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United Nations Office on Drugs and Crime

# Guidelines for national regulations concerning travellers under treatment with internationally controlled drugs

# GUIDELINES FOR NATIONAL REGULATIONS CONCERNING TRAVELLERS UNDER TREATMENT WITH INTERNATIONALLY CONTROLLED DRUGS

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# Preface

The guidelines have been developed by the United Nations International Drug Control Programme (UNDCP), in cooperation with the International Narcotics Control Board (INCB) and the World Health Organization (WHO), primarily to assist national authorities in introducing a regulatory framework to deal with situations in which patients under treatment with preparations containing internationally controlled drugs are travelling abroad and carrying with them small quantities of such preparations for personal use. Such regulations would enhance the security of patients by making them aware of national requirements in the country they intend to visit. The guidelines also present elements of unified procedures that can be implemented by national authorities responsible for the control of narcotic drugs and psychotropic substances.

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# I. Introduction

## A. General

1. The question of provisions regarding medical preparations containing controlled drugs carried by international travellers was raised during the forty-third session (March 2000) of the Commission on Narcotic Drugs. The Commission noted that relevant provisions were included in the Convention on Psychotropic Substances of 1971,[1] but that a problem existed concerning travellers being treated by means of medical preparations containing narcotic drugs controlled under the Single Convention on Narcotic Drugs of 1961,[2] and that Convention as amended by the 1972 Protocol.[3] In its resolution 43/11, the Commission therefore invited the International Narcotics Control Board (INCB) to examine existing provisions in that regard.

2. Pursuant to that resolution, a review of the issue was included in the report of INCB for 2000 (paras. 119-127). The review showed that in most of the States that had transmitted relevant information to INCB, travellers under treatment were permitted to carry small quantities of preparations containing narcotic drugs and/or psychotropic substances for personal use. However, considerable divergences existed between States with regard to the limits on the quantities of substances that may be carried, as well as to the requirements concerning documents confirming that the traveller is a bona fide patient under treatment.

3. During its forty-fourth session (March 2001), the Commission, in its resolution 44/15, invited the United Nations International Drug Control Programme (UNDCP), in cooperation with INCB and the World Health Organization (WHO), to convene a meeting of experts to develop guidelines for national regulations concerning travellers under treatment with internationally controlled drugs.

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[1]United Nations, *Treaty Series*, vol. 1019. No. 14956.

[2]Ibid., vol. 520, No. 7515.

[3]Ibid., vol. 976, No. 14152.

4. Resolution 44/15 indicated that the guidelines should cover the following topics:

*(a)* The type of drug that people under treatment can carry with them;

*(b)* The length of treatment involved and the maximum authorized quantities of drugs;

*(c)* The type of documentation required to demonstrate that the substances were lawfully obtained in the country of origin.

5. In November 2001, a questionnaire was sent to a number of Governments to obtain their views on those specific issues and draft guidelines were prepared by UNDCP, with the cooperation of INCB and WHO, and with the assistance of a consultant, for submission to the meeting of experts convened in Vienna on 12 to 14 February 2002, pursuant to resolution 44/15.

## B. Purpose and scope of the guidelines

6. The guidelines have been developed primarily to assist national authorities in introducing a regulatory framework to deal with situations in which patients under treatment with preparations containing internationally controlled drugs are travelling abroad and carrying with them small quantities of such preparations for personal use. Such regulations would enhance the security of patients by making them aware of national requirements in the country they intend to visit. The guidelines also present elements of unified procedures that can be implemented by national authorities responsible for the control of narcotic drugs and psychotropic substances. A wide application of those procedures would facilitate both the mutual disclosure of relevant information through INCB and the work of government authorities. However, it should be understood that countries have latitude to implement the guidelines only partially or with suitable modifications, depending on their legal requirements and practical considerations.

