WHO/EDM/PAR/99.2
Original: English
Distribution: General

Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies

World Health Organization
Churches' Action for Health of the World Council of Churches
ECHO International Health Services Ltd
International Committee of the Red Cross
International Federation of Red Cross and Red Crescent Societies
International Pharmaceutical Federation
International Solid Waste Association
Médecins Sans Frontières
Office of the United Nations High Commissioner for Refugees
OXFAM
Pharmaciens Sans Frontières
United Nations Children's Fund
United Nations Industrial Development Organization

Acknowledgements

The original text of this document was prepared by Mr Tim Grayling, Lead Public Health Engineer (WHO Office for Humanitarian Assistance in Bosnia and Herzegovina) as part of the Mostar Expired Pharmaceuticals Sorting Project. This project was coordinated by Dr Philip Rushbrook (WHO European Centre for Environment and Health, Nancy Project Office, France*) with assistance from Dr Giles-Bernard Forte, (Programme for Pharmaceuticals, WHO Regional Office for Europe, Copenhagen) and Mr David Brigham (Pharmaciens Sans Frontières).

We would like to thank all Pharmaciens Sans Frontières (PSF) and WHO staff in Bosnia and Herzegovina involved in the Mostar Expired Pharmaceuticals Sorting Project, including but not limited to, Professor Claudi M. Cuchillo who provided valuable information on pharmaceutical matters. Thanks are due to staff in the WHO Regional Office for Europe, and to Dr Peter Parnell and Dr David Ambrose of AEA Technology (United Kingdom).

The following persons and organizations contributed to the further development of the guidelines and their advice and support are gratefully acknowledged:

K.O. Asante, (Churches' Action for Health, World Council of Churches, Switzerland), A. Battersby (FBA Health Systems Analysts, South Africa), A.D. Bhide (National Environmental Engineering Research Institute, India), G.R. Boyd (Ministry of Health, New Zealand), J.Y. Cater (African Medical and Research Foundation, Kenya), M. Cone (International Federation of Pharmaceutical Manufacturers Associations, Switzerland), S.A. Chuchu (National Quality Control Laboratory, Kenya), A.W. Davidson (International Pharmaceutical Federation, Netherlands), E. Dena (Community Initiatives Support Services International, Kenya), L. Diaz (CalRecovery Inc., USA / International Solid Waste Association, Denmark), R. Florés (WHO/EHA), D. Fosse (Pharmaciens Sans Frontières, Comité International), M. Giannoni (France), M. Henkens (Médecins Sans Frontières International, Belgium), J.H.A. Heuvelmans (Médecins Sans Frontières, Netherlands), L.T.A. Hui (Ministry of Health, Malaysia), P. Hurst (International Labour Organization, Switzerland), S. Kopp-Kubel (WHO/EDM), M. Limoli (Food and Drug Administration, USA), F. Mas (United Nations Children's Fund, Denmark), Médecins Sans Frontières (Belgium, France, Luxembourg, Spain and Switzerland), W.C. Mfuko (Medical Stores Department, Tanzania), S. Muziki (WHO/EDM), K. Myhr (Board of Health,Norway), H. Ogawa (Western Pacific Regional Environmental Health Centre, Malaysia), P. Ollé (International Committee of the Red Cross, Switzerland), B. Olsen (International Federation of Red Cross and Red Crescent Societies, Switzerland), E.M.A. Ombaka (The Pharmaceutical Programme, Community Initiatives Support Services International, Kenya & World Council of Churches), T.L. Paál (WHO Collaborating Centre for Drug Information and Quality Assurance, Hungary), J. Parrot (International Pharmaceutical Federation, Netherlands), A.M. Prüss (WHO/EOS), M. Richardson (BASIC, UK), F. Rossi (Essential Drugs Programme, Bolivia), P. Saunders (Essential Drugs Project, UK), G.M. Savage (CalRecovery Inc., USA/International Solid Waste Association, Denmark), K. Schönbucher Seitz (Federal Office of Public Health, Switzerland), B. Snell

* Now moved to WHO European Centre for Environment and Health, Rome.

(Victorian Medical Postgraduate Foundation, Australia), P. Spivey (WHO / DAP), S. Srnec Pekas (Croatia), D. Subasic (Croatia), G. Szalay (WHO / SUP), N. van der Graaff (Food and Agriculture Organization of the United Nations, Italy), A. Wodageneh (Food and Agriculture Organization of the United Nations, Italy).

