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MODEL GUIDELINES
for the
**INTERNATIONAL PROVISION OF
CONTROLLED MEDICINES**
for Emergency Medical Care



WORLD HEALTH ORGANIZATION
Programme on Substance Abuse

ABSTRACT

Because of the risk of abuse, some essential drugs are under strict international control. The export-import control measures applicable to narcotic drugs, for example, make the timely international transportation of opioid analgesics to sites of emergencies virtually impossible. Faced with this difficulty, the World Health Organization (WHO) and the International Narcotics Control Board (INCB) agreed that there was an urgent need to find a practical solution to this problem. Through subsequent discussions at the United Nations Commission on Narcotic Drugs in April 1996, and the World Health Assembly in May 1996, an international consensus was established to support the application of simplified export-import control procedures in emergency situations, in order to improve the accessibility of disaster-stricken peoples to controlled medicines. With regard to the actual mechanism of such a simplified procedure, WHO was invited to draw up Model Guidelines to assist national authorities.

This document has been developed through an international consultation participated by representatives of several national regulatory authorities, relevant UN agencies and organizations providing emergency medical supplies. As the word "model" implies, this document describes an example of simplified control procedures for the international provision of controlled medicines for emergency medical care. It may be necessary for national regulatory authorities to modify this model to meet their national requirements.

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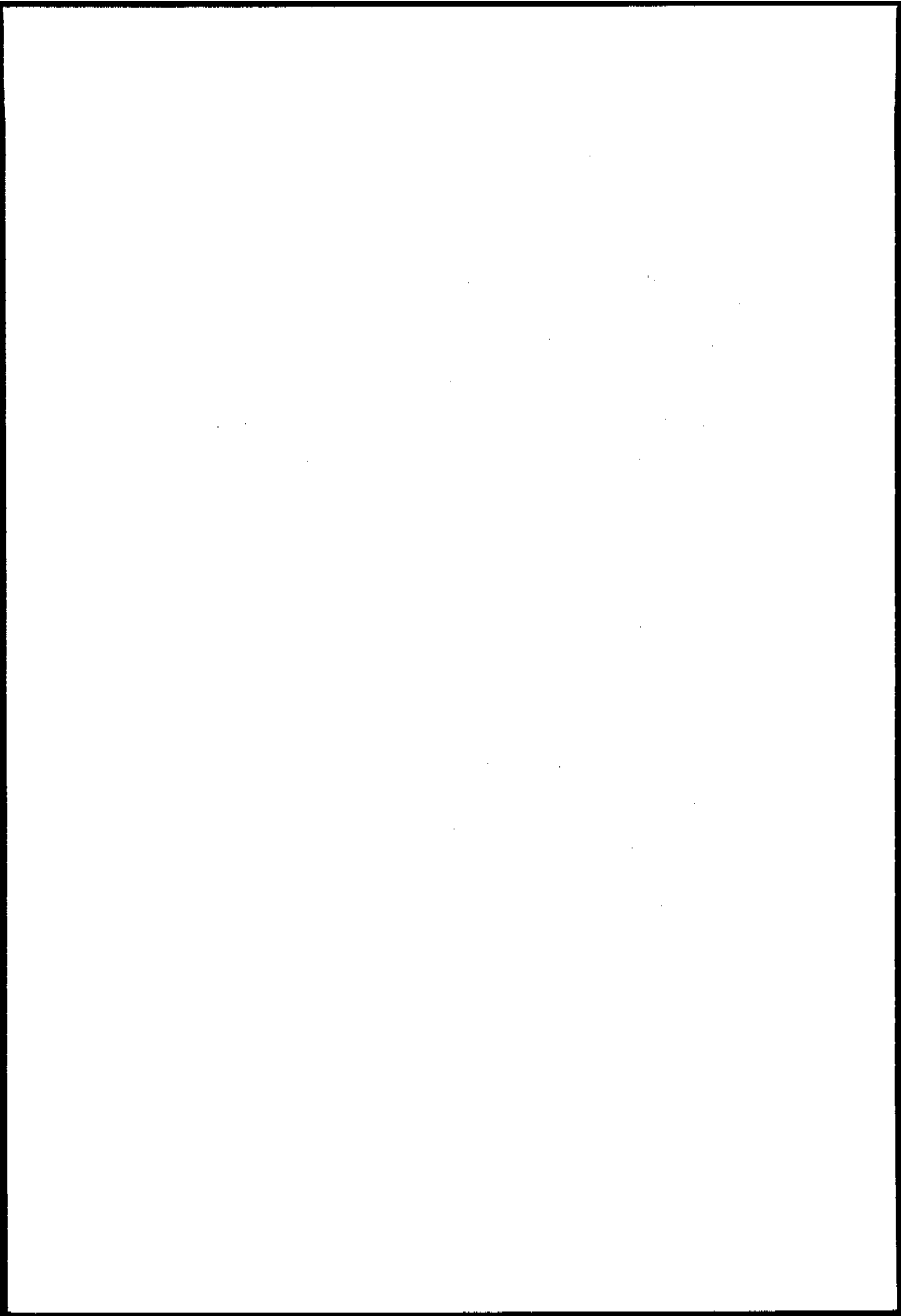
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I. INTRODUCTION

