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First Name: [REDACTED]
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Page 2: General Information

Q1 Focal point contact details

Name [REDACTED] Division 117 -
ational
ny; Phone +49
Mailto:

Q2 Please indicate your country Germany

Page 3: WHO Data Sharing Policy

Q3 Please confirm that you agree I agree for the information provided in this questionnaire to be published in a report

Page 4: General cannabis information

Q4 Do you have any information about the use of extracts and tinctures of cannabis for any purpose (including medical or non-medical use) in your country? Yes

Page 5: Medical use

Q5 At national level, are extracts or tinctures of cannabis legally approved for medical use in your country? Yes

Page 6: Medical use: Therapeutic indications

WHO ECDD Questionnaire: Extracts and tinctures of cannabis

Q6 Please indicate any approved therapeutic indications for the use of extracts and tinctures of cannabis in your country

Multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury

,

Other (please specify):

Concerning pharmacy-prepared medicinal products containing cannabis extracts and tinctures there are no limitations to specific therapeutic indications but there's the limitation that only severely ill patients can receive medicinal cannabis who according to a doctor's decision can't be treated properly with other medications.

Q7 Please indicate any symptoms that extracts and tincture of cannabis is approved to treat

Other (please specify):

Concerning pharmacy-prepared medicinal products containing cannabis extracts and tinctures there are no limitations to specific symptoms but there's the limitation that only severely ill patients can receive medicinal cannabis who according to a doctor's decision can't be treated properly with other medications.

Q8 Please indicate whether there are any permitted marketed products of extracts and tinctures of cannabis

Name of marketed product & CBD /THC content (if known):

Sativex®

Name of marketed product & CBD /THC content (if known):

Tilray THC25; permitted but not approved

Name of marketed product & CBD /THC content (if known):

Tilray THC10/CBD10; permitted but not approved

Name of marketed product & CBD /THC content (if known):

Cannabisextrakt Bionorika 5%THC; permitted but not approved

Q9 Are there any ongoing approved clinical trials in your country that are developing extracts and tinctures of cannabis for medical use?

Yes

Q10 Please indicate product name/ trial number/ study phase of any ongoing trials that are developing products of extracts and tinctures of cannabis for medical use

Product name

Sativex; Eudra-CT: 2004-002531-32; Phase: 3

Product name

Sativex; Eudra-CT: 2013-001247-31; Phase: 4

Product name

Sativex; Eudra-CT: 2013-001247-31; Phase: 4

Product name

Sativex; Eudra-CT: 2012-004800-37; Phase: Bioäquivalenz

Product name

Sativex; Eudra-CT: 2016-000564-42; Phase: 3

Page 7: Medical use: Access

Q11 Do individuals require a prescription to obtain medical extracts and tinctures of cannabis?

Yes

Q12 What types of professionals are allowed to prescribe extracts and tinctures of cannabis?

Medical doctor / psychiatrist

Q13 What kinds of settings are approved to legally dispense extracts and tinctures of cannabis in your country?

Pharmacies

Q14 If patients use medical extracts and tinctures of cannabis on prescription or recommendation of a health professional, will they be reimbursed for the costs of their medication?

Other (please specify):
Authorised finished medicinal products containing Cannabis extracts are reimbursed for the approved indications.
Pharmacy-prepared medicinal products containing Cannabis extracts are reimbursed for patients who are severely ill and who have no other alternative in therapies.

Q15 Are any clinical guidelines used in your country for the prescribing of medical extracts and tinctures of cannabis?

Yes (please specify):
The German Medical Association (Bundesärztekammer) has published a compilation of frequently asked questions relating to the medical prescription of Cannabis (see attached file).

Q16 Is there a regulatory agency in your country that monitors extracts and tinctures of cannabis for medical use?

Yes (please specify):
There is a non interventional companion survey from the Federal Institute for Drugs and Medical Devices to receive more data about the medical use and benefit of Cannabis. Furthermore, all medicinal Cannabis products are subject to the pharmacovigilance system.

Q17 How would you describe the trend in the number of users of extracts and tinctures of cannabis for medical use over the last 3 years?

Extracts and tinctures of cannabis

The number has substantially increased

Page 8: Medical use: National legislation

Q18 In the past 3 years, has your country changed its national legislation around access to cannabis-related substances for medical use?

Extracts and tinctures of cannabis

Yes, my country has changed its legislation

Q19 If yes, what types of legislative changes has your country made for medical use of extracts and tinctures of cannabis?

