired before they arrive in the recipient country, as they were free samples brought back to pharmacies by patients. This may display an example of double standards, since these left over drugs were returned in order to dispose them correctly.
4. Unsolicited drugs, which are donated in excess, may impose a financial burden to the recipient, since the costs of the correct disposal and storage have to be covered by the recipient country. Therefore inappropriate drugs create more problems in terms of sorting, transporting and supplying and can exceed the limited transport volume. Moreover, stockpiling of unsolicited drugs can increase black market sales.

The Christian Medical Commission of the World Council of Churches and the International Committee of the Red Cross were the first organizations to establish guidelines for drug donations in 1980.²⁷ The initial guidelines set out by the WHO were issued in 1990 in collaboration with more than 100 humanitarian organizations and individual experts and were later advanced by the WHO Expert Committee on the Use of Essential Drugs.²⁸ These guidelines are directed at major international programmes active in humanitarian relief to agree with these written policies.

Therefore the initial version was reviewed in cooperation with the Division of Drug Management and Policies as well as the Division of Emergency and Humanitarian Action, and several of global experts.²⁹

The final draft of the guidelines were issued by WHO and major international agencies in May 1996.⁵ This first version was revised in 1999, when the number of co-sponsors increased. Pharmaceutical organizations such as the International Pharmaceutical Federation and “Pharmaciens Sans Frontières“ were willing to alleviate poverty and widespread health issues, based on these guidelines. They are not considered as an international regulation, but aim to act as a basis for national or international guidelines, to be monitored, modified and established by governments and organizations active in humanitarian relief and drug donations.²⁷

1.6.1 The Four Core Principles

The Guidelines for Drug Donations comprise twelve articles based on four core principles.

1. All donations must benefit the recipient. This means that all drug donations should be made in response to an expressed request in order to prevent excess of unused drugs.
2. All donations should be provided with respect for the needs and authority of the recipient. Existing government health policies as well as administrative arrangements should be encouraged.
3. Double standards in quality are to be discouraged. Drugs that do not meet the required quality standard in the donor country are not also appropriate as a donation.
4. All donations should be made through successful communication between the

donor and the recipient.²⁹

1.6.2 The Articles

1. Drug donations must always be provided as a response to an expressed need and be related to the disease pattern in the recipient country.

This regulation aims to encourage the recipients to indicate their needs. It is crucial to prevent unsolicited and unannounced drug donations.

2. All drugs ought to comply with national quality standards in the recipient country and registered in the national list of essential drugs or in the WHO Model List of Essential Drugs.

This article was established in order to ensure the compliance of donations with national drug policies. Possible exceptions can occur if drugs are required in unexpected outbreak of new diseases,

3. The packaging, dosage and chemical composition of donated drugs needs to be similar to the medicines generally applied in the recipient country.

This was set issued in order to encourage the establishment of specific training programmes and healthcare education services for health workers in order to prevent incidents related to falsely used and dosed medicines. Health workers ought to be familiar with the donated drugs to help build confidence-basis with their patients.

4. *Drugs ought to be received from a trustworthy source and meet all required quality standards. The “WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce”³⁰ should be consulted.*

This article aims to avoid double standards: drugs that do not meet the quality standards in the donor country must not be provided to others. Drugs need to be warranted for sale in the donor country, and produced in compliance with the standards of Good Manufacturing Practice (GMP).

5. *Drugs that have been given to health professionals or returned to pharmacies for disposal should not be distributed.*

Some donations are composed of redundant drug samples and prescription medicines that were sent back to pharmacies in numerous European countries.² Furthermore national governments offer incentives to drug donating companies. These drugs tend to expire close to the date they are sent as donation goods.

6. *Donated medicines must have a remaining shelf-life of at least one year. Usual delivery through diverse storage levels may take 6-9 months.*

This article aims to obviate the donation of drugs just before they expire, since these medicines would be used by patients after they have expired.

7. *Drugs should be unmistakably and legibly labelled using the generic name and expiry date. Any information should be in the local language, accompanied by correct and proper instruction for the prescriber and the patient.*

Translations of labels can be time consuming, but it will contribute to the prescribers’

understanding of the proper usage of the provided drugs. All drugs must be labelled with their INN (International Nonproprietary Name ³¹) or their authorized generic name. Unknown brand names without the INN are complicated in their proper use and can leave health workers uncertain about the correct use.

8. *All donated drugs must be accessible in larger quantity units and hospital packs.*

Large quantity packs are more economic, better to transport and more likely to comply with the supply systems in most recipient countries. This article aims to obviate donations in sample packages that are hard to manage in order to prevent logistical problems.

9. *Drugs must be packed in compliance with international shipping policies, and come with a packing list that provides detailed information about the inside of every numbered carton by “INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions”.*²⁹

This article was implemented in order to ease the management, storage and supply of disaster-related drugs. The maximum weight of each carton must not exceed 50 kilograms.

10. *The communication between donor and recipient must give sufficient information of all donations that are being contemplated, planned, or sent.*

Numerous cases of unannounced drugs have been reported.³² Information about considered drug donations facilitates management, distribution and coordination of the drug supply to the recipient. The recipient should be informed about: the amount

of the drugs with their (INN) or authorized generic name, dosage form, producer and expiration date, the assessed date of arrival and the contact details of the donor.

11. *“In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent”.*²⁹

12. *Costs of logistics planning such as transports, storage and correct handling must be borne by the donor, if not expressly arranged otherwise with the recipient.*

This provision helps the recipient in terms of cost management of unannounced and unsolicited drugs.²⁹

CHAPTER 2

NON-GOVERNMENTAL ORGANIZATIONS - THE FEASIBILITY OF IMPROVING GLOBAL HEALTH STATUS

This section focuses on non-governmental organizations (NGOs), as well as international agencies active in humanitarian relief, that have been established over the past decades to fight poverty and general health issues. Examining global efforts is a significant element in helping to understand the purposes and quality of aid that NGOs are providing. The chapter also examines the power and authority of international health organizations such as the WHO, in order to assess the feasibility of improving global health status.

2.1 History and Background

The term “non-governmental” was first set out in the United Nations Charter in 1945.³³ Non-governmental organizations were declared to be institutions that were, neither run with the intention of making a profit, nor acting in any government’s interest. NGOs were engaged in order to provide assistance during emergency situations and to support both social and economic development programmes. They are founded in order to enable countries that represent the potential beneficiaries of support or assistance programmes, to be in charge of their own decisions. Furthermore, governments ought to provide their people’s rights in terms of implementing and managing aid guidelines, rather than leaving them as passive recipients.

Many international agencies and programmes were formed during the Second World War to use the resources of the world in more organized methods for support

in health and nourishment needs. Subsequently, many industrialized governments built up large bilateral programmes that were intended to increase education, family planning and literacy in order to indirectly enhance regional health status. Additionally, a large number of universities, including several in the developing countries, initiated research in medical and public health, focusing on major delivery programmes around the globe. Furthermore, the decade after the war was characterized by the establishment of numerous specialized agencies (e.g. WHO) that intended to support countries dealing with poverty and poor health status. Moreover, the wealthier states formed agencies or bureaux that financed bilateral programmes, aimed at decreasing global health problems. In addition a large number of the international public health programmes between 1960 and 1970 were devoted to the eradication and containment of certain diseases, most importantly to the control of malaria.¹⁷

International non-governmental organizations (INGOs) are defined as “international organizations that are not founded by an international treaty”.³⁴ Many INGOs obtain funds from government sources, supplying US \$300 million per year for international development aid.¹⁵ According to the Union of International Association, while in 1854 only six INGOs had been formed, this number had increased up to 163 around 1900 and to having more than thousand INGOs by 1945. In 2007 it was stated that over 60,000 INGOs in the world had been founded ³⁵, whereas national figures are estimated even higher: Russia reported over 277,000 non-governmental organizations ³⁶, India has about 1-2 million active NGOs ³⁷.

A large number of INGOs have been in the lead to assist in initiating social development. A well-known example is the “Grameen Bank initiative” ³⁸ in Bangladesh, which has established the idea of recovering loan money at low interest

rates between involved parties in order to assure repayment onto the groups themselves.

Non-governmental organizations first began sending medical personnel based on the intent to improve the colonial government's efforts, rather than to relieve suffering and famine. Unfortunately, this scheme still exists at the present point in time, meaning that severe health issues in areas of need are going to continue. Therefore, non-governmental organizations now need to fulfil defined criteria, set forth by the Union of International Association (UIA), which allow them to be legally labelled as such.³⁹ Thus NGOs must have been founded on private initiative and be absolutely independent from any governmental influence.

2.2 Staffing

Not everyone working for NGOs is an unpaid helper. In fact, NGOs often endeavour to please their donor by engaging expatriate personnel, due to the undervaluation of local skills.³⁶ However, foreign workers are more likely to be associated with higher costs and less expertise in terms of basic connections in the areas of need.