7. The guidelines are dealing with issues pertaining to medical preparations containing controlled substances that are licensed in the country of departure of the traveller in the dosage form only and not with individually compounded preparations. The provisions of the guidelines do not relate to the carrying of pure active substances (raw materials), such substances being mentioned in the guidelines only for the purpose of calculation of their amounts in medical preparations. Definitions

of key terms used in the draft guidelines are given in the glossary included in the present document.

## C. Treaty background

8. The issue of international travellers under treatment carrying preparations containing internationally controlled drugs is dealt with differently under the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971. The 1971 Convention explicitly envisages, in article 4, that Parties may permit the carrying by international travellers of small quantities of preparations for personal medical use, while the 1961 Convention does not contain any statement to that effect.

9. Article 30, paragraph 2 *(b),* of the 1961 Convention and article 9, paragraph 1, of the 1971 Convention require that medical prescriptions be issued by physicians to describe medical preparations that are to be used by patients. The conventions give only general indications concerning the contents of such documents, although the 1961 Convention, in article 30, paragraph 2 *(b)* (ii), mentions the use of prescriptions issued in the form of counterfoil books. There is a need therefore to describe those documents in greater detail in the guidelines, especially when they are intended to serve as evidence that medical preparations were lawfully obtained by the traveller in the country of departure.

10. It should also be understood that the carrying by travellers under treatment of medical preparations containing internationally controlled drugs from the country of departure to the country of destination does not constitute an export or import operation, that would require reporting under the international drug control treaties. The situation is instead similar to that described in article 32, paragraph 1, of the 1961 Convention and in article 14, paragraph 1, of the 1971 Convention, concerning the carriage of controlled substances in first-aid kits. However, when a country has pursuant to article 13 of the 1971 Convention notified that it prohibits the import into its territory of specific psychotropic substances, such prohibition will also apply to those substances when carried by travellers under treatment.

# II. Guidelines

## A. Legislative and regulatory context of the issue of carrying medical preparations containing internationally controlled drugs by travellers under treatment

11. The procedures related to the carrying by travellers of preparations containing internationally controlled drugs have to be consistent with national legal and administrative frameworks. Included therein are legislation and regulations related to the control of licit use of narcotic drugs and psychotropic substances for medical purposes and those related to the control of the cross-border movement of goods. For practical purposes, the procedures have to take into account existing regulations governing prescriptions for medical preparations containing internationally controlled drugs, as well as regulations and practices of customs authorities.

12. National regulations related to the carrying of medical preparations by travellers have to deal with two separate issues. The first concerns travellers entering the country and carrying for their medical use preparations containing internationally controlled drugs. The second concerns travellers departing from the country, who are required by the country of destination to hold a formal confirmation that they licitly possess medical preparations.

13. With regard to travellers entering the country, national regulations need to describe the document (prescription, certificate or permit, as the case may be) that will be required to confirm the licit status of medical preparations carried by the traveller, as well as the specific procedure, if any, to be followed by the traveller when entering the country. The establishment and implementation of such regulations will involve both national health authorities and customs/law enforcement authorities (police and special drug law enforcement bodies).

14. With regard to travellers departing from the country, the national health authorities in the country of departure need to designate an authority or authorities in charge of issuing appropriate documents (certificates) confirming that the medical

prescription held by the traveller was issued by an authorized medical practitioner and that the medical preparations were licitly acquired. This task may be entrusted to a single central authority or delegated to local authorities.

15. In States that, as a general rule, do not permit travellers (both those entering and those leaving the country) to carry internationally controlled drugs, it might be advisable to designate a competent authority able to issue, in exceptional circumstances, the necessary certificates or permits on compassionate grounds.

## B. Documents for travellers who carry medical preparations containing internationally controlled drugs

16. The medical prescription is the principal document which confirms the legal authority of the traveller to possess, for personal use, medical preparations containing internationally controlled drugs. Depending on the requirements of the country of destination, and on the quantities of preparations involved, the traveller may additionally be required to obtain (directly or with the assistance of his/her physician) a certificate issued by a competent authority in the country of departure, and/or a permit issued by a competent authority in the country of destination. Travellers who travel by land and cross the territory of third countries should also ascertain the documents required by the transit countries.