A sudden rise in the need for medical care in emergency situations following natural or man-made disasters creates an acute shortage of medical supplies. Several international organizations and nongovernmental organizations (NGOs) are actively involved in the provision of humanitarian assistance by delivery of medical supplies in emergency situations. However, they are often faced with serious difficulties in providing several essential medicines containing narcotic drugs or psychotropic substances partly because of the regulatory requirements concerning their importation and exportation. The lack of these medicines results in additional human suffering by depriving those in need of adequate pain relief and sedation.

In order to improve the provision of medical care for disaster-stricken peoples, there is an urgent need to work out a practical solution to this problem.

Cause of the Problem

Based on operational experiences, humanitarian aid agencies perceive the problem as follows:

The international transportation of humanitarian supplies containing narcotic drugs and psychotropic substances is regarded by the control authorities as "exportation" requiring prior import authorizations from the authorities of the receiving country. As such, the import/export authorization system makes the quick international transportation of controlled drugs to sites of emergencies virtually impossible. In addition, the rigorous application of the estimate system can further complicate the procedure. While the International Narcotics Control Board (INCB) has advised control authorities that emergency humanitarian deliveries are considered as being consumed in the exporting country and included as such in the estimate of the exporting country, in reality, authorities had often followed the procedure for normal import/export transactions. This procedure often takes too long to meet the acute need for relief in some emergency situations, particularly when the control authorities in the receiving country are rendered dysfunctional, or are not in a position to issue import authorizations for the inhabitants in the disaster-stricken area of the country.

Consequences

As a consequence, all humanitarian aid agencies have abandoned the provision of narcotic drugs in their emergency medical supplies. Instead, pentazocine or buprenorphine (in Schedule III of the Convention on Psychotropic Substances, 1971) has been provided as an alternative for narcotic analgesics. Even this has become increasingly difficult, as more and more Governments have introduced the export/import authorization and the "assessment" systems for Schedule III and IV psychotropic substances in response to the resolution adopted by the Economic and Social Council (ECOSOC). The same applies to diazepam and phenobarbital in Schedule IV of the 1971 Convention.

Furthermore, difficulty has been encountered even with ephedrine, ergometrine, ketamine, tramadol, thiopental, and chlorpromazine as some national control authorities apply similar export/import control systems to these medicines.

Search for a Solution

WHO brought this issue to the attention of the INCB in an effort to find a practical solution. The INCB, in its report for 1994, recommended that control obligations could be limited to the authorities of exporting countries in emergency situations. This principle was endorsed at the 38th session of the UN Commission on Narcotic Drugs in 1995, and was further reinforced by its resolution entitled "Timely provision of controlled drugs for emergency care" adopted at the 39th session in 1996 (Annex 1). This and a similar resolution adopted by the 49th session of the World Health Assembly (Annex 2) request WHO to prepare model guidelines to assist national authorities with simplified regulatory procedures for this purpose, in consultation with the relevant UN bodies and interested governments.