The medical recruitment categories usually include general practitioners such as doctors, physicians, surgeons, nurses, paediatricians, dentists, and pharmacists.⁴⁰ However, problems linked to the lack of skilled pharmaceutical personnel who are familiar with the proper usage of the donated drugs appear with increased frequency.⁵ Therefore NGOs ought to both establish specific training programmes and provide healthcare education service for regional pharmacists in order to prevent incidents related to falsely applied and dosed medicines.⁴¹

2.3 Programmes' Structure and Funding

Although the term **non-governmental** organization demands independence from any governmental influence, most NGOs would remain incapable of functioning without funding and donations from governments. It is estimated that NGOs obtain up to 46% of their takings from governmental sources.³⁰ Some NGOs involved in drug stock also offer funding to other non-governmental organizations.

The non-governmental humanitarian organization World Vision reportedly accepted US\$55 million in 1998 from the American government as a result of being integrated as a non-profit corporation under the control of the State of California.³⁰ At present World Vision's funding (almost 80 per cent) is provided from private sources, such as individuals, companies and multilateral agencies. In addition gifts-in-kind are accepted, usually in the form of food goods, medicine, and garments.³¹

The Nobel Prize winning programme Doctors Without Borders (MSF) represents a charitable cooperation free from income tax. Therefore the programme is obliged to declare the "form 990" in compliance with the Internal Revenue Service (IRS) regulations, providing a detailed insight into their finances, where a full list of grants and funding can be found. This financial report enables a reliable overview about contributions and grants, programme service revenue, investment income, benefits paid to or for members, salaries, employee benefits, professional fundraising fees and the total fundraising expenses. According to this form, Doctors Without Borders assigned about 85 percent of its expenditure to its social mission—programs and civic education activities, 13% to fundraising and 1.5% to management and general (Figure 1.)⁴²

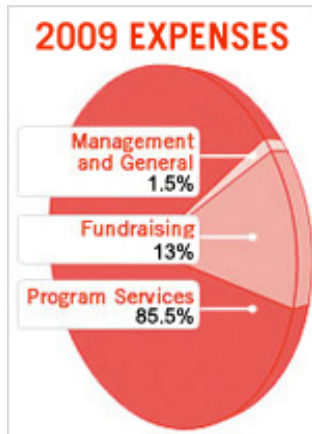


Figure 1. 2009 MSF allocated expenses ⁴²

However, the European Commission- Humanitarian Aid and Civil Protection (ECHO) programme, which was established by the European Union (EU) in 1992, offers the most detailed analysis and review of their financial resources. The EU represents the world's major humanitarian donor with ECHO being 30-40% of the whole Union humanitarian funding. The European Commission's humanitarian assistance is the only publicly funded department globally spending more than €640 million per annum on humanitarian aid. ECHO's resources were systematically strengthened, either in the course of the Emergency Aid Reserve (EAR), or by resources from the European Development Fund for totals spanning from €71 million in 2001 to €177 million in 2008.

The Commission is required to monitor the cost-effectiveness of their activities, and to eradicate any possible corrupt actions. ECHO regularly conducts audits and financial control reports in a transparent way ⁴³, showing a financial volume of €0,5 billion per annum, that the department expends for the support for more than 18 million people in over 60 countries in the world.⁴⁴

2.4 NGO Guidelines and Drug Donations

On the basis of the WHO essential drugs list, essential drug policies outline a good perspective for an appropriate supply of medicines of high quality and safety, and ensure their proper usage. Therefore limited resources are well handled and the money is invested at its best when it comes to drug donations. This concept is considered to be not only valuable at a national level.⁴⁴ Regional programmes could make use of these ideas on approved treatment and proper organization. Adherence to the WHO concept allows NGOs to control their scarce resources and to manage the supply of highly demanded medicines. Essential drug policies can lead to enhanced monitoring, education and instruction as well as more economically dispensed and stored drugs. Though many NGOs have encouraged the implementation of the concept by governments, only a small number of organizations incorporated it into their own system.⁴⁴

Unsystematic drug management can appear as a financial burden. In India, Nigeria and Kenya specialized groups aim to help and support NGOs by providing more training, communication and access to information. However the main goal of all units is to positively affect people's health status and quality of life.⁴⁵

According to ECHO, well-formulated drug policies come along with numerous advantages:

1. Scarce resources and capital are reasonably used in order to prevent the financial mishandling of limited resources.
2. Improves standard treatment monitoring to advance rational prescribing guidelines.
3. Supports reasonable drug use protocols by promoting communication between donor and recipient to avert excess and unsolicited donations.

4. Eradicates confusion
5. Clear guidelines can help in terms of making decisions such as declining non-essential drug donations.
6. Establishes proper funding activities as an aid to advising donors what to supply
7. Facilitates rational decisions in order to purchase financially sustainable products.⁴⁵

2.4.1 Implementing Essential Drugs Policies for NGOs

Drug policies ought to focus on main health issues and objectives.⁴⁵ Medicines that are distributed without awareness of the regional policy are less likely to meet the situations and needs of diverse organizations. Policies in compliance with the essential drug concept have to be clear and functional in order to plan, realize and assess health projects. Drug distribution is a difficult process and every phase of this process requires critical examination and management. Both the scope and aspect of the guidelines depend on the nature of the NGO that is concerned. Furthermore several questions need to be asked and considered. It is crucial to clarify in which manner the NGO is involved in distributing or allocating funding for drugs. The policy guidelines are also oriented towards the type of training the organization is implementing, concerning drugs and drug policy. In case of an already existing policy the need of review should be clarified.

Several key considerations ought to be the basis of debates to implement global essential drugs policy guidelines suitable to an organization's mission. The procedure of setting up an essential drugs policy will vary for each non-governmental organization. Ensuring conformity with national essential drug policies is crucial.

Collaboration, cooperation and mutual aid are fundamental for successful policy establishment.

Considering an essential drugs framework could support NGOs and other kinds of donors in order to assess funding requirements. Additionally, an evaluation of the regional health requests will decide which medicines are selected. Drugs that are donated without adequate comprehension of regional health issues lift up the possibility of wasting money on improper drugs and wrong dosages will increase. The WHO Drug Action Programme on Essential Drugs (DAP) provides key facts of every national drug policy and issues a consistently updated file of beneficial guidelines and public essential drugs lists in order to assess local drug requests.⁴⁵

2.4.2 Drug Selection

Using a limited list of essential drugs could relieve health workers in terms of understanding and managing the prescribed medicines. The restricted number also improves the communication among them and with their patients. Medicines that are complicated in their dosage and use are more likely to show patient nonadherence.⁴⁶ Therefore, educated health workers ought to be familiar with the donated drugs to build up a confidence-basis and trust with their patients. In order to guide the selection of drugs, the latest version of WHO's Model List of Essential Drugs can be consulted. Different parts of health care systems have different needs. Consequently, regional or district-level services will request a broader list while 20 or 30 drugs are chosen for primary health care level. In addition, in case of scarce drug supply the WHO Emergency List can be held for this level as well.

Medicines on the essential drugs list ought to be generics, except for therapeutic use exemptions that have been approved. Generic drugs have been

investigated and analysed over the past decade, therefore their use and advantages are well understood.⁴⁷ Additionally, brand-name drugs traded under patent are generally more expensive than generic products. The purchase, donation and prescribing of generics reduces the risks of misunderstanding directing to duplication of active components when numerous drugs are taken at the same time. They also make things easier in terms of training, in order to allow staff and patients to better acknowledge and understand the medicines they take. Furthermore, bulk packages are much more cost-effective than small packs.⁴⁵

2.4.3 Local Drug Production

The selling of drugs within recipient countries can decrease local manufacturing (when also sold in the country), or sale of an equivalent product.

Novartis, one of the world's largest pharmaceutical companies will cease to donate drugs to a country that produces a generic equivalent. This solution enables Novartis to have a monopoly on the market and enhances its profits.⁴⁸ Local manufacturing of drugs should be encouraging the local purchase as well. However, problems can occur if the quality has not been assured or if the prices are not sufficiently competitive. Drugs that do not comply with the necessary quality standards should not just be purchased to help the local industry. Luckily, non-governmental organizations and low-cost suppliers are a reliable source of acceptably priced drugs of adequate quality.