17. The medical prescription should be issued in the country of departure by the patient's treating physician, taking into account the approved indications for the medical product. The prescription should indicate the name of the patient, the name of the medicinal product (usually a trademark but also the international name of the active substance), the posology and total amount of the medical preparation prescribed. The prescription should be issued according to national regulations governing the prescribing of controlled drugs, including the use of appropriate forms. The amount of the preparation prescribed should be in conformity with the principles governing good medical practice. When the prescription is issued in a country where national regulations limit the maximum length of treatment with specific types of medical preparations containing internationally controlled drugs, the physician should abide with such regulations, unless there exists a specific exemption concerning patients travelling abroad.

18. Prescriptions for narcotic drugs are usually written using counterfoil books, the original being given to the patient and the copy remaining with the prescribing

physician. If the original of the prescription is retained in the pharmacy that dispensed the preparation, it is advisable for the physician to either give to the patient who intends to travel abroad a duplicate of the prescription, or issue a letter indicating that a preparation containing internationally controlled drugs was prescribed for the traveller and specifying the amount prescribed and the duration of treatment. The duplicate of the prescription retained by the traveller may contain an attestation (or stamp) from the dispensing pharmacy confirming the purchase of the product.

19. Certificates to be issued by the competent authority of the country of departure may be required to confirm the patient's legal authority to possess, for personal use, preparations containing internationally controlled drugs. Such certificates are issued on the basis of the medical prescription identifying the patient and indicating the type and amount of preparations that he/she is permitted to carry. In case of prescriptions of unusually high amounts, the competent authority should also ascertain that the prescription is in line with the patient's needs. Certificates should also indicate the total amount of the controlled substance contained in the medical preparation, using the international non-proprietary name (INN) of the substance in accordance with relevant schedules of the international drug control conventions. A model form for certificates is attached as annex I to the present guidelines.

20. Prescriptions are normally in the language of the country in which they are issued. Certificates should preferably be issued in a generally used language, such as English, French or Spanish. If the country of destination so requires, the traveller should obtain a translation of the prescription, of the letter produced by the physician, or of the certificate into a language generally used in the country of destination.

## C. National procedures for issuing certificates and permits

21. A procedure should be established by the national health authorities indicating the competent authority (or local bodies) authorized to issue certificates confirming the legal authority of the patient to possess, for personal use, preparations containing internationally controlled drugs that he/she intends to carry abroad. Certificates may either be produced by the issuing authority or completed, on a suitable form, by the treating physician, and presented to the competent authority for confirmation (stamp, seal and signature). The authority issuing the certificate should take due

account, to the extent possible, of the types and maximum amounts of preparations containing internationally controlled drugs that travellers are allowed to carry into the country of destination. The names and addresses of authorities responsible for issuing the certificates for travellers should be made generally available to medical practitioners.

22. States that require travellers under treatment to obtain a permit from the country of destination before arrival in that country should also establish suitable procedures to that effect. Such procedures should indicate the authority competent for the issuance of permits, establish the extent of medical information to be provided by the traveller, and describe any restrictions on the types and amounts of preparations that travellers are allowed to carry for their personal use. The requirement of a prior permit may apply to all types of internationally controlled substances or to specific types of substances only (for example, narcotic drugs).

## D. Types of preparations that travellers under treatment are frequently carrying with them and restrictions related to their amounts

23. The guidelines consider a period of 30 days of treatment as a period of sufficient length for prescription of medical preparations for travellers. Beyond that period, it should be possible for the traveller to obtain a prolongation of treatment in the visited country, if needed. However, a longer period may be acceptable for patients treated with psychotropic substances used as anticonvulsant agents.

24. Annexes II and III to the present guidelines include an indicative list of types of narcotic drugs and psychotropic substances contained in preparations frequently used for medical treatments. The quantities indicated in the annexes refer to the maximum total amount of controlled substance contained in the preparations for the prescribed medical treatment that may be carried by the international traveller.

