

Ketamine (INN)

Section 1. LEGITIMATE MEDICAL OR SCIENTIFIC USE

*Questions in Section 1 are intended for the Ministry of Health and National Regulatory Authority
Please read the entire section before responding to questions*

- 1.1 Do you know if approved medical products containing ketamine are available in your country for human or veterinarian indications? *(Check all that apply)*
- Human medical product
 - Veterinary medical product
 - Not available in medicinal products
 - Do not know
- 1.2 What are the **human** therapeutic indications approved for ketamine in your country?
(Check all that apply)?
- Anaesthesia
 - Pain management
 - Sedation
 - There are no approved human indications for ketamine
 - Other approved indications
- 1.3 In which situations or clinical settings can ketamine be the anaesthetic, sedative or analgesic agent of choice *(check all that apply)*?
- Emergency situations
 - Conducting procedures with paediatric patients
 - Short surgical procedures
 - Long surgical procedures
 - Surgery conducted outside a hospital without respiratory support facilities
 - Other.....
- 1.4 Is ketamine included in your National Essential Medicines List?
- Yes
 - No
 - Do not know
- 1.5 What is the annual consumption of ketamine in your country?
..... (in Grams)
..... (Please indicate other units, if information on *Grams* is not available)
- Do not know

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1.6 How many patients (in hospitals, private clinics, etc.) are treated with medical products containing ketamine per year in your country?

- 0 (i.e., ketamine is not used)
- 1-99
- 100-999
- 1000-5000
- > 5000

1.7 What are the **veterinary** therapeutic indications approved for ketamine in your country (Check all that apply)?

- Anaesthesia
- Pain management
- Sedation
- There are no approved veterinary indications for ketamine
- Other.....

1.8 Please indicate the marketed name, dosage form(s) and strength(s) of ketamine available in your country; also indicate (under **Remarks**) any special properties such as slow release, etc.

Marketed Name	Dosage form	Available strengths for this dosage form	Remarks
<i>(e.g., Ketalar)</i>	<i>examples: tablet, oral solution</i>	<i>examples: 10mg, 5mg/ml</i>	

1.9 Is ketamine currently used in medical or scientific research in your country (e.g., is it in clinical trials for any human or veterinary indication)?

- Yes
- No
- Do not know

If Yes, please specify

Section 2. LEGITIMATE NON-MEDICAL/NON-SCIENTIFIC USE

2.1 Is ketamine used for industrial or other non-medical/non-scientific purposes in your country?

- Yes
- No
- Do not know

If Yes to question 2.1 please specify:

2.2 What is the origin/source of ketamine when used for legitimate non-medical/non-scientific use?

- Manufactured in your own country
- Imported
- Both manufactured in your own country and imported
- Do not know

2.3 What is the estimated amount of ketamine used annually in your country for any legitimate non-medical/non-scientific use?

..... kg litre per year

- Do not know

2.4 Any additional information related to the questions in Section 2

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Section 3. CULTURAL, RELIGIOUS OR CEREMONIAL USE

3.1 Is ketamine used for cultural, religious or ceremonial purposes in your country?

- Yes
- No
- Do not know

If Yes, please specify (by whom, for what purposes, route of administration and typical amounts used):

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3.2 Any additional comments related to the questions in Section 3

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Section 4. EPIDEMIOLOGY OF NON-MEDICAL/NON-SCIENTIFIC USE – USE FOR PSYCHOACTIVE PURPOSES OR RECREATIONAL DRUG USE

Questions in Section 4 are intended for national research organizations or competent agencies/authorities on substance abuse

Please read the entire section before responding to questions

4.1 Is ketamine misused for its psychoactive properties (as a recreational drug) in your country?

- Yes
- No
- Do not know

If you responded Yes to 4.1, please answer the following questions (numbers 4.2 to 4.16); if you responded “No” or “Do not know” to 4.1, you do not need to answer questions number 4.2 to 4.15.

4.2 By what route(s) of administration is ketamine used for non-medical/non-scientific purposes in your country (if available, provide an estimated percent distribution for the various routes of administration used):

- Oral %
- Injection %
- Inhalation %
- Sniffing %
- Smoking %
- Other (please specify) %
- Do not know

4.3 In which formulations is ketamine used for non-medical/non-scientific purposes in your country: *(check all that apply)*

- Powder
- Tablets
- Liquid
- Injectable (e.g. ampoules)
- Other (please specify):

4.4 What is(are) the source(s) of ketamine for non-medical/non-scientific use in your country? *(all that apply)*

- Legal manufacturing
- Legal trade
- Illegal manufacturing
- Diversion *(from legal supply chain)*
- Smuggling *(from other countries)*
- Other (please specify):
- Do not know

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4.5. Are there any specific subpopulations in your country known to misuse ketamine?