Quality is not easy to assess and needs the surveillance of experts. Weak control in the production process leads to drugs that do not comply with the required standards. If the quality of local drugs is not sufficient and unless quality assurance is not considered as one of the key issues, then substandard drugs may be purchased

which could harm the patient. Laboratory testing as well as factory inspections/monitoring are examples of solutions to enable quality assurance. Laboratory testing is high-priced, time consuming and often the required facilities are not accessible. Subsequently NGOs should know their suppliers and communicate with other organizations. Every attempt should be made to purchase drugs from an approved, skilled, low-cost supplier such as a local medical store, a renowned NGO supplier or a trustworthy company. The WHO aims to establish a certification concept that can be used to get information about producers and their quality assurance.⁴⁹

Purchasing drugs from unknown suppliers is always high risk. The origin of each drug should be clarified and the inspection of samples can help to avoid a possible excess of useless drugs. Labelling may help to know whether falsifications and imitations are involved. Mistakes in writing, unusual addresses and labels attached over old ones may be evidence of fake drugs. Newly purchased drugs have to be inspected and tested right away in order to identify substandard products. Labels need to be examined and legible information such as the full generic name, producer's name and address, expiration date, lot numbers and storage information, need to be provided. The contents should be free from breakages, discoloration and other substandard appearances. In addition, health workers need to identify insufficient or broken packaging.⁴⁵

2.4.4 Management

Insufficient management of drugs, such as inventory mistakes, can become a financial burden to the recipient country. The distribution network requires a well-conceived system and sound planning. Storage and transport, as well as inventory work requires strict and consistent monitoring. Allocated funds to management

training activities enable donor NGOs to ensure that the financial resources spent on pharmaceuticals are acceptable, as it is estimated that 20-40 percent of health budgets are used for drugs and their management.³⁴ Reducing waste is one of the key elements to make sure that the money available was well spent. The costs of its correct disposal may lead the recipient country into more problems and appears less likely to meet the country's needs. Good assessment and procurement as well as supply systems will help to cut waste, as will instruction and training for health workers and consumers in addition to the implementing of treatment guidelines.

2.4.5 Labelling

Drugs should be unmistakably and legibly labelled using the generic name and expiry date. Any information should be in the local language, accompanied by correct and proper instruction for the prescriber and the patient. Translations of labels can be time consuming, but it will contribute to the prescribers' understanding of the proper usage of the provided drugs.

A case study in Russia demonstrates the importance of correctly labelled medicines: Doctors Without Borders relabelled Drugs that were meant for Georgia and Azerbaijan in Russia. This process was without doubt very time-consuming, but it helped the prescribers to explain the drug to their patients, which was helpful in terms of the patient's compliance with these western donated drugs.³

2.5 Conclusion

Most of the non-governmental organizations that have been found within the frame of this report are genuine and overall well-intentioned. However, health-related goals

are about to fail to be achieved. Issues linked to drug donations such as poor educated health-workers, absent communication, greed, political instability and increasing reliance on external sources for health in war-torn and third world countries, are threatening the purposes and endeavours of many organizations' efforts. Plans and ideas by non-governmental organizations do exist and head in the right direction. It is important that NGOs are aware of these persistent problems in order to change and improve current drug procurements. Furthermore, humanitarian programmes ought to agree to a written drug policy on the basis of the provision and reasonable use of donated drugs. Non-governmental organizations' efforts in terms of international aid need to find a way to ensure quality and safe drug donations in order to help achieve an equal health status. Along with the World Health Organization's implemented policies and guidelines concerning essential drug donations, these goals may be achieved in the near future.

CHAPTER 3

GLOBAL DISEASES AND THEIR IMPACT ON GLOBAL HEALTH EFFORTS

The global health issues related to infectious diseases have a vast effect on the people in developing countries. Precise numbers of infectious diseases throughout Africa and other third world countries are not easy to determine, as most of the reported diseases represent endemic issues in developing countries. Insufficient access to essential pharmaceuticals has significantly contributed to morbidity and mortality throughout the world. Consequently, numbers and statistics of annual deaths caused by epidemic diseases are constantly rising. This chapter illustrates a list of the most common infectious diseases that are combated by several humanitarian programmes, as they are a global burden to the world's population. The current idea and aim of international aid is to fight the burden of those diseases the third World and therefore numerous specialized programmes have been established to relieve suffering endemic diseases can cause.

3.1 World Health and Infectious Diseases

At an approximate estimate half of the deaths induced by infectious diseases every year are allocated to only three diseases: AIDS, tuberculosis and malaria, which are responsible for more than 300 million infections and over 5 million deaths every year.¹⁶ Most of the case studies as well as literature and figures are referring to the present situation in Africa, as statistics show, that the burden of infections are the highest in African countries.⁵⁰

In terms of AIDS Sub-Saharan Africa, in particular, is currently the most fatally

hit area with 22 million people living with the HIV virus and the disease being the primary cause of death.

AIDS, or Acquired Immune Deficiency Syndrome and other venereal infections are prevalent all over Africa. The human immunodeficiency virus (HIV) that attacks and destructs the human immune system was first acknowledged in 1983, and thought to be derived from Sub-Saharan Africa. This deadly and incurable ailment leaves the patient exposed to diseases that lead to death. The most common examples amongst these opportunistic illnesses are Pneumocystis carinii pneumonia (destruction of lungs lung tissue caused by parasites), and acute infections with herpes virus, yeast, and parasites (Kaposi's sarcoma, a skin cancer). Patients with HIV show a large variety of symptoms, such as a constant cough, fever, and shortness of breath. HIV can also lead to irreparable brain damage. The main form of transmission is through the sexual exchange of bodily fluids, but it can also be transmitted by infected needles among drug users, or through blood transfusion.

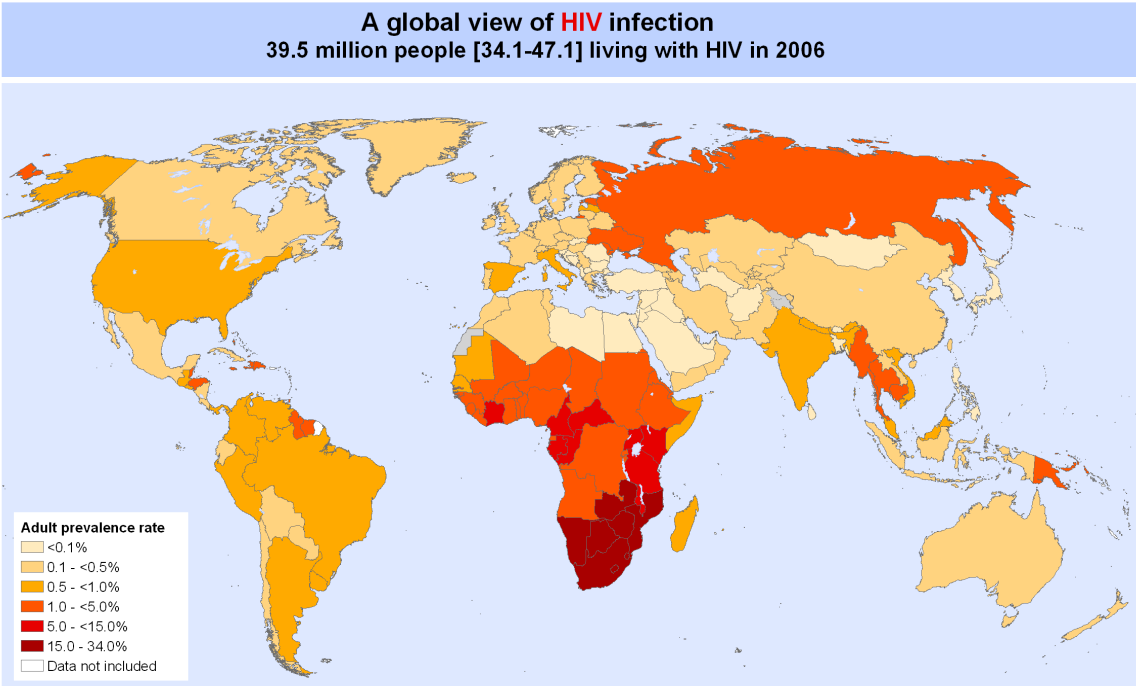


Figure 2: A Global View of HIV Infection.⁵⁰

Various subtypes of HIV have been found, but not sufficiently studied to date.⁵¹

AIDS is a significant health issue throughout the world. However, as mentioned before Sub-Saharan Africa is the most seriously affected area with 22 million people infected with the virus. In comparison to 0.8% worldwide HIV infections, in Sub-Saharan Africa this number is estimated to be about 5% with a prevalence of HIV infection of more than 30% in the worst affected countries. Globally, men represent a slight majority of HIV infected people. In Sub-Saharan Africa though, 61% of the patients are women, due to sex work and prostitution as a result of low education levels and extreme poverty in the region.⁵² Experts believe the number of people living with AIDS will continue to grow if access to adequate medical treatment is not provided soon.⁵³

Tuberculosis (TB) is estimated to cause two million deaths each year. Without essential medical care one billion people will suffer from TB by 2020.⁵¹ The bacteria *Mycobacterium tuberculosis* that causes tuberculosis is transmitted through respiratory droplets when an infected individual coughs or sneezes, mostly affecting the lungs leading to a dreadful cough. Poor health conditions and malnutrition inhibit an efficient immune system of the population in developing countries. The prevalence of TB infection differs in many areas and countries and is closely linked to the AIDS/HIV epidemic^{17 (p. 148)}. At present, one-third of the world's population is carrying the TB mycobacterium. Again, the Sub-Saharan region shows the highest tuberculosis incidence rate with more than 350 cases per 100 000 people.