Change to the legal status of medical cannabis ,

Changes to the supply of medical cannabis (e.g. changes in licensing, import – or export of products) ,

Changes to access to medical cannabis (e.g. variety in products, therapeutic indications etc)

Q20 Is your country currently considering changes to its national legislation around access to cannabis and cannabis-related substances for medical use?

Extracts and tinctures of cannabis

No, my country is not preparing changes in its legislation

Q21 In your opinion, how do you feel the changed legislation around access to extracts and tinctures of cannabis for medical use would impact / has impacted public health in your country?

Increased availability for medical use

There would be/ has been a slightly positive impact on public health

Decreased availability for medical use

There would be /has been a slightly negative impact on public health

Please explain your response::

See uploaded file: Summary of a scientific analysis concerning the potential and risks of cannabis (CaPRis)

Page 9: Non-medical use

Q22 On a national level, are extracts and tinctures of cannabis legally available for non-medical use in your country?

No

Q23 Are extracts and tinctures of cannabis used for cultural, ceremonial, or religious purposes in your country?

No

Q24 Does your country collect prevalence data around the use of extracts and tinctures of cannabis?

No

Page 10: Prevalence of non-medical cannabis use

WHO ECDD Questionnaire: Extracts and tinctures of cannabis

Q25 Prevalence of use of extracts and tinctures of cannabis amongst adults (over 18 years of age)

Respondent skipped this question

Q26 Prevalence of use of extracts and tinctures of cannabis for non-medical use amongst young people (below 18 years of age)

Respondent skipped this question

Q27 How would you describe the number of users extracts and tinctures of cannabis for non-medical use over the last 3 years in your country?

Respondent skipped this question

Page 11: Public health impact of use: Primary Care

Q28 Does your country collect data about presentations to primary care settings due to the use of extracts and tinctures of cannabis?

No

Page 12: Primary Care II

Q29 Number of primary care presentations relating to extracts and tinctures of cannabis

Respondent skipped this question

Q30 Does your country collect data about presentations to emergency care settings due to the use of extracts and tinctures of cannabis?

No

Page 13: Public health: Emergency settings

Q31 Number of individuals in the past year presenting to emergency settings relating to the use of extracts and tinctures of cannabis

Respondent skipped this question

Q32 Please list the adverse effects presented for extracts and tinctures of cannabis at the emergency room/department

Respondent skipped this question

Q33 Does your country collect data about presentations to substance misuse treatment settings due to the use of extracts and tinctures of cannabis?

No

Page 14: Public health: Substance misuse treatment

WHO ECDD Questionnaire: Extracts and tinctures of cannabis

Q34 Number of individuals in the past year presenting to substance misuse treatment due to extracts and tinctures of cannabis **Respondent skipped this question**

Q35 Does your country collect data about calls to poison centres due to the use of extracts and tinctures of cannabis? **No**

Page 15: Public health impact: Poison control centres

Q36 Number of calls to poison control centres due to the use of extracts and tinctures of cannabis **Respondent skipped this question**

Q37 Does your country collect data about cases of impaired driving due to the use of extracts and tinctures of cannabis? **No**

Page 16: Public health impact: Impaired driving

Q38 Number of cases of impaired driving due to extracts and tinctures of cannabis **Respondent skipped this question**

Page 17: Non-Medical Use: National legislation

Q39 In the past 3 years, has your country changed its national legislation around access to extracts and tinctures of cannabis for non-medical use?

Extracts and tinctures of cannabis **No, my country has not changed its legislation**

Q40 If yes, what types of legislative changes has your country made for non-medical use of extracts and tinctures of cannabis? **Respondent skipped this question**

Q41 Is your country currently considering changes to its national legislation around access to extracts and tinctures of cannabis for non-medical use?

Cannabis plant and cannabis resin **No, my country is not preparing changes in its legislation**

Q42 In your opinion, how do you feel the changed legislation around access to extracts and tinctures of cannabis for non-medical use would impact / has already impacted public health in your country?

Increased availability for non-medical use

There would be/ has been a significantly negative impact on public health

Decreased availability for non-medical use

There would be/ has been a significantly positive impact on public health

Please explain your response::

See uploaded file: Summary of a scientific analysis concerning the potential and risks of cannabis (CaPRis)

Page 18: Additional comments / information

Q43 Comments

Respondent skipped this question

Q44 File upload

FAQ Cannabis_Bundesärztekammer.pdf (269.5KB)

Q45 File upload

Kurzbericht_CAPRis.pdf (190KB)

Q46 File upload

Respondent skipped this question