This document was finalized by:

R.C.F. Gray	Department of Essential Drugs and Other Medicines, WHO
H.V. Hogerzeil	Department of Essential Drugs and Other Medicines, WHO
A.M. Prüss	Department of Protection of the Human Environment, WHO
P. Rushbrook	WHO European Centre for Environment and Health, Rome Division

First edition 1999

Comments and observations by users are welcome, and should be sent to the following address:

Department of Essential Drugs and Other Medicines
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27
Switzerland

Tel: 41 22 791 3528
Fax: 41 22 791 4167
E-mail: hogerzeilh@who.ch

Table of contents

Table of figures

1. Introduction

1.1 Background

During conflicts and natural disasters large quantities of pharmaceuticals are often donated as part of humanitarian assistance. Undoubtedly many of the pharmaceuticals save lives and alleviate suffering, but some donations given by well-meaning but uninformed people may cause problems. Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs, be unrecognizable because they are labelled in a foreign language or may have been sent in unwanted quantities. Donated pharmaceuticals with a long shelf-life may be mismanaged, particularly in the confusion during and after armed conflict or a natural disaster. Staff and storage space may be lacking and the pharmaceutical management system in disarray. Such problems also occur when drug donations form part of development assistance. Smaller quantities of pharmaceutical waste may accumulate in the absence of emergency situations, due to inadequacies in stock management and distribution, and to lack of a routine system of disposal. Safe disposal of these unwanted or expired drugs often creates a major problem.

These disposal guidelines are based on a report on the safe disposal of unwanted and unusable drugs in Mostar, which had accumulated during the war in Bosnia and Herzegovina. Quantifying pharmaceutical waste may be difficult. One report states that 50–60% of the 27,800-34,800 metric tons of medical supplies donated to Bosnia and Herzegovina between 1992 and mid-1996 were considered to be inappropriate, and by mid-1996 there were an estimated 17,000 metric tons of unusable drugs stockpiled in warehouses and clinics throughout the country[1]. These dramatic figures are contested: something in the region of 1,000 metric tons is considered by some to be more reasonable. A recent figure of 2,000 metric tons of pharmaceutical waste in Croatia is regarded as accurate. Unusable donated drugs hindered the efficient operation of pharmacies in many of the states of the former Yugoslavia and represented a significant disposal problem.

1.2 Prevention of waste from pharmaceutical donations

Appropriate donations

Inappropriate donations may be minimized by donors adhering to the interagency *Guidelines for Drug Donations*[2]. The key principles are that drugs donated shall address the expressed needs of the recipients and that the date of expiration on arrival shall be no less than one year, unless there is clear evidence from the recipients that they have the logistic and managerial capacity to store and distribute shorter–dated drugs efficiently. The blind donation of pharmaceuticals based on unsubstantiated assumptions of recipient needs and logistic capacities is a major factor in the production of pharmaceutical waste.

Good donations may be wasted

Mismanagement of received donations may turn a good donation into pharmaceutical waste.

1.3 The cost of disposal of waste pharmaceuticals

The cost of waste pharmaceutical high temperature incineration

Pharmaceuticals are ideally disposed of by high temperature (i.e. above 1,200ºC) incineration. Such incineration facilities, equipped with adequate emission control, are mainly to be found in the industrialized world. Quotations for disposing of the pharmaceutical waste in Croatia and Bosnia and Herzegovina in this way range from US$2.2 / kg to US$4.1 / kg. To incinerate the current stockpile of waste pharmaceuticals in Croatia would therefore cost between US$4.4 million and US$8.2 million.

Quoted weights of pharmaceutical waste

The gross weights mentioned previously include packaging. Actual pharmaceutical contents may be half, or less than half, of the gross weight.

1.4 Purpose of the guidelines

These guidelines provide advice on the implementation of safe disposal of unusable pharmaceuticals in emergencies and in countries in transition where official assistance and advice may not be available. They are not meant to supersede local, regional or national laws regarding disposal of drugs, but to provide assistance where there is insufficient guidance or none at all.

A number of methods for safe disposal of pharmaceuticals are described. These are methods which involve minimal risks to public health and the environment, and include those suitable for countries with limited resources and equipment. The adoption of the guidelines by ministries of health, environment and other relevant ministries, and their practical application, will contribute to the safe and economical elimination of stockpiles of unusable pharmaceuticals