According to the World Health Organization, TB caused more than 1.3 million deaths in 2008. The highest rate of mortality per capita has been reported in the WHO Africa Region.⁵⁴ In addition, the co-infection of *Mycobacterium tuberculosis* and HIV has become a major public health problem in Sub-Saharan Africa. Also, the unexpected escalating emergence of multidrug-resistance to the two diseases

overextends the resources and efforts of both national and international facilities.⁵⁵

There have been 247 million incidents and one million deaths from **malaria** reported in the WHO African region in 2008 (85%). In comparison, only 10% were reported in the South-East Asia Region. At present, 20% of all deaths of children under five years in Africa are attributed to malaria each year. Malaria is caused by the bites of the Anopheles mosquitoes or “malaria vectors” that carry plasmodium parasites such as the most common *Plasmodium falciparum* and *Plasmodium vivax*. Malaria is a serious, febrile disease. The symptoms such as high fever, headache, and nausea may occur seven days after the mosquito bite. Without the required medication, malaria can progressively lead to death.

According to the WHO, 50% of the world's population is in danger of malaria infection. The highest malaria incidence rates appear in Sub-Saharan Africa. Furthermore, malaria is currently reported in 108 countries. However, malaria can be controlled and cured with adequate medical treatment. Early care of malaria decreases transmission and illness. Unfortunately, vectors have been shown to develop drug resistance against most of the medications, which hinders most of the present malaria control efforts.⁵⁴

Over the years there has been a constantly growing number of programs to decrease morbidity and mortality from common infectious diseases in developing countries. Numerous efforts have been made, including several combinations of

- *vector control*: malaria, dengue, yellow fever and onchocerciasis (river blindness)
- *vaccination*: smallpox, measles, polio, neonatal Tetanus, diphtheria, hepatitis A+B
- *mass chemotherapy*: hookworm

Many organizations and humanitarian programmes have specialized in other specific, infectious diseases in developing countries such as Bilharzia (Schistosomiasis), Cholera, Diarrhoea and sickness, Amoebic Dysentery, Lassa Fever, Meningococcal Meningitis, Polio, Sleeping sickness (African Trypanosomiasis) and Typhoid.

Deaths related to diarrhoea and respiratory diseases are exceptional in developed countries but represent the main cause of death of children in the third world. Many infectious diseases that do not appear in high-income countries, e.g. malaria and schistosomiasis, cholera and tuberculosis, are a serious burden on the population in developing countries. Numerous medicines that have been developed can reduce morbidity and mortality in the third world, however vaccines require enhanced development. One cause of inequality in health status may be the consequence from disparity in access to medicines that already exist in addition to hygiene and clean water, that have a significant impact on the transmission of the majority of diseases. A study in the 1980s about access to essential medicines in Sub-Saharan Africa revealed that there have been important losses in therapeutic assistance due to inefficient distribution systems.⁵⁶ This situation has not changed, as indicated by WHO's estimates of the extent of insufficient access to essential pharmaceuticals. Sub-Saharan Africa in particular needs to concentrate on well-established and organized distribution systems. National governments ought to implement policies and analysis in order to guide global efforts. Each disease needs to be analysed and evaluated first in order to reduce the burden by access to existing licensed medicines and vaccines (including 95% of the WHO model list of essential drugs).⁵⁷

The following Table 1 shows a list of the most significant contagious diseases, which caused an alarming amount of deaths in 1998. Even though other tables of

more current statistics exist, this particular table best outlines the significance of each disease in terms of annual deaths and morbidity.

Table 1: Deaths from infectious diseases worldwide, 1998.⁵⁷

Causes	Deaths
<i>NO satisfactory vaccine available when data compiled</i>	
AIDS	2 285 000
Tuberculosis	1 498 000
Malaria	1 110 000
Pneumococcus	1 100 000
Rotavirus	800 000
Shigella	600 000
Enterotoxigenic <i>E.coli</i>	500 000
Respiratory syncytial virus	160 000
Schistosomiasis	150 000
Dengue	15 000
Leprosy	2000
Subtotal	8 319 000
<i>Satisfactory vaccine available</i>	
Hepatitis B	1 000 000
Measles	888 000
<i>Haemophilus influenzae type B</i>	500 000
Tetanus	410 000
Pertussis	364 000
Cholera	120 000
Diphtheria	5000

Japanese encephalitis	3000
Poliomyelitis	2000
Subtotal	3 274 000
Grand total	11 593 000

3.2 Programmes

3.2.1 Partnership and Cooperation

Global attention to HIV/AIDS includes facing poverty and health problems in both low and middle-income countries and needs co-operation at an international level. Industrial pharmaceutical and other companies concerning health have established a large number of programmes in cooperation with public and civil society organizations to enable regular access to essential medicines. A list of more than 70 collaborations has been set up based on the “Geneva Initiative on Public–Private Partnerships for Health”.⁵⁷

Health partnerships are not privatized and imply a large range of activities such as well-organized management, policy-monitoring, donations, and aid.⁵⁷ Their main aim is to control diseases by coordinating both the development and distribution of urgently required drugs. However, criticism has been raised against these public-private partnerships. In the absence of other services the partnerships may not meet the most important health issues.⁵⁸ Most of the programmes are controlled by international organizations. The position of a partnership within an organization has a notable influence on the policies leading its actions. Certain partnerships may be more precisely portrayed as for-profit public programmes with for-profit private contribution. Examples such as Roll Back Malaria and Stop TB initiatives all hold an office in the in WHO secretariat. These partnerships depend on the goodwill of the pharmaceutical industry, which is not ever-present. Not many partnerships have

attempted to enlarge the sale of health products, for instance by opening new market sectors. Exceptions may be the establishment of an unserviceable market in the most affected developing countries for latest vaccines, managed by the Global Fund for Children's Vaccines (GAVI) in collaboration with UNICEF and the WHO.

The idea that all participants of drug donations benefit and no one loses is certainly unattainable and not realistic. Low-income country governments will collaborate with multilateral agencies to raise the number of children receiving newly developed and high-priced vaccines. As long as inequality in access to vaccines remains, the children who cannot be reached by vaccination programmes will lose out.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a widely known non-governmental organization, representing the research-specialized pharmaceutical production, together with the biotechnology and vaccine field. Their members include both international companies and regional industry cooperatives, in high as well as low-income countries. The IFPMA website provides the "Developing World Health Partnerships Directory" which itemizes the R&D (Research and Development) long-term partnership programmes to achieve their health-related goals. This directory can be accessed for everyone in an on-line database, categorized by the country, disease, donation type and by partner associations.⁵⁹ The *Medicines for Malaria Venture* and the *International AIDS Vaccine Initiative* represent the main public-private partnerships, whereas the *Global Alliance for TB Drug Development* has just been established.⁵⁷

3.2.2 Vaccination campaigns

Despite low vaccination coverage in some African countries, most of the vaccination campaigns in Africa have not been very sustainable as they were based on the idea of mass vaccination. Ethiopia, for example, had enhanced its polio vaccination coverage to about 80% in 2001 from 10 per cent in 1992, mostly through vaccination campaigns and only 37 new polio cases have been notified since December 2004. Formerly polio-free countries are facing reinfection in the last two years: Somalia reported 215 cases in 2006, although it was declared polio free in 2002. Other countries in the Sub-Saharan region, such as Kenya, Nigeria, Namibia, the Democratic Republic of Congo and Chad, have experienced similar cases over the past few years.⁶⁰

3.3 Chronic diseases

Besides the infectious disease burden, there is an increasing global burden of chronic diseases and mental health conditions.⁶¹ This is mainly a consequence of the ageing population due to falling child mortality and fertility rates. The ageing will lead to a larger number of total deaths attributed to non-infectious diseases. Public health initiatives have led to these positive changes, although other aspects have also been significant, and especially women's education and empowerment.

According to the WHO the world will face a considerable transition in the distribution from infectious diseases to chronic diseases in the next 25 years, whereby non-communicable diseases are predicted to be responsible for over three-quarters of all deaths in 2030.⁶¹ A large number of countries are already beginning to face an epidemiological burden of cardiovascular diseases, chronic conditions, cancers, and diabetes as leading causes of death. In South Africa children from poor

families experience generally the burden of infectious diseases, whereas the urban and mainly poorer, adult population are facing growing rates of hypertension, chronic lung diseases, and diabetes. Cardiovascular diseases are the leading cause of death worldwide. Coronary heart diseases killed more than 7.2 million people in 2004, whereas 5.7 million died from stroke and other cerebrovascular diseases in 2005.⁶¹

In order to provide adequate treatment for these conditions, international aid needs to supply long-term drug donations, which is a challenging undertaking as financial resources are limited. The fact that non-communicable diseases are a growing threat to the population of low-income countries is likely to be disregarded, as there is no one-time vaccination to cure high blood pressure, diabetes or mental diseases. Therefore, non-governmental organizations have not yet implemented any programmes that tackle the issues linked to chronic diseases. Their main focus is to distribute newly developed vaccines to the population in need, improve mortality rates or even control the spread of certain diseases, but then leave. Diseases that need to be treated over the long-term, embracing high costs and care, are mostly neglected.