These model guidelines are prepared in response to the above resolutions. In essence, the procedures proposed would allow certain suppliers to make international shipments of controlled medicines at the request of recognized agencies providing humanitarian assistance without prior export/import authorizations in emergency situations, following defined procedures acceptable to the control authorities and the INCB.

II. DEFINITIONS

The following definitions are used in this document.

Emergency

Any acute situation (e.g. earthquakes, floods, hurricanes, epidemics, conflicts, displacement of populations) in which the health conditions of a group of individuals are seriously threatened unless immediate and appropriate action is taken, and which demands an extraordinary response and exceptional measures.

Availability of control authorities

Control authorities are considered unavailable, when an emergency occurs which results in a disruption of the function of such authorities to issue import authorizations.

When an emergency occurs in areas outside the control of the government, a solution should be found, on a case by case basis, through discussions with the control authorities of the exporting countries and the INCB.

Control authorities

Control authorities mean the competent national authorities designated by their governments in accordance with the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971 (ref. United Nations publication "*Competent national authorities under the international drug control treaties*", available from the United Nations).

Operator

International, governmental and/or nongovernmental organizations engaged in the provision of humanitarian assistance in health matters recognized by the control authorities of exporting countries (e.g. UNICEF, UNHCR, WHO, ICRC (International Committee of the Red Cross), IFRC (International Federation of Red Cross and Red Crescent Societies), MSF (Médecins sans Frontières), national aid agencies and bona fide NGOs).

Supplier

Supplier of drugs for humanitarian assistance at the request of operators. A supplier may either be a separate entity or a section or department of an operator.

III. PURPOSE AND PRINCIPLE

The model guidelines are aimed at enabling operators to supply, across international boundaries, essential narcotic drugs and psychotropic substances for emergency medical care.

To strike a delicate balance between the need for the timely provision of essential medicines, and the need to minimize the risk of their diversion, the procedures should be based on the principle of limiting control obligations to the control authorities of exporting countries.

IV. SCOPE OF APPLICATION

These procedures would be applicable to the international provision of essential narcotic and psychotropic medicines by a limited number of operators in acute emergency situations, either with or without control authorities in the receiving country, as well as to less urgent humanitarian assistance by these operators in situations where the control authorities are not available in the receiving country.

V. SELECTION OF SUPPLIERS

Suppliers should be limited to those recognized by the control authorities of exporting countries. They should at least have:

- (1) adequate experience as a supplier of good quality emergency medical supplies
- (2) managerial capability to assess the appropriateness of requests for the simplified procedure from operators
- (3) adequate level of stock and a responsible pharmacist
- (4) sufficient knowledge about the relevant international conventions
- (5) standard agreement with the control authorities of exporting countries (see section VI below)

VI. OUTLINE OF STANDARD AGREEMENT BETWEEN SUPPLIERS¹ AND CONTROL AUTHORITIES OF EXPORTING COUNTRIES

The standard agreement should at least cover:

- (1) criteria for acceptance of shipment requests from operators (a model form is attached at the end)

The criteria for immediate acceptance of shipment requests from operators should at least specify the essential information to be furnished to the supplier concerning:

- a. credibility of the requesting operator

A pre-determined list of credible operators ought to be prepared. A credible operator should (a) be an established organization; (b) have adequate experience for international provision of humanitarian medical assistance; (c) have responsible medical management (medical doctor(s) or pharmacist(s)); and (d) appropriate logistic support.

- b. nature of the emergency and the urgency of the request

A statement to the supplier on the nature of the emergency by the operator, or if appropriate, by a UN agency.

- c. availability of control authorities in the receiving country

¹ When an operator is also a supplier, the agreement will be between the operator and the control authorities.

d. diversion prevention mechanism after delivery

Indicate if the requesting operator itself is the user of the supplies. If not, the name and organization of the person responsible for receipt and internal distribution of the supplies should be indicated. As far as possible, the recipients in the receiving country should be identified.

