

# Annex.

## Questionnaire sent in 2014 to competent national authorities of Member States on the availability of internationally controlled substances for medical and scientific purposes

### Questionnaire for National Competent Authorities on the availability of Internationally Controlled Substances for medical and scientific purposes

#### Part 1 of 2 – Narcotic drugs

Please return this questionnaire by 31 October 2014 to:

INCB Secretariat  
Vienna International Centre  
P.O. Box 500  
1400 Vienna  
Austria

Fax: (+43-1) 26060-5867  
Tel.: (+43-1) 26060-4933  
E-mail: [secretariat@incb.org](mailto:secretariat@incb.org)

**Please state the name of the submitting authority:**

Country: .....

Authority: .....

Contact person: .....

Tel.: ..... Fax: ..... E-mail: .....

Please provide the names of authorities and contact persons who might be able to provide additional information if required:

Authority/ies: .....

Contact person/s: .....

Tel.: ..... Fax: ..... E-mail: .....

**Instructions for filling out this questionnaire.**

This questionnaire consists of two parts:

**Part 1 relates to the availability of narcotic drugs subject to international control under the 1961 Single Convention on Narcotic Drugs**

**Part 2 relates to the availability of psychotropic substances subject to international control under the 1971 Convention on Psychotropic Substances**

According to the national regulatory framework in place in each State, these substances may be dealt with by the same competent authority or be controlled by two distinct institutional actors. In both cases, each part should be duly filled out by the appropriate stakeholder, and the consolidated questionnaire, containing both parts, should be returned to the INCB secretariat using the contact details provided on the cover page by the deadline indicated.

For the purpose of expediency, electronic submission of the completed questionnaire is encouraged.

## Part 1. Narcotic drugs

### A. Availability of narcotic drugs

1. How would you qualify the situation in your country with respect to the availability of opioid analgesics for medical and scientific purposes?
  - Entirely satisfactory
  - Satisfactory
  - In need of some improvement
  - In need of significant improvement
  
2. What factors are taken into account by your national competent authority in the quantification of your country's consumption needs for narcotic drugs? (Please select one or more answers as appropriate.)
  - Consumption patterns in previous year(s)
  - Existence of specialized treatment services (e.g. oncology, palliative care, opioid substitution or therapy)
  - Information of planned manufacture submitted by industry
  - Epidemiological data, including prevalence rates for common illnesses
  - Other (please specify):
  
3. Please describe the methodology employed by your national competent authorities in establishing consumption estimates for medical and scientific use of narcotic drugs:
  
  
  
  
  
  
  
  
  
  
4. Are you aware of the procedure to submit supplementary estimates for narcotic drugs to INCB to meet greater than expected need or due to unforeseen circumstances (e.g. natural disasters, epidemics)?
  - Yes
  - No

5. Are you aware of the INCB training materials published by the Board in order to assist States in preparing their estimates of narcotic drug requirements for submission to the Board, which are available from: [http://www.incb.org/documents/Narcotic-Drugs/Training-Materials/English/NAR\\_2\\_English\\_2005.pdf](http://www.incb.org/documents/Narcotic-Drugs/Training-Materials/English/NAR_2_English_2005.pdf)?

Yes

No

6. Are you aware of the joint WHO/INCB *Guide on Estimating Requirements for Substances under International Control*, available from: [http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating\\_requirements/NAR\\_Guide\\_on\\_Estimating\\_EN\\_Ebook.pdf](http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf)?

Yes

No

## B. Appropriate use of narcotic drugs

7. Is the use of narcotic drugs in your country restricted to specific medical conditions, including treatment for palliative care?