Table 2 shows the 10 leading causes of deaths globally in 2004, revealing the significance of chronic diseases that are often neglected in the third world.

Table 2: The 10 leading causes of death (WHO 2004)⁶¹

Cause	Deaths in million	Deaths in %
Coronary heart disease	7.20	12.2
Stroke and cerebrovascular diseases	5.71	9.7
Lower respiratory infections	4.18	7.1

Chronic obstructive pulmonary disease	3.02	5.1
Diarrhoeal diseases	2.16	3.7
HIV/AIDS	2.04	3.5
Tuberculosis	1.46	2.5
Trachea, bronchus, lung cancers	1.32	2.3
Road traffic accidents	1.27	2.2
Prematurity and low birth weight	1.18	2.0

3.4 Case study: AIDS and Aid in Sub-Saharan Africa

Sub-Saharan Africa (SSA) includes 48 countries, 42 situated in the land sub-regions of Eastern, Western, Central, and Southern Africa as well as six island nations. Life expectancy fell between 1999 and 2005, most likely due to severe poverty, the influence of the HIV epidemic, the decrease in health facility provision, and war. At an approximate estimate, 1.7 million [1.4 million–2.4 million] people have been infected with the virus in 2007 with 22.5 million [20.9 million–24.3 million] living with the virus, (68% of the worldwide total of HIV infected people and 76% of all deaths caused by the disease). Unlike other regions in Africa, the greater part of HIV infected people in SSA (61%) are women.⁶²

In 2007, 33.2 million people were infected with HIV/AIDS worldwide.⁶² Compared to the West, where AIDS is mostly related to homosexuals and drug addicts, the general transmission in Africa is through the exchange of bodily fluids during heterosexual sex. Pregnant women who are infected with the disease can easily transmit HIV to the foetus or to the breastfeeding baby. In 2003, approximately 1.9 million children were infected due to mother-child transmission in SSA.⁵²

It is estimated that half of the reported HIV infections in SSA appear under the age of 25 and result in death before 35. Life expectancy in Zimbabwe was 52 years in 1990, but decreased to 34 years in 2003.⁵⁵ The UNAIDS Report on the Global AIDS Epidemic 2008 suggests that the epidemic in Africa will affect the entire world if it is not brought under control soon.⁵⁵ National and international travelling has facilitated the spread of disease. Additionally, if the issues related to the transmission of HIV/AIDS are not approached, they will deteriorate and more difficult to control.

The connection between HIV, tuberculosis and malaria is a major threat and will be a key influence on the AIDS epidemic in the future. In addition, war as well as family, communal, and ecological disorder caused by European colonization, have always been ever-present issues. Also, after many countries' independence environmental, political, and social structures remained disordered and unstable. Of the 48 SSA countries, 13 have been affected with war, and bordering countries are also affected due to population movement. The collapse of the distribution of many social and health services is a common side effect of war. In 2001, 24 armed conflicts worldwide were reported, half of which took place in Africa.^{17 (p.61)} A war-torn country has to deal with instability of its political system, and these circumstances increase the AIDS epidemic, as health facilities are unable to provide adequate treatment. The 2006 State of the World's children Report indicates that, worldwide, the countries where one-fifth of all children die under the age of five have been involved in a war since 1999.⁶³

3.4.1 Aid for AIDS

Numerous international health and development related organizations aim to combat AIDS in Africa. The UN and its specialized agencies have established several

programmes helping the affected regions in prevention activities and campaigns as well as fund-raising for the development of new vaccines. Additionally, many development aid models generally referred to as Global Health Initiatives (GHIs) have been established. The most noted programmes active in the combat against AIDS are the World Bank's AIDS programme, the Global Alliance for Vaccines and Immunization (GAVI), the US President's Emergency Plan for AIDS Relief and the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM).

Educational programmes have joint with community and church organizations to establish prevention projects to get through to larger parts of the public. These programmes have helped to qualify many volunteers, mostly women, to encourage others in their communities by education and the support of women's understanding of safe sex and condom use. Additionally, many international doctors in SSA aim to work with traditional healers as they are more likely to reach many populations. People trust them due to their tradition and the absence of sufficient health care. AIDS has always been considered as a shame and in their culture. One healer even said that "we have adopted too many Western things without thinking, and we lost respect for our bodies" ^{17 (p.63)}, supporting attitudes and concerns which complicate the acceptance of western-donated medicines. ⁶⁴

Even though no cure exists at present, antiretroviral (ARV) medicines and therapy will extend and increase the quality of life for people living with the disease. In the past decade numerous donor organizations have provided financial and human resources to develop AIDS treatment and care services, mostly through the provision of antiretroviral drug donations in the affected countries. In 2008, more than 4 million people were receiving antiretroviral therapy (ARV) and the number of facilities offering HIV testing and counselling had increased by 35% (from 25000 in

2007 to 33600 in 2008).⁶⁵ ARV treatment will relieve those living with AIDS by improving their disease status.

On a national scale, both Uganda and Senegal have made remarkable accomplishments in controlling HIV/AIDS by decreasing the infection rate through persistent public education programmes as well as condom promotion campaigns, extensive treatment efforts for other sexually transmitted diseases, and the establishment of non-governmental organizations. Senegal, for example, implemented their public education campaigns to encourage condom use in 1990. According to a study in South Africa the understanding of risk and its prevention has been more important than any drug donations.⁶⁶

Over the past 30 years, the World Bank has become a major player. However, this has not been the best progress in terms well-intentioned and genuine humanitarian goals, as more money can lead to more power and influence. Other major actors are UNICEF, governmental agencies (USAID), funds (Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, GAVI), the UN Population Fund, foundations (Bill and Melinda Gates) as well as many other programmes and NGOs, public or private, with determined priorities. On the other hand, a strong international leadership may encourage the political management of public health practice on a national level.⁶⁴

Notwithstanding the growing political interest paid to AIDS, and the financial resources provided to enable the fight against the illness, the money is not used in a satisfactory manner regarding effectiveness and coordination. AIDS funding may be locked up in government bank accounts or drawn off by regulations of international funders.^{17 (page 63)} The bureaucratic barrier to provide funds along with the absence of understanding about the correct ARV therapy guidelines lead to the fact that 8,000

people every day are still dying from a condition that could have been prevented and treated.

Although the World Health Organization assesses that about 700,000 people had received ARV Therapy in December 2004 (compared with 444,000 in July 2004) and that this figure showed an important increase, treatment remained lowest in SSA, where only 310,000 HIV infected people were treated with ARV with 72% of their requirement for treatment stays unmet. Moreover, 41% of total need for ARV therapy in SSA falls upon Nigeria and South Africa.⁶⁷

The WHO, through the HIV/AIDS Department and programmes such as the 3 by 5 programme in 2003, represents one of the main actors in terms of supporting the provision of ARV therapy in the third world. The initiatives aim to enable access to ARV treatment, as well as the ability to distribute information and to support disease management. This includes improving understanding of ARV therapy initiatives in the country and establishing tracking methods to supervise the patients who have received treatment.^{17 (page 63)} Unfortunately as with most of the international humanitarian programmes, these initiatives depend on long-term political help and funding. Reduced support for ARV projects often means a reduction of AIDS treatment. This represents a major and common problem and tends to reverse the movement of increasing quality of life and diminishing morbidity and mortality rates. In addition the HIV virus may develop drug resistance due to inappropriate use of the provided medicines. Strains of the virus that have become drug resistant may multiply quickly and turn all treatment initiatives ineffective. Another obstacle is the lack of health professionals in SSA as many of them have gone to work in higher-income countries. The shortage of health education remains a major problem for efficient ARV treatment. Patients purchase ARV drugs without medical information

and prescriptions, which causes drug resistant HIV strains, as the drug is not taken correctly. In addition, people who really need treatment receive drugs that worsen their condition or are unsuccessful against their specific HIV strain.^{17 (page 64)}

In many African countries the HIV/AIDS epidemic is affecting large sectors of the population and overloading existing health services. Although many donations and price reductions have been organized, anti-retroviral drugs are very high-priced and not yet accessible for most of the patients. Furthermore the healthcare infrastructure in the majority of affected countries is not sufficient to handle the growing caseload. Additionally, drug donations are not always the best way in order to control the spread of the disease. In fact, sex education campaigns, which aim to discourage numerous sex partners and encourage the use of condoms, are more effective than the purchase of medicines that are not fully understood. However, some developing countries have shown that controlling AIDS is achievable, but it requires steady and sound political leadership along with newly developed resources and reinforced primary health service infrastructure.⁶⁴

3.4.2 Workforce and Initiatives

The HIV/AIDS epidemic impinges on the health workforce in a major way. This includes a decrease in educated personnel through death, as illustrated by the unusually high death rates among health workers in Malawi⁶⁸ as well as a decrease in human resource production capacities. A national study on health personnel, patients and facilities in South Africa performed in 2002 revealed that 15 per cent of health personnel were HIV-infected, 16.2 per cent had suffered from stress-related diseases with 65 per cent taking sick leave and one-third indicated low work morale because of stressful working conditions, extreme patient workload, workforce shortages, and

insufficient salaries.⁶⁹ Additionally the HIV/AIDS epidemic in Sub-Saharan Africa has affected the ability of health systems to provide adequate health care.