(2) timing and mode of reporting to the control authorities and the INCB

When control authorities are available in the receiving country, they should be notified as soon as possible by the control authorities of the exporting country and the operator of a consignment of the emergency delivery, while their import authorization may not have to be required under the circumstances of an emergency situation.

Suppliers should inform the control authorities of the exporting country of each emergency shipment being made in response to a request from an operator so that the control authorities can intervene if necessary.

Suppliers should submit to the control authorities of the exporting country an annual report on emergency deliveries and quantities of drugs involved as well as their destinations in duplicate, so that one copy can be forwarded to the INCB.

Suppliers, or operators through the suppliers, should inform the control authorities of the exporting countries, with copy to the INCB, of any problems encountered in the working of emergency deliveries.

(3) other relevant matters

As appropriate, the agreement may include provisions on other relevant matters such as inspection and guidance by the control authorities. Although the quantities involved would be rather small, it may touch upon estimated/assessed requirements based on the principle that the drugs provided should be regarded as having been "consumed" in the exporting country.

VII. SUMMARY OF THE REQUEST PROCEDURE

(1) Operator's role

The operator should make a written request for emergency supplies of controlled substances to the supplier, using the attached model form. The operator is responsible for:

- information provided on the form;

- actual handling of controlled drugs at the receiving end or adequate delivery to the reliable recipient;
- reporting to the control authorities of the receiving country (whenever they are available) as soon as possible;
- reporting to the control authorities of the receiving country on unused quantities, if any, when the operator is the end-user or to arrange for the end-user to do so;
- reporting to the control authorities of the exporting country through the supplier, with copy to the INCB, any problems encountered in the working of emergency deliveries.

(2) Supplier's role

Before responding to the request from the operator, the supplier should be convinced that the nature of the emergency justifies the application of the simplified procedure without export/import authorizations. The supplier is also responsible for:

- submitting immediately a copy of the shipment request to the control authorities of the exporting country;
- submitting an annual report on emergency deliveries and quantities of drugs involved as well as their destinations, with copy to the INCB;
- reporting to the control authorities of the exporting country, with copy to the INCB, any problems encountered in the working of emergency deliveries.

(3) Control authorities' role

The control authorities of the exporting country should inform their counterpart in the receiving country (whenever they are available) of the emergency deliveries.

The control authorities of the receiving country have the right to refuse the importation of such deliveries. Emergency deliveries need not be included in the estimate of the receiving country, since they are regarded as having been consumed in the exporting country.

**Model Shipment Request/Notification Form
for Emergency Supplies of Controlled Substances**

Operator:

Name:.....
Address:.....
Name of the responsible medical director/pharmacist:.....
Title:.....
Phone No. Fax No.....

Requests the supplier:¹

Name:.....
Address:.....
Responsible pharmacist:.....
Phone No. Fax No.....

For an emergency shipment² of the following medicine(s) containing controlled substances:

Name of product (in INN/generic name) and dosage form, amount of active ingredient per unit dose, number of dosage units in words and figures

Narcotic drugs as defined in the 1961 Convention (e.g. morphine, pethidine, fentanyl)

[e.g. Morphine injection 1 ml ampoule; morphine sulfate corresponding to 10 mg of morphine base per ml; two hundred (200) ampoules]

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.....

Psychotropic substances as defined in the 1971 Convention (e.g. buprenorphine, pentazocine, diazepam, phenobarbital)

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.....
.....

Others (nationally controlled in the exporting country, if applicable)

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.....

¹ If the operator is exporting directly from its emergency stock, it should be considered as a supplier.

² Emergency deliveries do not affect the estimate of the recipient country since they have already been accounted for in the estimate of the exporting country.

To the following recipient (whichever applicable) :

Country of final recipient:.....

Responsible person for receipt:

Name:.....

Organization/Agency:.....

Address:.....