Yes

No

If you answered "Yes", please provide details as to the types of conditions for which the use of narcotic drugs is allowed:

8. Does your country use narcotic drugs for the treatment of drug dependency (e.g. substitution therapy)?

Yes

No

If you answered "Yes", please provide details:

## C. Regulatory framework governing prescriptions for narcotic drugs

9. According to your national legislative and regulatory framework, which of the following professional categories is permitted to prescribe narcotic drugs for medical treatment?
- General practitioners
  - General practitioners licensed to issue prescriptions for narcotic drugs
  - Medical specialists (e.g. psychiatrists, oncologists, surgeons, dentists)
  - Nurses (including nurse practitioners)
  - Veterinarians
  - Others (please specify):
10. Is a second opinion a requirement prior to the issuance of a prescription for narcotic drugs?
- Yes
  - No

If you answered “Yes”, please provide details:

11. How long is a prescription for narcotic drugs valid from the date of issuance?

Is the issuance of prescriptions for narcotic drugs subject to any particular legal/regulatory formalities compared to other prescription medications (e.g. requirements for additional authorizations, shorter validity period of prescription)?

- Yes
- No

If you answered “Yes”, please provide details:

12. Can a single prescription for narcotic drugs cover the entire duration of the treatment, or is it limited to a shorter period?

Yes

No

If you answered “No”, please provide details:

13. Are there any circumstances that exist where a prescription for narcotic drugs may be deemed refillable?<sup>a</sup>

Yes

No

If you answered “Yes”, please provide details:

## D. Regulatory framework governing the dispensing of narcotic drugs

14. Are narcotic drugs dispensed in:

Licensed hospital pharmacies

Specially licensed pharmacies

Pharmacies

Others (please specify):

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<sup>a</sup>Please note that the term “refillable” is defined as not requiring subsequent doctor’s approval.

## E. Record-keeping and prescription drug monitoring

15. Are prescribers legally required to keep records of prescriptions issued for narcotic drugs?

Yes

No

If you answered "Yes", please provide details, including the length of time for which records should be kept:

16. Are dispensing agents (see question 14) legally required to keep records of prescriptions issued for narcotic drugs?

Yes

No

If you answered "Yes", please provide details including the length of time for which records should be kept:

17. Does the legislative/regulatory framework in place in your country provide for penalties for inadequate record-keeping?

Yes

No

If you answered "Yes", please provide details:

## F. Measures to promote adequate availability and rational use of narcotic drugs

18. Who pays for narcotic drugs prescribed?

- Government (social security)
- Patients themselves
- Health insurance schemes
- Others

19. Does the educational curriculum for medical practitioners in your country include any content with respect to the rational prescription and use of prescription narcotic drugs?

- Yes
- No

If you answered “Yes”, please provide details:

20. Have any awareness-raising measures been implemented by the authorities of your country to foster a deeper understanding of responsible prescribing practices for narcotic drugs among health-care professionals?

- Yes
- No

If you answered “Yes”, please provide details:

21. In the last 10 years, has your Government taken any legislative or regulatory action to increase the availability of narcotic drugs for medical purposes?

- Yes
- No

If you answered “Yes”, please provide details:



## G. Impediments to availability

22. In the context of your country, have any of the factors below had the effect of unduly limiting the availability of narcotic drugs needed for medical or scientific purposes (please select all applicable factors)?

- Limited financial resources
- Problems in sourcing from industry/imports
- Fear of diversion into illicit channels
- Fear of criminal prosecution/sanction
- Lack of awareness/training among members of the medical profession regarding the rational use of narcotic drugs
- Onerous regulatory framework for the prescription of narcotic drugs for medical use
- Fear of addiction
- Cultural attitudes towards the treatment of pain
- Control measures applicable to international trade, such as requirements for import or export authorizations
- Action by the Board
- Other(s):

Please elaborate as applicable:

23. What do you consider to be the most significant obstacle to the availability of narcotic drugs in your country to meet medical and scientific needs?

24. Are any particular measures in place in your country to facilitate the availability of narcotic drugs for medical purposes in rural or remote regions of your country?

- Yes
- No

If you answered "Yes", please provide details:

25. Are there any additional measures that could be taken by INCB to contribute to greater availability of narcotic drugs for medical and scientific purposes in your country?

## H. Overprescription of narcotic drugs

26. Has your country experienced the following with respect to narcotic drugs:

- Overprescription
- “Doctor shopping”<sup>b</sup>
- Self-medication
- Parallel unregulated markets
- Counterfeiting of prescription narcotic drugs

Please provide details, as applicable:

### Additional information (as required):

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<sup>b</sup>“Doctor shopping” or “double doctoring” refers to the practice of a patient requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers.