- Yes
- No

If Yes to question 4.5 please specify which groups:

.....

4.6 What is the estimated number or proportion of the population using ketamine for non-medical use?

(Either provide the number of people using the substance, or a percentage of the total population – whatever is the easiest for you. If not known, please leave blank)

User group	Absolute number	Percentage
General population		
Subpopulation		

4.7 Please provide any information on the extent and magnitude of public-health problems or social harm from the use of ketamine in your country:

.....

4.8 As an expert, to what level is it your perception that ketamine has a negative health-impact originating from ketamine's non-medical consumption?

- Negligible
- Substantial
- Serious
- Do not know

If *Substantial* or *Serious*, please specify:

4.9 If available, please provide the number of emergency room/department visits related to the non-medical use of ketamine (supply data for the most recent completed year available):

	Number of visits
a. Ketamine was the only substance involved	
b. Other substances were also involved	
c. Unknown if other substances were involved	
Total (a+b+c)	

Applies to year: 20.....

4.10 Please list the adverse effects (non-fatal intoxications etc.) presented for ketamine at the emergency room/department:

.....

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4.11 If available, please provide the mortality rate where ketamine was involved (supply data for the most recent completed year available):

	Number of casualties
a. Ketamine was the only substance involved	
b. Other substances were also involved	
c. Unknown if other substances were involved	
Total (a+b+c)	

Relates to [year] 20.....

4.12 Has ketamine been proven to be dependence producing in your country?

- Yes
- No
- Do not know

4.13 Number of people known to be dependent on ketamine in your country:

-(relates to [year] 20.....)
- Do not know

4.14 Number of people in treatment for being dependent on ketamine:

-(relates to [year] 20.....)
- Do not know

4.15 Please provide references to relevant literature published on the abuse of ketamine in your country that you think might be particularly informative

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4.16 Please provide any additional comments to the questions in Section 4

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Section 5. CURRENT CONTROL

Questions in Section 5 are intended for the national competent authority for drug control

5.1. Is ketamine currently controlled under national legislation in order to regulate its availability in your country?

- Yes
- No
- Do not know

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If Yes to 5.1, please continue with question 5.2; otherwise skip questions 5.2 – 5.10 and continue with question 5.11.

If Yes, please indicate on which legislation the current control is based and provide the exact title of the Act: *(all that apply)*

- Medicines act:
- Controlled substances act, etc.:
- Tobacco or alcohol control act:
- Other consumer protection act:
- Criminal law act:
- Other specific legislation (analog; generic; temporary/emergency; etc.):
- Other:

5.2 What is the scope of this control: *(check all that apply)*

- Production
- Manufacture
- Export
- Import
- Distribution
- Use
- Possession
- Other (please specify):
- Do not know

5.3 Is the current control a temporary provision?

- Yes If Yes, for how long/since when _____
- No
- Do not know

5.4 Do you think national controls are a barrier to access ketamine for medical or scientific use?

.....

Please specify:

5.5 Any additional comments regarding ketamine's use, its control, or availability you would like to make

.....

5.6 Have there been challenges to implementing controls of ketamine in your country?

- Yes
- No
- Do not know

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If Yes to question 5.6 please specify in which area and explain: *(all that apply)*

- Forensic laboratory capacity:
- Resources to implement and/or enforce:
- Expertise to detect or enforce:

- Other:

5.7 Are there illicit activities involving ketamine: *(all that apply)*

- Manufacture of the substance by chemical synthesis
- Manufacture of the substance by extraction from other products
- Production of consumer products (dosage forms, packaging)
- Trafficking
- Diversion
- Internet sales:
 - Internet sales (seller or website located in your country)
 - Internet sales (from abroad to buyers in your country)
 - Internet sales (other or location of sellers and website unknown)
- Sales to people who use this substance
- Other (please specify):
- Do not know

5.8 Number of seizures:

2013:
 2014:
 2015:

5.9 Quantity of seizures:

Type of material	2013	2014	2015
bulk material (by weight)	kg	kg	kg
bulk material (by volume)	l	l	l
ampoules (counted)	pcs	pcs	pcs
ampoules (weighed)	kg	kg	kg
tablets (counted)	pcs	pcs	pcs
tablets (weighed)	kg	kg	kg
other:			

(please do not declare the same quantity double: either by the weight, by volume, or by number)

5.10 If ketamine is not controlled, and there were seizures, what was the reason for seizing it?

.....

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5.11 If ketamine would be placed under international control, will your country have the capacity to enforce the control at the national level?

- Yes
- No
- Do not know

5.12 If ketamine would be placed under international control, does your country have the forensic laboratory capacity to analyse the substance (identification, purity)?

- Yes
- No
- Do not know

5.13 Any additional information related to the questions in Section 5

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