25. The quantities were calculated on the basis of a 30 day-period of treatment and defined average daily doses used by INCB for statistical purposes. Those doses correspond, in most cases, to the doses recommended by WHO for drug utilization studies. In the case of substances used for the treatment of chronic or severe pain for terminally ill patients and in the case of substances used for maintenance treatment and/or substitution treatment of drug dependence, the quantities indi-

cated were calculated taking into account doses actually used for those categories of patients. This mode of calculation may be used by countries, which, due to local considerations, need to establish maximum quantities for additional types of preparations or introduce modifications to the quantities indicated in the examples.

26. Annex II provides examples of narcotic drugs listed in Schedules I and II of the 1961 Convention and psychotropic substances listed in Schedules II and III of the 1971 Convention, and the maximum total quantities of controlled substance contained in preparations for the prescribed medical treatment allowed to be carried by international travellers. For amounts exceeding the indicated limits, the traveller should be required to possess a certificate.

27. Annex III provides examples of psychotropic substances listed in Schedule IV of the 1971 Convention and the maximum total quantities of controlled substance contained in preparations for the prescribed medical treatment allowed to be carried by international travellers. For amounts exceeding the indicated limits, the traveller should be required to possess a prescription. The possession of a prescription should not be required from travellers carrying preparations containing psychotropic substances listed in Schedule IV of the 1971 Convention in amounts not exceeding the quantities indicated in Annex III.

28. It should be understood that narcotic drugs included in Schedule IV of the 1961 Convention cannot be carried by international travellers, even if their use is permitted in the country of departure. Furthermore and as already indicated in paragraph 9 above, prohibition of the import of specific psychotropic substances into countries that made a notification pursuant to article 13 of the 1971 Convention (see the "Green List" issued periodically by INCB) will entail the prohibition of the carrying by travellers under treatment of medical preparations containing such psychotropic substances.

29. It is also understood that preparations, intended for personal use, of narcotic drugs listed in Schedule III of the 1961 Convention may usually be carried by international travellers without restrictions.

30. Finally, no prescription should be required for travellers carrying up to one retail package (usually 20 unit doses or less) of any preparation containing internationally controlled drugs.

## E. Procedures to be followed by travellers entering the country of destination

31. When entering the country of destination and depending on the type of preparation and amount of controlled substances involved, the traveller should have in his/her possession the documents required by that country: medical prescription, certificate and/or permit, confirming his/her legal authority to possess, for personal use, medical preparations containing internationally controlled drugs.

32. In many countries, the traveller will not be required to spontaneously present those documents to the customs authorities. However, those documents should be in the traveller's possession during the stay in the visited country, and should be available on request for presentation to the authorities.

33. In some countries, however, the traveller may be required to present the required documents to the customs authorities on entering the country of destination. In such situations, the document is usually confirmed by an annotation of the customs officer.

34. Travellers who travel by land and cross in transit the territory of a third country have to comply with the required procedures when entering and leaving the transit country in respect of possession of suitable documents, and, as the case may be, to their presentation to customs authorities.

## F. System of notification from countries on restrictions for travellers carrying medical preparations containing internationally controlled drugs

35. INCB in its report for 2001 (paragraph 164) stated that it would publish information on restrictions on the carrying by travellers of medical preparations containing internationally controlled drugs.

36. Furthermore, there is a need for mutual disclosure among countries of the following data:

*(a)* Information on the type of documents required for incoming travellers indicating whether a medical prescription or a letter issued by the treating physician

is required, or/and a certificate or/and a permit as well as on specific language demands, if any, for those documents;

*(b)* Information as to whether travellers carrying internationally controlled drugs are required to present, on entering the country of destination, the above-mentioned documents for confirmation by the customs officer;

*(c)* Where required, the names and addresses of the authorities responsible for issuing permits for travellers carrying preparations containing internationally controlled drugs, when those are different from the competent national authorities empowered to issue certificates and authorizations for the import and export of narcotic drugs and psychotropic substances in accordance with the 1961 and 1971 Conventions (see Directory of Competent National Authorities published yearly by UNDCP).