As the Global Health Initiatives (GHI) represent an excellent source for bankrupted governments for sustainable funding, the provided resources need to be examined with reference to the mixed experiences with health policy implementation in the past two decades. For instance, not long after the foundation of the GFATM, objection had arisen “that this new public-private partnership fund would (yet again) be donor-led. As a result undue emphasis would be put on supplying drugs rather than building up capacity to implement and sustain effective treatment and preventive programmes”.⁷⁰ This concern is confirmed by surveys of African health systems, which show that initiatives to fight diseases will fail over the long-term if efficient and well-organized health care systems are not in place. Consequently, international aid needs to support a development strategy that tackles the reinforcement of very weakened health systems and structures in order to improve the provision of health care services.⁷¹ Fortunately, following GAVI’s lead, several GHIs such as the GFATM, have decided to assign a higher percentage of their funds to “health system development” rather than to drug donations.⁷²

CHAPTER 4

CASE STUDIES

Although it is more than a decade after the Guidelines for Drug Donations were issued by the WHO, humanitarian aid concerning drug donations in severe disaster situations has not yet improved.⁷³ Instead, it has become worse with growing numbers and types of donors, mainly in high profile emergencies. However, it is difficult to determine compliance with the Guidelines as the Bulletin of the World Health organization 2010 presents 12 disaster-related drug donation examples in the period of 2000-2008, that have not given the required information for a correct assesment.⁷⁴

In these emergency situations in which human resources, as well as infrastructure and logistical capacity are scarce, donations of medicines are of no use. In the phase after the emergency, food, first aid and shelter are the most crucial requirements in order to give immediate assistance. Furthermore, technical support ought to be provided by pharmaceutical professionals to the recipient's health authorities.

4.1 Inappropriate Drug Donations: Examples and cases

Drug donations are an essential part of humanitarian aid efforts, nevertheless they might not always be the best way to assist a country in an emergency situation. The false belief that any drug is helpful causes more problems than good. After an earthquake, for example, the priority needs are generally refuge and construction equipment. The first requirements are uncontaminated water, sanitation and food. The requirements for medicines need to be defined by an extensive assessment of

health issues.⁷³

Excess medicines received from hospitals or pharmacies in developed countries are clearly not the best assistance in an emergency situation. These drugs often comprise inappropriate and unsolicited drugs, such as gastrointestinal medicines, treatment for cardiovascular conditions, hormones, or anti-rheumatic medication, many of which have already expired.^{2;73} Drugs that are highly demanded in an emergency, might not be among the frequently donated drugs that are provided by hospitals in the developed countries. In 1991, Doctors Without Borders indicated that 20% out of 4 million kg of medicines, donated by more than 4000 French pharmacies for humanitarian aid initiatives, contributed to the recipient's benefit, whereas 80% had to be destroyed.²

Despite all the established and well thought out guidelines, more examples of inappropriate drugs arise in every emergency situation. For example, in Zaire in 1994 one organization active in humanitarian aid, hired an airplane to transport a grand delivery of commercial energy drinks, assuming that it may be an appropriate cholera treatment. Instead, this product had severe consequences when given to infants. Additionally, it was complicated to store, produced extensive waste and did not show any cost-effectiveness compared to the usual oral rehydration therapies applied to treat diarrhoea.² There are several other reported cases about humanitarian programmes, as well as private groups, governments that have provided useless, expired, dangerous medicines or similar inappropriate aid supplies.⁷³

Assistance from the pharmaceutical industry may be an opportunity to gain tax deduction on unused supply, or to foster a new market for specific goods. This was the case in Albania in 1999, when many problems occurred due to inappropriate drugs of quality, that were given to the country in the Kosovo war. According to the

World Health Organization, about 50% of the provided medicines were unsolicited and inadequate and had to be burnt. Moreover, 65% expired within the first year, and 32% were unknown to Albanian health workers, who indicated that the medicines could not be handed out before their expiry date. Albania had to face massive costs to manage the handling of the donated medicines, such as storage and the proper disposal.⁷⁵

Furthermore, Bosnia and Herzegovina reported 17 000 tonnes of useless drug donations, from 1992 until 1996, leading to a total disposal cost of US\$34 million.⁷⁶ Additionally, large amounts of 14-year old ampicillin, and expired facial cosmetics with covered expiry dates were given by the US to hospitals in Bosnia.¹

In Georgia, authorities received 20 tonnes of expired drugs that took several weeks to burn. In 1993 over 10 women in Lithuania lost their sight after being given a drug that was only designated as a veterinary worm medicine. The drug was provided by Caritas without any information or instruction leaflet. Caritas then appeared very reluctant to carry out further investigations.⁴¹

In Sudan the donations included useless products such as garlic pills and appetite stimulants, during the starvation crisis. Also, the medicines were labelled in a language unfamiliar to health workers.⁷⁷ Unfortunately, many more cases of highly unsolicited donations have been reported. For instance, after the Gujarat earthquake, donors sent a load of bikinis to the affected areas in India, and a hospital in Malawi received several packages of breast implants, which shows the extent of inappropriate distributions that have been made within the frame of international aid.⁷⁷

4.2 Long-term donations

The WHO Guidelines are also valid for long-term drug donations. These donations are more likely to act in accordance with the 12 articles than donations provide in emergency situations, mainly in terms of quality and data administration. This might be the result of the fact that long-term programmes may be conducted by pharmaceutical corporations with adequate systems in terms of quality assurance and surveillance, while donors in disaster struck areas provide donations without performing quality analysis. However, donations provided over the long term could harm the recipient. They may not comply with the countries' requirements or promote the use of high-priced brand products. Also, long-term medicines that are not persistent may not be helpful to people who need constant treatment. The WHO Guidelines could be adapted for pharmaceutical concerns that are providing medicines, suggesting an agreement on a sustained supply of long-term medicines.^{73;78}

4.3 A Case Study: Tsunami 2004

At the end of 2004, a vast earthquake caused a tsunami that shattered great parts of southern and south-eastern Asia, including India, Indonesia, Sri Lanka, Thailand, Myanmar, Malaysia, the Maldives and even Somalia in Africa. The Tsunami killed over 230,000 people and left 10 million homeless. The area around Aceh, Indonesia, was reportedly worst affected. Consequently, the Indonesian Government authorized foreigners to enter the province in order to receive international support and immediate transport.³²

As mentioned before, the areas in these kind of emergency situations need several other goods first before drug donations. Numerous organizations and

programmes, as well as international companies, individuals and international governments raised over US\$6,2 billion in order to assist the affected countries with goods, food, shelter, and drugs.⁷⁹

This report has outlined the most common drug related problems that have occurred in many recipient countries. Unfortunately the Indonesian authorities had to face many problems linked to the provided drug donations as well, as they failed in their aim to help the country. Health workers were swamped with inappropriate donations of expired medicines, labelled in a foreign language and medications that were highly unsolicited such as antidiabetics and other unused drugs returned to western pharmacies. In addition, the cost of the proper disposal of the excessive drugs had to be borne by the recipient. In response to these drug related issues, Pharmaciens Sans Frontières-Comité International (PSFCI) established an initiative to assist the regional and governmental authorities in February 2005. The programme was implemented to support managing and monitoring drug donations and its establishment was funded with EUR 520,000 by the Directorate General for Humanitarian Aid of the European Commission-ECHO.³²

The programme was based on a national survey, performed and financed by the World Health Organization in collaboration with the Indonesian health authorities.³² In the tsunami-affected areas of the Aceh Province, the survey was undertaken from 20 May to 20 July 2005, involving numerous health facilities such as hospitals and pharmaceutical storehouses, in order to measure the actual benefit of the provided drugs. The objective of the survey was to gather crucial information about the location, storage as well as an accurate estimate of quantity and quality of donated medicines, donors' recognition, identification of inappropriate drugs, and adequate administration of pharmaceutical waste.

