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WHO Expert Committee on Drug Dependence Pregabalin

Annex 1: Member State Questionnaire

1. Overview of Responses (Q1-Q5)

Q1: Please indicate your country.

- Representatives of 82 countries answered the questionnaire

Q5: Do you have any information on the use of **Pregabalin** in your country for either medical, scientific, industrial or other professional purposes, or for non-medical consumption, recreational purposes, or any other purpose?

- 72 (89%) answered yes, nine (11%) answered no.

2. Section 1: Approved medical or scientific use (Q6-Q13)

Q6: Do you know if approved medical products containing **Pregabalin** are available in your country for human or veterinary indications?

- **“Human medical product”**
 - N=71 countries
- **“Veterinary medical product”**
 - N=3 countries
- **“Not available in medical products”**
 - N=0 countries
- **“Do not know”**
 - N=2 countries (

Q7: What are the therapeutic indications approved for **Pregabalin** in your country?

- In 60 out of 71 responses, Pregabalin was described as being prescribed for neuropathic pain. Other prevalent indications include (generalized) anxiety disorders, epilepsy, and fibromyalgia.

Q8: Please indicate the marketed name, dosage form(s) and strength(s) of any of **Pregabalin** available in your country; also indicate the exact substance name and any special properties such as slow release, etc?

- About 300 responses have been given to this question. The drug strength varied between 20mg and 300mg and Pregabalin was reported to be mainly available as capsule, but also as gel, oral solution, and tablets in selected countries.

Q9: Is **Pregabalin** currently used in medical or scientific research (excluding use as an analytical reference standard) in your country (e.g. , is it in clinical trials for any human or veterinary indication)?

- 21 (30%) answered yes, 30 (42%) answered no and 20 (28%) answered “Do not know”.

Q11: What types of professionals are allowed to prescribe **Pregabalin**?

- **“Medical doctor/psychiatrist”**
 - o N=71 countries
- **“Osteopath”**
 - o N=4 country
- **“Nurse/nurse prescriber”**
 - o N=1 country
- **“Pharmacist”**
 - o N=1 country
- **“Psychologist”**
 - o N=2 countries
- **“Physiotherapist”**
 - o N=2 countries
- **“Healthcare worker”**
 - o N=2 countries
- **“No prescription is required”**
 - o N=1 country
- “

Q12: Are any clinical guidelines used in your country for the prescription of **Pregabalin**?

- Out of 68 responses, 26 (38%) indicated available guidelines.
- There were 23 no (34%).

Q13: If Yes, please specify.

- Pregabalin guidelines are either based on recommendations for treatment of epilepsy, (neuropathic) pain, or anxiety disorders. Several guidelines are published by scientific or medical associations, while others are issued by national institutions.
- In some countries, product information leaflets provided by the pharmaceutical produces are indicated as only source.

3. Section 2: Non-approved medical and non-medical or non-scientific use (Q14-Q21)

Q14: Is **Pregabalin** used for industrial or other non-medical/non-scientific purposes in your country?

- Out of 71 responses, five indicated that Pregabalin is used for industrial or other non-medical/non-scientific purposes in their country (7%).
- In the majority of countries, no non-approved use was identified (68%).
- There were 18 “Do not know” responses (25%).

Q16: What is the origin/source of **Pregabalin** when used for legitimate non-medical/non-scientific use?

- **“Manufactured in your own country”**
 - N=1 countries
- **“Imported”**
 - N=15 countries
- **“Both manufactured in your own country and imported”**
 - N=4 countries
- **“Do not know”**
 - N=29 countries

Q17: What is the estimated amount of **Pregabalin** used annually in your country for any non-medical/nonscientific use? Please specify where information is available, referring to the specific amounts (kg/litre) and the reference year.

In most countries, data on the estimated amount used was not available.

4. Section 3: Cultural, religious or ceremonial use (Q17-Q20)

Q19: Is **Pregabalin** used for cultural, religious or ceremonial purposes in your country?

- Out of 70 responses, 1% (N=1) indicated cultural, religious or ceremonial use. The majority of respondents indicated no such use (N=53; 76%), while 16 country representatives answered “Do not know” (20%).

5. Section 4: Epidemiology of non-medical/non-scientific use – psychoactive purposes/recreational use (Q22-Q40)

Q22: Is **Pregabalin** misused for their psychoactive properties (as a recreational drug) in your country?

- Out of 71 responses, 35% (N=25); indicated misuse of Pregabalin.
- In 21 countries (30%); Pregabalin is reportedly not misused, while 25 country representatives answered “Do not know” (35%).

Q23: By what route(s) of administration is **Pregabalin** used for non-medical/non-scientific purposes in your country?

Oral (N=23)	
Injection (N=2)	
Inhalation (N=1)	
Sniffing (N=5)	
Smoking/Waterpipe (i.e., adding Pregabalin to waterpipe) (N=2)	
Do not know (N=2)	
Other (please specify) (N=1)	

Q24: What is the most common route of administration for **Pregabalin** for non-medical/non-scientific purposes?

- Oral administration of Pregabalin was reported to be the most common route (N=20);

Q25: In which formulations is **Pregabalin** used for non-medical/non-scientific purposes in your country?

Powder (N=3)	
Tablets (N=23)	
Liquid or solution for oral administration/use (N=0)	
Solution for injection (N=1)	
Other (please specify) (N=1)	

Q27: What is (are) the source(s) of **Pregabalin** for non-medical/non-scientific use in your country?

Legal manufacturing (N=3)	
Legal trade (N=8)	
Illegal manufacturing (N=0)	
Diversion (from legal supply chain) (N=14)	
Smuggling (from other countries) (N=8)	
Do not know (N=3)	
Other (please specify) (N=3)	

Q28: Are there any specific subpopulations in your country known to misuse **Pregabalin**?