# Annex I. Model form of a certificate for the carrying by travellers under treatment of medical preparations containing narcotic drugs and/or psychotropic substances

**A. Country and place of issue**

Country:
Place of issue:
Date of issue:
Period of validity:*

**B. Prescribing physician**

Last name, first name:
Address:
Phone: country code, local code, number
Number of licence:

**C. Patient**

Last name, first name:
Sex:
Place of birth:
Date of birth:
Home address:
Number of passport or of identity card:
Intended country of destination:

**D. Prescribed medical preparation**

Trade name of drug (or its composition):
Dosage form:
Number of units (tablets, ampoules etc.):
International name of the active substance:

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*A three month period of validity from the date of issue is recommended.

Concentration of active substance:
Total quantity of active substance:
Instructions for use:
Duration of prescription in days:
Remarks:

**E. Issuing authority**

Official designation (name) of the authority:
Address:
Phone: country code, local code, number
Official seal of the authority:
Signature of responsible officer:

# Annex II. Examples of narcotic drugs and psychotropic substances contained in medical preparations and the maximum total quantities of those substances, in base form, beyond which the traveller should be required to possess a certificate

## A. Narcotic drugs listed in Schedule I of the 1961 Convention

| *Narcotic drug* | *Quantity* |
|---|---|
| Fentanyl | 100 mg as transdermal patches<br>20 mg as other dosage forms (tablets, etc.) |
| Hydrocodone | 450 mg |
| Hydromorphone | 300 mg |
| Methadone | 2 g |
| Morphine | 3 g |
| Oxycodone | 1 g |
| Pethidine | 12 g |

## B. Narcotic drugs listed in Schedule II of the 1961 Convention

| *Narcotic drug* | *Quantity* |
|---|---|
| Codeine | 12 g |
| Dextropropoxyphene | 6 g |
| Dihydrocodeine | 12 g |

## C. Psychotropic substances listed in Schedule II of the 1971 Convention

| *Psychotropic substance* | *Quantity* |
|---|---|
| Dronabinol | 1 g |
| Methylphenidate | 2 g |

## D. Psychotropic substances listed in Schedule III of the 1971 Convention

| *Psychotropic substance* | *Quantity* |
|---|---|
| Buprenorphine | 300 mg |
| Butalbital | 1 g |
| Flunitrazepam | 30 mg |
| Pentazocine | 6 g |
| Pentobarbital | 3 g |

# Annex III. Examples of psychotropic substances listed in Schedule IV of the 1971 Convention contained in medical preparations and the maximum total quantities of those substances, in base form, beyond which the traveller should be required to possess a prescription

| *Pschotropic substance* | *Quantity* |
|---|---|
| Barbital | 15 g |
| Chlordiazepoxide | 1 g |
| Clorazepate | 600 mg |
| Diazepam | 300 mg |
| Lorazepam | 75 mg |
| Medazepam | 600 mg |
| Meprobamate | 40 g |
| Oxazepam | 1.5 g |
| Phenobarbital | 6 g* |
| Prazepam | 1 g |
| Temazepam | 600 mg |
| Tetrazepam | 3 g |

*Calculation based on two months average treatment.

# Glossary

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|---|---|
| Country of departure (country of origin) | Country where the traveller obtained the medical preparations containing internationally controlled drugs in his/her possession |
| Country of destination (host country) | Country visited by the traveller |
| Internationally controlled drugs | Substances controlled under the 1961 and 1971 Conventions |
| Medical practitioner (registered medical practitioner) | A physician duly authorized to prescribe internationally controlled drugs |
| Prescription | A document, also called medical prescription or prescription order, issued by a physician and indicating name of patient, medical preparations to be used by the patient and their posology |

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