The core principle of the survey was the development of four tools:

- Surveillance of pharmaceutical storehouses
- Surveillance of health facilities and health centres
- Monitoring and questionnaire for Non-governmental organizations
- Record of inventory drugs

The study was conducted by three teams, consisting of public health professionals, pharmacists and assistant-pharmacists. Moreover, in order to enable transparency and tracking, at least one participant was skilled at data entry.

In total, 8 hospitals, 9 storehouses (including ports and airports where medicines were taken immediately outside the area of customs), 60 health facilities and 124 non-government organizations were monitored in the Province of Aceh. The inventory was taken by using the Essential Drugs List of Indonesia in order to identify an unacceptable and improper drug. Unfortunately, many donors had left the country shortly after the disaster, leaving authorities without any information. There were 140 donors identified, including 39 foreign governments, 53 national and 48 international organisations such as NGOs corporations, public groups, political parties and the military.

Even though no medicine was asked for, the quantity of medicines received was estimated to be over 4,000 tonnes of drugs for a population of less than 2 million people. Furthermore, 22 tonnes of excessive medicines needed to be disposed by health authorities and were not mentioned in the survey. In addition, the survey revealed very disturbing and devastating percentages, showing that international aid was facing one of its largest failures in terms of drug donations:

1. 60% of the provided drugs were not found on the Essential Drug List of Indonesia and were highly unsolicited.

2. 70% of the donated medicines were unknown to health workers as they were labelled in a foreign language. Additionally, the staff had to spend a large part of their time sorting out useful medicines from medicines that were unsolicited.
3. 25% of the provided drugs had already been expired on arrival date

On the other hand, the drugs that had been appropriate for the needs of the affected population, were delivered in excessive quantities. Regarding the present consumption rate, the region of Aceh has now many years of drug supply, which will not be needed before their date of expiry. The largest donated quantities were donations such as Oral Rehydration Salts, Dextromethorphan and Tetracycline.

Problems such as poor storage capacity and unorganized infrastructure had already been present in Indonesia before the disaster. Additionally, the tsunami killed almost 50% of the health professionals in Aceh Province and destroyed several facilities, which further diminished the amount of space and equipment. According to the conducted survey in the Province, several storage sites could be found: hospitals, health facilities, private houses, NGO and army storehouses as well as port areas provided storage capacity. However, facing the issue of limited space, the arrival of drug donations was a tough task to manage: Health workers in at least 3 hospitals needed to give up their office space as well as treatment rooms to provide a stockroom for inappropriate medicines. Furthermore, approximately 30 tonnes of medicines were not stored correctly and put into barns or farmyards. 84% of the observed facilities could not provide air-conditioning, which would have been crucial to assure good storage conditions. Moreover, excess numbers of drugs seriously obstructed the effort and activities of both health workers and patients in health facilities.

The survey could not find any information about a proper waste disposal protocol in at least 5 affected provinces. Approximately 17% (600 tonnes) of already expired medicines or medicines that expired 6 months from the date of donation, needed to be disposed immediately. With costs of 4€/kg destroyed, the financial burden for the recipient country was estimated to be €2,400,000, costs that exceed the value of the donated medicines.³²

The survey illustrated the need of local health to establish structures in order to increase emergency preparedness and to provide immediate disaster responses. By implementing their own disaster-related health structures and regional programmes, excess of unsolicited and inappropriate donations can be prevented. Also, it would allow more independence from international donors.

4.4 The Pharmaceutical Industry in the United States: Good Examples

Apart from the many cases, which have revealed the real intentions of big donor companies, it needs to be mentioned that not all drug donation initiatives are bad. A few of them do support and help the recipient health structures, usually if the pharmaceutical company owns the patent for drugs used as treatment for eradicable diseases.

For example, Merck's Ivermectin Donation Programme has been donating the drug Mectizan® for River blindness since 1988 along with the World Health Organization, the World Bank, several NGOs, and the United Nations, in order to treat more than 25 million people. This initiative represents a good example for a decent corporate donation system. For example, the company agreed to continue the programme until River Blindness is entirely under control and eradicated.⁸⁰ To date, over 85% of the population are getting treatment with an approximate estimate of

onchocerciasis being reduced by 86%.⁷³

Another example of well-organized and genuine corporate donation programme is the Aventis Foundation's initiative in order to fight African Sleeping sickness.⁷³ The programme is based on a partnership with Doctors without Borders and the World Health Organization. The pharmaceutical company has donated more than \$25 million to guarantee the supply of three drugs. Aventis entered the partnership with the World Health Organization in order to ensure proper drug administration and utilization as well as assistance for health structures and facilities.⁷⁷

4.5 The Pharmaceutical Industry in the United States A "Charitable Donor"?

The pharmaceutical industry is one of world's most profitable and powerful industries. In the United States it provides more funds to political institutions than any other business. For many people the industry is perceived as mostly driven by their own corporate interest rather than being well intentioned to help those on need.¹ Drug companies often see drug donations as a suitable opportunity to offload their unneeded and unsellable goods to enhance their revenue as well as their corporate PR. Drugs that could not have been sold, are sent as "charitable donations", with the aim to create an honourable image, when really these initiatives should be referred as "drug dumping", for emptying the company's shelves.¹

Again, the perception of many people is that pharmaceutical companies often take advantage of loopholes in drug policies and management of the recipient country in order to meet their own interests. This results in additional costs and health threats to the recipient country.

The industry in the United States spends a great amount of money to lobby political parties. In 2002, ten pharmaceutical concerns provided more than \$9 million

to Congress.⁸¹ These figures suggest that companies may also donate their medicines under the influence of the US government, meaning that donations are not politically independent. Consequently, the industry is not going to donate their medicines to countries that are not approved by the US government, or that could upset politicians.¹ The current US tax system rewards companies that give their products to humanitarian initiatives. The system enables the donating company to claim a tax relief up to double the cost of production of the provided drugs. Companies are generally authorized to declare the cost basis of their medicines against tax when donated. In case of the donation being recorded as charity for people in need, the invalid and for caring institutions, the regulation permits the company to claim either double the drugs' cost basis or the cost basis in addition to 50% of the "fair market value".⁸¹

Furthermore, pharmaceutical companies are able to donate medicines that they would not be allowed to put on the market in the United States due to The Food and Drug Administration which controls the trade of every drug really strictly. One crucial requirement is that the drug needs to have a shelf life for at least one year. Nevertheless, this provision does not seem to be followed or even existent concerning the donation of drugs to developing countries at all. Regardless of the WHO Guidelines, which unmistakably advocate "After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year", drug donations from US companies often comprise medicines with a shelf life of less than 12 months. Additionally, the US pharmaceutical industry is reluctant to acknowledge a 12-month shelf life as their standard. In fact, they have violated this normative provision in every action, since the Compliance with the WHO Guidelines for drug donations is purposely not a criterion for tax relief eligibility.¹

It is crucial to stop the donation of medicines just before they expire, since they would be distributed to the patient after they have expired. The excuse that drugs with a short shelf life can be donated in severe emergency situations, since they will be used immediately, does not apply. Moreover, the distribution in the course of several storage levels such as health centres and hospitals could take six to nine months.³² Most of the recipient countries are facing logistical challenges, particularly in the phase after a natural catastrophe. The usual drug supply system has to deal with significant difficulties in terms of instant delivery. In those circumstances the systems for receiving, storing and distributing donated medicines are usually disordered and overstretched, so that the majority of them will accumulate.

If companies are not able to sell their medicines, they have to pay additional expenses for warehousing and disposing them. Therefore the law enables them to claim these expenses against tax, which is a credit far lower than in case of a drug donation. Moreover, the industry may donate medicines that are no longer wanted. These include medicines of an older variety that may be less efficient than their newer version, or drugs that have poor sales. Other reasons for donations may be an excess stock, or a fresh business concept of opening up a brand new market in the third world. Apart from prescribed drugs, donations can also include vitamins, cosmetics, tapes, tampons or shower gel, basically everything can be a “generous” donation for people in need, even clothes. Companies now have the possibility of claiming a higher tax deduction by such ‘charitable’ donations.