- In 10 out of 24 responding countries (42%); there are specific subpopulations misusing Pregabalin.
- In the remaining 14 countries (58%) specific subpopulations are not known to misuse Pregabalin.

Q30: Please provide any information on the extent and magnitude of public health problems or social harm caused by the use of **Pregabalin** in your country:

- In one out of 11 countries, no data is available to describe public health problems with regard to Pregabalin.
- In three countries), the public health impact was explicitly considered to be small or decreasing.
- In three countries), the public health impact was explicitly considered to be large or rising.
- In four countries the magnitude was described by using data on prevalence of abuse on addiction treatment admissions. on usual dosages or by highlighting adverse effects on the society.

Q31: As an expert, what negative health impact do you believe the non-medical consumption of **Pregabalin** has in your country?

- Out of 23 responses, a total of 13 country representatives evaluated the negative health impact of Pregabalin as either “serious” (22%) In 5 countries, Pregabalin were found to have a

“negligible” negative health impact (22%). Five country representatives answered “Do not know” (17%).

Q32: If Substantial or Serious, please specify:

- Most respondents refer to adverse effects on the individual, such as fatal events when mixed with other *drugs*, abuse and dependence of Pregabalin increased Poison Severity Scores sleep and anxiety disorder, and traffic accidents.

Q33: Are you aware of any emergency room/department visits related to the use of **Pregabalin** in your country?

- Out of 23 responses, 9 country representatives (39%) were aware of any emergency room/department visits related to the use of Pregabalin. The remaining 14 responses (61%) were unaware of such visits.

Q35: Please list the adverse effects (non-fatal intoxications, etc.) patients have presented with at emergency rooms/departments in your country after use of **Pregabalin**:

- The following adverse effects have been reported:

	drowsiness
	confusion, atrioventricular block, dependence, withdrawal syndrome, somnolence, craving, euphoria
	The average Poison Severity Score (PSS) was documented as 1 (minor). Eighty cases had a PSS of 0 (none), 210 cases had a PSS of 1 (minor), 88 cases had a PSS of 2 (moderate), 18 cases had a PSS of 3 (severe) and in 16 cases the PSS was not documented.
	it is mainly interactions with other drugs
	memory difficulties
	agitated, irritable, hostile and aggressive behavior
	ataxia, blurred vision, diplopia, dizziness, drowsiness, headache, tremor, speech disturbance
	faintness, drowsiness, dizziness
	seizures, unconsciousness
	exception of polydrug use; adverse effects of this substance are toxic epidermal necrolysis, bone marrow failure, cardiac failure acute, hyponatremia, anaphylactic shock, respiratory acidosis, respiratory depression, drug abuse
	most observed symptom is seizures.

Q38: Are you aware of people presenting for drug dependence treatment due to the use of **Pregabalin** in your country?

- Out of 24 responses, 13 country representatives (54%) were aware of people presenting for drug dependence treatment due to Pregabalin use.
- In three countries (13%), Pregabalin dependence treatment was not reported and 8 answered “Do not know” (33%).

6. Section 5: Current Control (Q41-Q52)

Q41: Is **Pregabalin** currently controlled under national legislation in order to regulate its availability in your country?

- Out of 71 responses, about half of countries have a national control legislation in place (49%).
- In 32 countries (45%) no national legislation exists.
- Four respondents answered “Do not know” (6%)

Q44: Is the current control a temporary provision in your country?

- Out of 34 responding countries, the current control is a temporary provision in one country (3%).

Q46: Have there been challenges to implementing controls of **Pregabalin** in your country?

- Out of 38 responding countries, challenges in implementing controls were reported by five countries (13%) and four country representatives answered “Do not know” (11%).
- In the remaining countries, no challenges in implementing controls were reported (N=29; 76%).

Q50: If **Pregabalin** was to be placed under international control, will your country have the capacity to enforce the control at the national level?

- Out of 67 responses, 58 reported sufficient capacities (87%).

- In two countries (3%); the local capacities do not suffice to enforce control of Pregabalin.
- Seven country representatives answered “Do not know” (10%).

Q51: If **Pregabalin** was to be placed under international control, does your country have the forensic laboratory capacity to analyse the substance (identification, purity)?

- Out of 66 responses, 53 reported sufficient capacities (80%).
- In six countries (9%) the laboratory capacities do not suffice to analyse Pregabalin.
- Seven country representatives answered “Do not know” (11%).

7. Conclusions

The survey was taken by country representatives from every WHO region. Nine out of ten respondents of this questionnaire were able to supply information on Pregabalin from the countries. In most responding countries, Pregabalin is available in different dosages and formulations for treating neuropathic pain, epilepsy and/or anxiety disorders. In the vast majority of countries with approved Pregabalin use, the substance is only available against prescription.

The extent of cultural or religious use of Pregabalin is negligible but recreational use and abuse of Pregabalin has been reported by about one third of responding country representatives. According to the provided data, recreational use and abuse of Pregabalin is most prevalent among youths and (poly-) drug users and addicts in general and opioid users/addicts in specific.

In the majority of countries where Pregabalin is being abused or used for recreational purposes, the magnitude of negative public health effects of Pregabalin has been reported to be substantial or serious. Data on treatment admissions and deaths are not available from every country. This is also corroborated by an increase in seizure figures in these countries. Further, Pregabalin abuse is associated with polydrug use, drug dependence, and sleep disorders.

Some countries have expressed both favorable, other have expressed sceptical positions regarding the international control of Pregabalin. With regard to controlling of Pregabalin in their jurisdictions, the vast majority of countries report sufficient capacities.