## Questionnaire for National Competent Authorities on the availability of Internationally Controlled Substances for medical and scientific purposes

### Part 2 of 2 – Psychotropic substances

Please return this questionnaire by 31 October 2014 to:

INCB Secretariat  
Vienna International Centre  
P.O. Box 500  
1400 Vienna  
Austria

Fax: (+43-1) 26060-5867  
Tel.: (+43-1) 26060-4933  
E-mail: [secretariat@incb.org](mailto:secretariat@incb.org)

**Please state the name of the submitting authority:**

Country: .....

Authority: .....

Contact person: .....

Tel.: ..... Fax: ..... E-mail: .....

Please provide the names of authorities and contact persons who might be able to provide additional information if required:

Authority/ies: .....

Contact person/s: .....

Tel.: ..... Fax: ..... E-mail: .....

#### Instructions for filling out this questionnaire.

This questionnaire consists of two parts:

**Part 1 relates to the availability of narcotic drugs subject to international control under the 1961 Single Convention on Narcotic Drugs**

**Part 2 relates to the availability of psychotropic substances subject to international control under the 1971 Convention on Psychotropic Substances**

According to the national regulatory framework in place in each State, these substances may be dealt with by the same competent authority or be controlled by two distinct institutional actors. In both cases, each part should be duly filled out by the appropriate stakeholder, and the consolidated questionnaire, containing both parts, should be returned to the INCB Secretariat using the contact details provided on the cover page by the deadline indicated.

For the purpose of expediency, electronic submission of the completed questionnaire is encouraged.

## Part 2. Psychotropic substances

### A. Availability of psychotropic substances

27. How would you qualify the situation in your country with respect to the availability of psychotropic substances for medical and scientific purposes?
- Entirely satisfactory
  - Satisfactory
  - In need of some improvement
  - In need of significant improvement
28. What factors are taken into account by your national competent authority in the quantification of your country's consumption needs for psychotropic substances? (Please select one or more answers as appropriate.)
- Consumption patterns in previous year(s)
  - Existence of specialized treatment services (e.g. specialized mental health services, palliative care, opioid substitution therapy)
  - Information on planned manufacture submitted by industry
  - Epidemiological data including prevalence rates for mental health conditions
  - Other (please specify):
29. Please describe the methodology employed by your national authorities in establishing annual assessments of requirements for psychotropic substances.
30. Are you aware of the procedure to submit supplementary assessments for psychotropic substances to INCB to meet greater than expected need or due to unforeseen circumstances (e.g. natural disasters, armed conflicts)?
- Yes
  - No

31. Are you aware of the INCB training materials published by the Board in order to assist States in preparing their assessments of psychotropic substances requirements for submission to the Board, which are available from: <http://www.incb.org/documents/Psychotropics/training-materials/training-material-eng-2013-86360.pdf>?
- Yes
- No
32. Are you aware of the joint WHO/INCB publication *Guide on Estimating Requirements for Substances under International Control*, available from: [http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating\\_requirements/NAR\\_Guide\\_on\\_Estimating\\_EN\\_Ebook.pdf](http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf)?
- Yes
- No

## B. Appropriate use of psychotropic substances

33. Is the use of psychotropic substances in your country restricted to specific mental health disorders, including ADHD, insomnia, anxiety, palliative care?
- Yes
- No

If you answered “Yes”, please provide details:

34. Does your country use psychotropic substances for the treatment of drug dependency (e.g. substitution therapy)?
- Yes
- No

If you answered “Yes”, please provide details:

### C. Regulatory framework governing prescriptions for psychotropic substances

35. According to your national legislative and regulatory framework, which of the following professional categories is permitted to prescribe psychotropic substances for medical treatment?