Additionally, the recipient gives in return a receipt, as soon as they accept the donations, which allows the donor to claim the tax relief. This implies that although the donations may still be in the United States, they turn into the responsibility of the

recipient, meaning that they may have to bear the expenses of shipping and other transport duties. Furthermore, many countries are left with additional costs of import taxes for customs and excise. After the earthquake in Gujarat, India in 2001, US companies imposed the expenses for import tax on the Indian Ministry of Health.¹

“About 70% of donations tend to be company initiated...A certain amount of product is coming into the warehouse that’s part of a procedure that the company has instigated rather than somebody asked for it”^{1;82} One of the biggest loopholes in the present US drug donation policies is that the medicines are usually selected based on the stock management demands of the industry, rather than the health problems of the recipient country.^{1;82} Problems concerning donated antibiotics have appeared due to western antibiotics being numerous generations more developed than the antibiotics used in the third world, which can cause drug resistance.⁸³ The application of diverse drugs from different brands in different doses can lead to many problems, since those people who need a long-term treatment may not receive the same drug next time.^{1;82}

4.5.1 PR and Trade Advantages

“By donating overseas you’re gaining a product recognition, like you’re getting people comfortable using your pharmaceuticals and people who aren’t buying them today will potentially be in a position to buy them a couple of years down the road”^{1;82}

Donated medicines for the needy can become advantageous when used for enhanced brand recognition in a promising market. In 1993, a US pharmaceutical company provided \$13 million of polio vaccines to Russia, driven by the belief that Russia can become a potential market someday. “So while meeting a need, maybe they can plant seeds”.^{1;82} The industry’s aims generally do not include donations to

the United States since they may impact their market. In fact, pharmaceutical companies are more willing to donate drugs out of the US, regardless of the needs in their own country, because donations would hurt their home market. It is also quite usual that drug donations harm the recipient's generic drugs industry, due to drugs being distributed for free.⁴⁷ This may undercut the country's effort to establish sustainable cost-recovery initiatives and to support its economy. Sometimes drugs may be more helpful and cheaper when bought locally rather than imported from overseas. The thought of disposing products that are not sellable on the American market is probably the most driving reason for drug donations to "charitable" pharmaceutical companies.

It is alleged that the US company Bristol Meyers Squibb (BMS) has been disguising¹ a sale of drugs as a donation: The company which owns the patent on the two most essential anti-retroviral drugs used in the combat of AIDS, charged an "administration fee", when Doctors without Borders wanted to buy a shipment of anti-retroviral medicines for the treatment of AIDS in Guatemala in 2002. The company stated that they would "donate" the medicines, but only in exchange of outrageous "fees". Nevertheless, BMS has labelled this trade as a donation, aiming for an upgrade of the company's reputation along with Guatemala becoming a potential future trading partner. This purchase could enable the company to claim a tax deduction on this "donation" which actually has been paid for.¹

Another prominent example of donations for PR reasons was the case of Eli Lilly. In 1994, the company donated over six million Ceclor CD tablets, which were not permitted and without licence in the United States. Also, the medication was not included *in the WHO's essential drugs list. However, they promoted the donation as being "yet another example of Lilly's commitment to giving, especially in times of*

*human tragedy. We are responding to the dire needs of the Rwandan refugees”.*¹ In fact, the donation was rather made because of tax benefits and a superior way to get rid of drugs that were of no use to the business.⁸⁴

The American tax system should aim to acknowledge companies for effective, sustainable and WHO based programmes rather than granting state funding for the disposal of excessive stockpiles in order to prevent the delivery of unwanted goods for people in need.

CONCLUSION

At first view, people might think that donating drugs is an appropriate and charitable option for countries that are desperately in need of essential medicines. However, many studies, which this report has referred to, have been conducted throughout the years in several developing countries and have shown that western drug donations often included inappropriate and unacceptable medicines, which have caused more damage than good. Yet it is crucial to distinguish from donations provided as a support during natural catastrophes or other kind of emergency situations, and those that aim to improve the global health status by immunization programmes to fight epidemic diseases on a long-term basis.

The report has revealed a few examples for the fail to meet the countries needs and the burden of the proper disposal of excessive drugs. Over the past decades, many governments in developing countries have established policies on foreign donations to meet their population's needs. As outlined in this report, the basic ideas and principles for such policies did exist, but were often unrealistic to accomplish. Local governments in developing countries appeared to be too weak to implement their own guidelines or express their specific interests to international donors. Therefore, international aid should focus on supporting local facilities to strengthen their ability to manage emergency situations on their own. This will be the initial step towards helping developing countries to become more independent from big donor companies, which impose the conditions of drug donation on the recipient in order to achieve their personal interests. The recipient should be able to reject inappropriate and unsolicited drug donations without fearing economic consequences. In order to prevent a financial burden to the recipient country, it is crucial to avert excess of expired or useless medicines. In terms of medical support,

it may be more efficient to provide a standardized kit of medicines and basic equipment essential for general health care. This can be practical in the absence of expressed needs in an unexpected emergency situation.

Humanitarian programmes ought to agree to a written drug policy on the basis of the provision and reasonable use of essential, donated drugs. However, case studies conducted in Africa in particular show that health-related goals constantly fail to be accomplished due to many problems related to drug donations, such as corruption, poor communication, corporate greed, political instability and increasing reliance on external health sources in developing countries. Also, donations and international interference is not always the best way to help countries in emergency situations. In fact, external assistance may even be unwanted and not helpful at all. Basically, the support for establishing effective and economic healthcare systems in the developing world is more important than any drug donation in the first place. If developing countries can rely on local health systems, they can help the population without external sources and will be able to respond to disasters immediately and more efficiently. A donation in cash for local procurement of essential medicines is probably better than additional drug donations in kind, as cash represents a great support for actions of the regional government and pharmaceutical production. Furthermore locally produced medicines are easier to identify by health workers and patients.

Alternatively, drug donations can also concentrate on specific diseases in certain areas, in order to supply the poor and underprivileged, rural and marginalized populations through vaccine initiatives. Programmes like “Aid for Aids” or the “Polio Eradication Programme” reached great success in terms of sustainable control over common infectious diseases. It is also important to mention that not all drug

donations are bad. Although the “Malaria Eradication Programme” stands for the WHO’s greatest failure, the organizations’ vaccination programmes have been overall very successful. The question is merely whether these vaccines are distributed equally and accessible for EVERY individual suffering in epidemic areas. Donors tend to neglect the “true” problems in the regions, meaning that they simply choose an area to be active in, give the vaccines, and leave. Chronic diseases that need to be treated over the long-term, implying high costs and care, are mostly neglected.

Additionally, the pharmaceutical industry and many significant and powerful companies have provided vaccines and drug donations in the past decade. It has been very difficult to assess the amount of drug donations that have actually been made as a result of the tax relief system in the United States. This system has been established to reward companies that “donate” their unneeded drugs by allowing them to claim a tax relief on their products. Once money gets involved, the intentions for a donation may change, since the companies have realized that donating expired and unsellable drugs has become more beneficial than disposing them. But sometimes, corporate compassion needs to come without a tax benefit. On the donors’ websites, many companies stated different quantities about their donations, leaving the reader with unofficial information about the extent of their shipments. Of course, each pharmaceutical company aims to portray their charitable activities in the best possible way to the public eye. However, by browsing through the Internet, many articles about drug donations/pharmaceutical industries and companies as well as terms such as “corporate greed” and “tax deduction” can be found and reveal reliable and consistent information about numbers and facts regarding donors and their “not so genuine” intentions. Their prior aim is basically taking advantages of the fine Public Relations that donations imply as well as the clearance of excessive

stockpiles in a tax efficient way.

Transparency and accountability are the key words in order to assess and improve the quality as well as the benefit of drug donations. Details including facts about the donor company, precise information about donated medicines with their generic and brand name as well as drug quantity, dosage, date of shipment and expiry should be accessible for everyone. Furthermore, WHO Guidelines ought to be respected and regarded as a crucial condition in order to be allowed for any kind of tax repayments. Donations that do not meet the guidelines should not be considered qualified for a tax deduction. Any kind of violation needs to be immediately regarded as tax fraud and forbidden by law. Donors ought to value the four core principles these guidelines are based on, as well acknowledge the national policies regarding drug donations. Moreover, the tax benefits should be based on the locally and currently required drugs with the developing country being the prior recipient of these credits, and not the pharmaceutical business.

This report has been focusing on the issues related to corporate donations because the public in donor countries is not sufficiently informed about the everyday issues linked to drug donations. Governments as well as committed individuals in these high-income countries need to support public awareness of these problems in order to achieve “good donor practice” through the media. It is crucial that governments bring an end to the present support for pharmaceutical companies based on a tax deduction system. The donations based on the benefit of this system are often unsafe and unwanted. Furthermore, loopholes in the American tax relief policies ought to be found and closed in order to assist the developing world with their needs specified by coordinated and local health workers, who are able to identify the true needs of the disaster affected region. Additionally it is important for drug

companies to design donation schemes based on the WHO Guidelines. It is much to be hoped that the mistakes of the past will be seen as a chance to learn and attempt a sincere effort to make sure these mistakes do not happen again.

Drug donations may be an essential part in humanitarian aid efforts, nevertheless they might not always be the best way to assist a country in an emergency situation. Often the reasons and roots for major problems in the third world lie deeper than simply the lack of medicines, and no drug donation is able to change that. Poor sanitation, hygiene, bad water quality, non-existing education, war, governmental corruption and many other aspects represent the true roots for numerous problems in low-income countries. International aid ought to focus on these issues first, before they send drug donations that can cause more harm than good. Obviously, tackling these roots is a lot more difficult, costly and requires more organization and commitment than just sending packages to some area on the world map without actually getting involved into the real issues.

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