Phone No. Fax No.

For use by/delivery to:

Location: Organization/Agency:.....

.....
.....

Consignee (If different from above e.g. transit in a third country):

Name: Organization/Agency:.....

Address:.....

Phone No. Fax No.

Nature of the emergency (Brief description of the emergency motivating the request):

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.....
.....
.....

Availability of, and action taken to contact the control authorities in the receiving country:

.....
.....

I certify that the above information is true and correct. My Organization will:

- Take responsibility for receipt, storage, delivery to the recipient/end-user, or use for emergency care (strike out what is not applicable) of the above controlled medicines;
- Report the importation of the above controlled medicines as soon as possible to the control authorities (if available) of the receiving country;
- Report the quantities of unused controlled medicines, if any, to the control authorities of the receiving country (if available), or arrange for the end-user to do so (strike out what is not applicable).

Title:

Date:

Location:

.....
(Signature)

Annex 1**Resolution 7 (XXXIX)****Timely provision of controlled drugs for emergency care**The Commission on Narcotic Drugs,

Recognizing that some controlled drugs are essential medicines for the treatment of human suffering,

Underlining the fact that timely international supplies of essential medicines are often vital for humanitarian disaster relief operations in emergency situations,

Aware that the speedy international transportation of narcotic drugs and psychotropic substances to sites of emergencies is difficult within the established international drug control system,

Noting with satisfaction the attention given to the issue by the International Narcotics Control Board in its report for 1994¹, and the positive reaction of the Commission to the opinion expressed by the Board and the further proposals of the Board in its report for 1995²,

1. Endorses the position of the International Narcotics Control Board that the transportation and provision of controlled drugs needed for humanitarian aid in acute emergencies justify the application of simplified control procedures;

2. Further endorses the existing practice by some countries of applying simplified controls in emergency situations;

3. Recommends that the national authorities of exporting countries conclude, where appropriate, standing agreements with bona fide suppliers of humanitarian aid, specifying operational procedures to ensure the proper handling of controlled drugs;

4. Also recommends that the authorities of the recipient countries report to the exporting countries and to the Board, wherever possible, the quantity of the unused drugs for emergency care, if any, in order to permit the re-evaluation of the estimated annual requirements;

5. Invites the World Health Organization, in consultation with the Board and interested Governments, to draw up model guidelines to assist national authorities in developing such standard agreements with bona fide humanitarian organizations.

6. Requests the Secretary-General to transmit the present resolution to all Governments for consideration and implementation.

¹Report of the International Narcotics Control Board for 1994 (United Nations publication, Sales No. E.95.XI.4).

²Report of the International Narcotics Control Board for 1995 (United Nations publication, Sales No. E.96.XI.1).

**Collaboration within the United Nations system and
with other international organizations:
Supply of controlled drugs for emergency care**

The Forty-ninth World Health Assembly,

Recognizing that some controlled drugs, such as opioid analgesics, are essential medicines for the treatment of human suffering;

Also recognizing that timely international supplies of essential medicines are often vital for humanitarian disaster relief operations in emergency situations;

Concerned because speedy international supply of opioid analgesics to sites of emergencies is impossible because of the export and import control measures that apply to narcotic drugs;

Concerned further about the similar difficulties experienced even with regard to psychotropic substances, as an increasing number of national authorities apply stricter control measures than are provided under the relevant international treaty;

Noting, with satisfaction, that the International Narcotics Control Board shares such concern;

Convinced that a practical solution to this problem should be found through intensified dialogue between the health and drug control authorities at all levels,

1. URGES Member States to initiate or intensify dialogue between health and drug control authorities in order to establish simplified regulatory procedures that allow timely international supply of narcotic drugs and psychotropic substances in emergency situations;
2. REQUESTS the Director-General to prepare, in consultation with the relevant United Nations bodies involved in the international control of narcotic drugs and psychotropic substances, model guidelines to assist national authorities with simplified procedures for this purpose.

Sixth plenary meeting, 25 May 1996
A49/VR/6