- General practitioners
- General practitioners licensed to issue prescriptions for psychotropic substances
- Medical specialists (e.g. psychiatrists, oncologists, surgeons, dentists)
- Nurses (including nurse practitioners)
- Veterinarians
- Others (please specify):

36. Is a second opinion a requirement prior to the issuance of a prescription for psychotropic substances?

- Yes
- No

If you answered “Yes”, please provide details:

37. How long is a prescription for psychotropic substances valid for from the date of issuance?

Is the issuance of prescriptions for psychotropic substances subject to any particular legal/regulatory formalities compared to other prescription medications (e.g. requirements for additional authorizations, shorter validity period of prescription)?

- Yes
- No

If you answered “Yes”, please provide details:

38. Can a single prescription for psychotropic substances cover the entire duration of the treatment, or is it limited to a shorter period?

Yes

No

If you answered “No”, please provide details:

39. Are there any circumstances that exist where a prescription for psychotropic substances may be deemed refillable?<sup>c</sup>

Yes

No

If you answered “Yes”, please provide details:

## D. Regulatory framework governing the dispensing of psychotropic substances

40. Are psychotropic substances dispensed in:

Licensed hospital pharmacies

Specially licensed pharmacies

Pharmacies

Other (please specify):

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<sup>c</sup>Please note that the term “refillable” is defined as not requiring subsequent doctor’s approval.

## E. Record-keeping and prescription drug monitoring

41. Are prescribers legally required to keep records of prescriptions issued for psychotropic substances?

Yes

No

If you answered “Yes”, please provide details, including the length of time for which records should be kept:

42. Are dispensing agents (see question 40) legally required to keep records of prescriptions issued for psychotropic substances?

Yes

No

If you answered “Yes”, please provide details, including the length of time for which records should be kept:

43. Does the legislative/regulatory framework in place in your country provide for penalties for inadequate record-keeping?

Yes

No

If you answered “Yes”, please provide details:



## F. Measures to promote adequate availability and rational use of psychotropic substances

44. Who pays for psychotropic substances prescribed?

- Government (social security)
- Patients themselves
- Health insurance schemes
- Others

45. Does the educational curriculum for medical practitioners in your country include any content with respect to the rational prescription and use of psychotropic substances?

- Yes
- No

If you answered “Yes”, please provide details:

46. Have any awareness-raising measures been implemented by the authorities of your country to foster a deeper understanding of responsible prescribing practices for psychotropic substances among health-care professionals?

- Yes
- No

If you answered “Yes”, please provide details:

47. In the last 10 years, has your Government taken any legislative or regulatory action to increase the availability of psychotropic substances for medical purposes?

- Yes
- No

If you answered “Yes”, please provide details:

## G. Impediments to availability

48. In the context of your country, have any of the factors below had the effect of unduly limiting the availability of psychotropic substances needed for medical or scientific purposes? (Please select all applicable factors.)

- Limited financial resources
- Problems in sourcing from industry/imports
- Fear of diversion into illicit channels
- Fear of criminal prosecution/sanction
- Lack of awareness/training regarding the rational use of psychotropic substances among members of the medical profession
- Onerous regulatory framework for the prescription of psychotropic substances for medical use
- Fear of addiction
- Cultural attitudes towards the treatment of mental health disorders
- Control measures applicable to international trade such as requirements for import or export authorizations
- Action by the Board
- Other(s):

Please elaborate as applicable:

49. What do you consider to be the most significant obstacle to the availability of psychotropic substances in your country to meet medical and scientific needs?

50. Are any particular measures in place in your country to facilitate the availability of psychotropic substances for medical purposes in rural or remote regions of your country?

- Yes
- No

If you answered “Yes”, please provide details:

51. Are there any additional measures that could be taken by INCB to contribute to greater availability of psychotropic substances for medical and scientific purposes in your country?

## G. Overprescription of psychotropic substances

52. Has your country experienced the following with respect to psychotropic substances:

- Overprescription
- “Doctor shopping”<sup>d</sup>
- Self-medication
- Parallel unregulated markets
- Counterfeiting of prescription drugs containing psychotropic substances

Please provide details, as applicable:

53. Does your country permit the advertising of psychotropic substances to the general public?

- Yes
- No

If you answered “Yes”, please provide details:

## Additional information (as required)

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<sup>d</sup>“Doctor shopping”, or “double doctoring”, refers to the practice of a patient requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers.